BIOMARIN PHARMACEUTICAL INC
Form 10-Q
October 29, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

Or

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

For the transition period from to .

Commission File Number: 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.)**
105 Digital Drive, Novato, California	**94949**
(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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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 x No ¨

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

Large accelerated filer x	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 x

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: 123,826,066 shares of common stock, par value $0.001, outstanding as of October 12, 2012.

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BIOMARIN PHARMACEUTICAL INC.

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BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

September 30, 2012 and December 31, 2011

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

	September 30, 2012 (unaudited)	December 31, 2011(1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 181,330	$ 46,272
Short-term investments	245,125	148,820
Accounts receivable, net (allowance for doubtful accounts: $341 and $513, respectively)	117,290	104,839
Inventory	120,825	130,118
Other current assets	54,816	39,753
Total current assets	719,386	469,802
Investment in BioMarin/Genzyme LLC	848	559
Long-term investments	106,741	94,385
Property, plant and equipment, net	273,724	268,971
Intangible assets, net	165,624	180,277
Goodwill	51,543	51,543
Long-term deferred tax assets	229,771	222,649
Other assets	19,739	15,495
Total assets	$ 1,567,376	$ 1,303,681
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 111,489	$ 94,125
Convertible debt	23,440	0
Total current liabilities	134,929	94,125
Long-term convertible debt	324,861	348,329
Other long-term liabilities	92,392	88,179
Total liabilities	552,182	530,633
Stockholders equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at September 30, 2012 and December 31, 2011: 123,790,150 and 114,789,732 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively.	124	115
Additional paid-in capital	1,505,776	1,197,082
Company common stock held by Nonqualified Deferred Compensation Plan	(6,603)	(3,935)
Accumulated other comprehensive income	2,333	4,887
Accumulated deficit	(486,436)	(425,101)
Total stockholders equity	1,015,194	773,048

Total liabilities and stockholders equity	$ 1,567,376	$ 1,303,681

(1) December 31, 2011 balances were derived from the audited consolidated financial statements.

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

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BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Three and Nine Months Ended September 30, 2012 and 2011

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
REVENUES:				
Net product revenues	$ 126,310	$ 112,891	$ 365,540	$ 331,583
Collaborative agreement revenues	1,210	97	1,729	375
Royalty and license revenues	597	437	1,516	1,554
Total revenues	128,117	113,425	368,785	333,512
OPERATING EXPENSES:				
Cost of sales (excludes amortization of certain acquired intangible assets)	24,619	22,445	65,298	62,504
Research and development	66,209	58,577	217,855	156,466
Selling, general and administrative	46,337	44,880	143,124	126,969
Intangible asset amortization and contingent consideration	1,443	3,040	5,819	28
Total operating expenses	138,608	128,942	432,096	345,967
LOSS FROM OPERATIONS	(10,491)	(15,517)	(63,311)	(12,455)
Equity in the loss of BioMarin/Genzyme LLC	(336)	(608)	(968)	(1,817)
Interest income	778	722	1,819	2,302
Interest expense	(1,837)	(2,168)	(5,709)	(6,531)
Debt conversion expense	0	(1,896)	0	(1,896)
Other income (expense)	125	(264)	(15)	(114)
LOSS BEFORE INCOME TAXES	(11,761)	(19,731)	(68,184)	(20,511)
Provision for (benefit from) income taxes	(6,404)	(2,078)	(6,849)	6,590
NET LOSS	$ (5,357)	$ (17,653)	$ (61,335)	$ (27,101)
NET LOSS PER SHARE, BASIC AND DILUTED	$ (0.04)	$ (0.16)	$ (0.52)	$ (0.24)
Weighted average common shares outstanding, basic and diluted	123,434	112,290	118,810	111,358
COMPREHENSIVE LOSS	$ (7,674)	$ (10,426)	$ (63,889)	$ (25,985)

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

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BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2012 and 2011

(In thousands of U.S. dollars)

(Unaudited)

	Nine Months Ended September 30, 2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (61,335)	$ (27,101)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	33,438	26,466
Amortization of discount on investments	3,075	3,055
Equity in the loss of BioMarin/Genzyme LLC	968	1,817
Stock-based compensation	35,414	32,721
Deferred income taxes	(10,610)	6,844
Excess tax benefit from stock option exercises	(96)	(109)
Impairment of intangible assets	6,707	0
Unrealized foreign exchange (gain) loss on forward contracts	(4,846)	5,699
Changes in the fair value of contingent acquisition consideration payable	(3,325)	(2,390)
Debt conversion expense	0	1,896
Changes in operating assets and liabilities:		
Accounts receivable, net	(12,451)	(20,481)
Inventory	9,293	(5,930)
Other current assets	(8,154)	(6,147)
Other assets	(6,905)	110
Accounts payable and accrued liabilities	15,825	1,459
Other long-term liabilities	8,625	1,019
Net cash provided by operating activities	5,623	18,928
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(30,676)	(64,539)
Maturities and sales of investments	165,459	227,094
Purchase of available-for-sale investments	(276,817)	(215,298)
Investments in BioMarin/Genzyme LLC	(1,258)	(1,903)
Net cash used in investing activities	(143,292)	(54,646)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options and Employee Stock Purchase Plan	37,667	23,436
Proceeds from public offering of common stock, net	235,499	0
Excess tax benefit from stock option exercises	96	109
Net payment on debt conversion	0	(2,234)
Payment of contingent acquisition consideration payable	0	(1,894)
Repayment of capital lease obligations	(535)	(524)
Net cash provided by financing activities	272,727	18,893

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		135,058		(16,825)
Cash and cash equivalents:				
Beginning of period	$	46,272	$	88,079
End of period	$	181,330	$	71,254
SUPPLEMENTAL CASH FLOW DISCLOSURES:				
Cash paid for interest, net of interest capitalized into fixed assets	$	3,597	$	4,019
Cash paid for income taxes		5,591		3,386
Stock-based compensation capitalized into inventory		3,042		3,978
Depreciation capitalized into inventory		4,744		4,067
SUPPLEMENTAL CASH FLOW DISCLOSURES FROM INVESTING AND FINANCING ACTIVITIES:				
Decrease in accrued liabilities related to fixed assets	$	1,488	$	2,373
Change in asset retirement obligation		415		0

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

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2012

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

(Unaudited)

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

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

Through September 30, 2012, the Company had accumulated losses of approximately $486.4 million. Management believes that the Company s cash, cash equivalents and short-term and long-term investments at September 30, 2012 will be sufficient to meet the Company s obligations for the foreseeable future based on management s current long-term business plans and assuming that the Company achieves its long-term goals. If the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and other acquisitions of complementary technologies, products or companies, the Company may need additional capital. The Company expects to continue to finance future cash needs that exceed its operating activities primarily through its current cash, cash equivalents, short-term and long-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners.

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying Condensed Consolidated Financial Statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for Quarterly Reports on Form 10-Q and do not include all of the information and note disclosures required by U.S. generally accepted accounting principles (U.S. GAAP) for complete financial statements. The Condensed Consolidated Financial Statements should therefore be read in conjunction with the Consolidated Financial Statements and Notes thereto for the fiscal year ended December 31, 2011 included in the Company s Annual Report on Form 10-K filed with the SEC on February 22, 2012.

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with U.S. GAAP, which requires management to make estimates and assumptions that affect amounts reported in the Condensed Consolidated Financial Statements and accompanying disclosures. Although these estimates are based on management s best knowledge of current events and actions that the Company may undertake in the future, actual results may be different from those estimates. The Condensed Consolidated Financial Statements reflect all adjustments of a normal, recurring nature that are, in the opinion of management, necessary for a fair presentation of results for these interim periods. The results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2012.

The Company has evaluated events and transactions subsequent to the balance sheet date. Based on this evaluation, the Company is not aware of any events or transactions that occurred subsequent to the balance sheet date but prior to filing this Quarterly Report on Form 10-Q that would require recognition or disclosure in the Condensed Consolidated Financial Statements, except for the transaction discussed in Note 16.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2012

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

(Unaudited)

Significant Accounting Policies

There have been no material changes to the Company s significant accounting policies during the nine months ended September 30, 2012, as compared to the significant accounting policies disclosed in Note 2 of the Consolidated Financial Statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2011.

Reclassifications

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

(3) RECENT ACCOUNTING PRONOUNCEMENTS

In July 2012, the Financial Accounting Standards Board issued Accounting Standards Update No. 2012-02, *Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment (ASU 2012-02)*. This ASU states than an entity has the option to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that an indefinite-lived intangible asset, other than goodwill, is impaired. The results of the qualitative assessment will determine whether it is necessary to perform the quantitative impairment test described in Topic 350. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, which for the Company means January 1, 2013. Early adoption is permitted, including for annual and interim impairment tests performed as of a date before July 27, 2012, if an entity's financial statements for the most recent annual or interim period have not yet been issued. Because the measurement of a potential impairment has not changed, the adoption of ASU 2012-02 will not have a material impact on the Company s financial position or results of operations.

(4) STOCKHOLDERS EQUITY

In June 2012, the Company sold 6,500,000 shares of its common stock at a price of $36.28 per share in an underwritten public offering pursuant to an effective registration statement previously filed with the SEC. The Company received cash proceeds of approximately $235.5 million from this public offering.

On May 30, 2012, the Company entered into Amendment No. 1 (the Amendment) to the Amended and Restated Rights Agreement, dated February 27, 2009, between the Company and Computershare Shareowner Services LLC (formerly known as Mellon Investor Services LLC) as Rights Agent (the Rights Agreement). The Amendment accelerated the final expiration date of the Company s preferred share purchase rights (the Rights) under the Rights Agreement from September 23, 2012 to May 30, 2012. As a result, each outstanding share of the Company s common stock is no longer accompanied by a Right. The holders of common stock were not entitled to any payment as a result of the expiration of the Rights Agreement and the Rights issued thereunder.

See Note 17 to the Consolidated Financial Statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, for additional information related to the Company s equity plans.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2012

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

(Unaudited)

(5) SHORT-TERM AND LONG-TERM INVESTMENTS

All investments were classified as available-for-sale at September 30, 2012 and December 31, 2011. The principal amounts of short-term and long-term investments by contractual maturity as of September 30, 2012 and December 31, 2011, are summarized in the tables below:

	Contractual Maturity Date for the Years Ending December 31,						
	2012	2013	2014	2015	Total Book Value at September 30, 2012	Unrealized Gain (Loss)	Aggregate Fair Value at September 30, 2012
Certificates of deposit	$ 10,929	$ 34,537	$ 7,406	$ 0	$ 52,872	$ 20	$ 52,892
Commercial paper	17,988	30,310	0	0	48,298	34	48,332
Corporate securities	24,324	137,489	27,619	25,338	214,770	375	215,145
U.S. Government agency securities	0	8,526	6,401	20,503	35,430	19	35,449
Greek government-issued bonds	0	0	0	48	48	0	48
Total	$ 53,241	$ 210,862	$ 41,426	$ 45,889	$ 351,418	$ 448	$ 351,866

	Contractual Maturity Date for the Years Ending December 31,					
	2012	2013	2014	Total Book Value at December 31, 2011	Unrealized Gain (Loss)	Aggregate Fair Value at December 31, 2011
Certificates of deposit	$ 38,547	$ 17,195	$ 0	$ 55,742	$ 13	$ 55,755
Commercial paper	24,730	0	0	24,730	(9)	24,721
Corporate securities	85,595	40,899	3,100	129,594	53	129,647
U.S. Government agency securities	0	32,877	0	32,877	13	32,890
Greek government-issued bonds	0	192	0	192	0	192
Total	$ 148,872	$ 91,163	$ 3,100	$ 243,135	$ 70	$ 243,205

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of September 30, 2012. The investments are in institutions that have strong financial ratings and management expects full recovery of the carrying amounts.

See Note 11 for additional discussion regarding the Greek government-issued bonds held by the Company.

The aggregate amounts of unrealized losses and related fair value of investments with unrealized losses as of September 30, 2012 and December 31, 2011 were as follows:

	Less Than 12 Months to Maturity		12 Months or More to Maturity		Totals at September 30, 2012	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	$ 1,719	$ (1)	$ 333	$ (1)	$ 2,052	$ (2)
Commercial paper	2,390	(3)	0	0	2,390	(3)
Corporate securities	30,702	(15)	21,091	(90)	51,793	(105)
Total	$ 34,811	$ (19)	$ 21,424	$ (91)	$ 56,235	$ (110)

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2012

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

(Unaudited)

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

(6) PROPERTY, PLANT AND EQUIPMENT

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

	September 30, 2012	December 31, 2011
Leasehold improvements	$ 65,362	$ 49,456
Building and improvements	143,773	141,484
Manufacturing and laboratory equipment	76,659	72,039
Computer hardware and software	53,011	48,566
Furniture and equipment	10,578	7,679
Land	10,056	10,056
Construction-in-progress	54,898	55,436
	414,337	384,716
Less: Accumulated depreciation	(140,613)	(115,745)
Total property, plant and equipment, net	$ 273,724	$ 268,971

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. Depreciation expense for the three and nine months ended September 30, 2011 was $8.1 million and $22.8 million, respectively, of which $2.1 million and $4.1 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, 2012 and 2011 was insignificant.

(7) INTANGIBLE ASSETS

Intangible assets consisted of the following:

	September 30, 2012	December 31, 2011
Intangible assets:		
Finite-lived intangible assets	$ 118,242	$ 118,242
Indefinite-lived intangible assets	63,689	70,396
Total intangible assets, gross	181,931	188,638
Less: Accumulated amortization	(16,307)	(8,361)
Total intangible assets, net	$ 165,624	$ 180,277

Finite-Lived Intangible Assets

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

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2012

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

(Unaudited)

Indefinite-Lived Intangible Assets

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

Intangible assets related to IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D assets below their respective carrying amounts. During the first quarter of 2012, the Company recorded an impairment charge of $6.7 million related to certain Firdapse IPR&D assets. These IPR&D assets were associated with marketing rights in the U.S. The Company was exploring strategic options for the Firdapse U.S. program, including the potential outlicense of rights in the U.S. In March 2012, the Company recognized an impairment charge based on the status of business development efforts at the time and the related discounted cash flow projections that no longer supported the carrying-value of the IPR&D intangible assets. The impairment charge is included in Intangible Asset Amortization and Contingent Consideration on the Condensed Consolidated Statements of Comprehensive Loss for the nine months ended September 30, 2012.

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

(8) SUPPLEMENTAL BALANCE SHEET INFORMATION

Inventory consisted of the following:

	September 30, 2012	December 31, 2011
Raw materials	$ 13,768	$ 12,145
Work-in-process	67,718	75,903
Finished goods	39,339	42,070
Total inventory	$ 120,825	$ 130,118

Other current assets consisted of the following:

	September 30, 2012	December 31, 2011

Non-trade receivables	$ 9,018	$ 6,093
Prepaid expenses	11,415	7,551
Forward foreign currency exchange contracts	3,544	4,705
Current deferred tax assets	23,951	21,115
Deferred cost of goods sold	4,012	0
Short-term restricted investments	2,132	0
Other	744	289
Total other current assets	$ 54,816	$ 39,753

See Note 11 for additional discussion regarding the fair value of restricted investments and forward foreign currency exchange contracts.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2012

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

(Unaudited)

Accounts payable and accrued liabilities consisted of the following:

	September 30, 2012	December 31, 2011
Accounts payable	$ 11,459	$ 12,239
Accrued accounts payable	36,385	23,849
Accrued vacation expense	7,891	6,530
Accrued compensation expense	21,935	17,619
Accrued interest expense	2,681	1,300
Accrued royalties payable	4,444	5,866
Accrued rebates payable	8,956	6,025
Other accrued operating expenses	7,873	9,259
Value added taxes payable	1,476	3,165
Current portion of contingent acquisition consideration payable	5,921	5,555
Current portion of deferred rent	1,084	342
Other	1,384	2,376
Total accounts payable and accrued liabilities	$ 111,489	$ 94,125

Other long-term liabilities consisted of the following:

	September 30, 2012	December 31, 2011
Long-term portion of deferred rent	$ 7,720	$ 950
Long-term portion of contingent acquisition consideration payable	29,369	33,059
Long-term portion of asset retirement obligation liability	3,406	2,991
Long-term portion of deferred compensation liability	13,134	8,768
Long-term income taxes payable	5,165	5,165
Deferred tax liabilities	32,698	35,127
Other	900	2,119
Total other long-term liabilities	$ 92,392	$ 88,179

(9) 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 and Firdapse 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 follow below. See Note 11 for additional discussion regarding the fair value of forward foreign currency exchange contracts.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2012

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

(Unaudited)

At September 30, 2012, the Company had 124 forward foreign currency exchange contracts outstanding to sell a total of 67.2 million Euros and eight forward foreign currency exchange contracts outstanding to buy 9.6 million Brazilian Reais with expiration dates ranging from October 31, 2012 through May 2014. These hedges were entered into in order to protect against the fluctuations in revenue associated with Euro denominated Naglazyme, Firdapse and Aldurazyme sales and operating expenses denominated in the Brazilian Real. 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 Financial Accounting Standards Board s Accounting Standards Codification 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 the foreign currency exchange rates.

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 expenses in the Condensed Consolidated Statements of Comprehensive Loss. At September 30, 2012, separate from the 132 contracts discussed above, the Company had one outstanding forward foreign currency exchange contract to sell 33.4 million Euros that was not designated as a hedge for accounting purposes that matures on October 31, 2012.

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 May 2014. Over the next twelve months, the Company expects to reclassify $3.5 million from accumulated other comprehensive income to earnings as the forecasted revenue transactions and operating expenses occur.

At September 30, 2012 and December 31, 2011, the fair value carrying amounts of the Company s derivative instruments were as follows:

	Asset Derivatives September 30, 2012		Liability Derivatives September 30, 2012	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 3,544	Accounts payable and accrued liabilities	$ 366
Forward foreign currency exchange contracts	Other assets	88	Other long-term liabilities	258
Total		$ 3,632		$ 624
Derivatives not designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 0	Accounts payable and accrued liabilities	$ 167
Total		0		167
Total value of derivative contracts		$ 3,632		$ 791

	Asset Derivatives December 31, 2011		Liability Derivatives December 31, 2011	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 4,705	Accounts payable and accrued liabilities	$ 189
Forward foreign currency exchange contracts	Other assets	1,977	Other long-term liabilities	26
Total		$ 6,682		$ 215
Derivatives not designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 0	Accounts payable and accrued liabilities	$ 5
Total		0		5
Total value of derivative contracts		$ 6,682		$ 220

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

(Unaudited)

The effect of the Company s derivative instruments on the Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2012 and 2011 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Derivatives Designated as Hedging Instruments:				
Net gain (loss) recognized in Other Comprehensive Income (OCI) (1)	$ (3,952)	$ 7,913	$ (4,612)	$ 1,705
Net gain (loss) reclassified from accumulated OCI into income (2)	2,362	(1,740)	4,916	(3,854)
Net gain (loss) recognized in income (3)	218	(1,164)	753	(1,016)
Derivatives Not Designated as Hedging Instruments:				
Net gain (loss) recognized in income (4)	$ (1,388)	$ 1,770	$ 1,286	$ (961)

(1) Net change in the fair value of the effective portion classified as OCI
(2) Effective portion classified as net product revenue and selling, general and administrative expense
(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, 2012 and December 31, 2011, accumulated other comprehensive income before taxes associated with forward foreign currency exchange contracts qualifying for hedge accounting treatment was a gain of $3.3 million and $8.0 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.

(10) CONVERTIBLE DEBT

In April 2007, the Company sold approximately $324.9 million of senior subordinated convertible notes due 2017 (the 2017 Notes). 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.

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, and in each of the three-month and nine-month periods ended September 30, 2012 and 2011 the Company recognized amortization of expense of $0.2 million and $0.6 million, respectively.

In March 2006, the Company sold $172.5 million of senior subordinated convertible notes due 2013 (the 2013 Notes) of which $23.4 million remains outstanding at September 30, 2012. The debt was issued at face value and bears interest at the rate of 2.5% 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 $16.58 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 March 29, 2013. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

In connection with the placement of the 2013 Notes, the Company paid approximately $5.5 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 approximately $27 and $81 for the three and nine months ended September 30, 2012, compared to $0.1 and $0.2 million for the three and nine months ended September 30, 2011, respectively. The decrease in amortization expense for the three and nine months ended September 30, 2012 was attributed to the conversion of $29.2 million in aggregate principal of the 2013 Notes in September 2011.

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In September 2011, the Company entered into separate agreements with nine of the existing holders of its 2013 Notes pursuant to which such holders converted $29.2 million in aggregate principal amount of the 2013 Notes into 1,760,178 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 2013 Notes, the Company paid the holders future interest of approximately $1.1 million along with an aggregate of approximately $0.8 million related to varying cash premiums for agreeing to convert the 2013 Notes, which was recognized in total as debt conversion expense on the Consolidated Statement of Operations for the year ended December 31, 2011. Additionally, the Company reclassified $0.2 million of deferred offering costs to additional paid-in capital in connection with the conversion of the 2013 Notes. During the fourth quarter of 2011, certain note holders voluntarily exchanged an insignificant number of convertible notes for shares of the Company s common stock.

Interest expense on the Company s convertible debt for the three and nine months ended September 30, 2012 was $1.7 million and $5.0 million, respectively, compared to $1.8 million and $5.5 million for the three and nine months ended September 30, 2011, respectively. The decrease in interest expense related to the Company s convertible debt for the three and nine months ended September 30, 2012, compared to the three and nine months ended September 30, 2011 was attributed to the conversion of $29.2 million in aggregate principal of the 2013 Notes in September 2011.

(11) 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 at September 30, 2012 and December 31, 2011.

	Fair Value Measurements at September 30, 2012			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents				
Overnight deposits	$ 62,575	$ 62,575	$ 0	$ 0
Money market instruments	118,755	0	118,755	0
Total cash and cash equivalents	$ 181,330	$ 62,575	$ 118,755	$ 0
Available-for-sale securities				
Short-term				
Certificates of deposit	$ 41,679	$ 0	$ 41,679	$ 0
Commercial paper	48,332	0	48,332	0
Corporate securities	146,579	0	146,579	0
U.S. Government agency securities	8,535	0	8,535	0
Long-term				
Certificates of deposit	11,213	0	11,213	0

Corporate securities	68,566	0	68,566	0
U.S. Government agency securities	26,914	0	26,914	0
Greek government-issued bonds	48	0	48	0
Total available-for-sale securities	$ 351,866	$ 0	$ 351,866	$ 0
Restricted investments (1)	5,731	0	5,731	0
Nonqualified Deferred Compensation Plan assets (2)	4,272	0	4,272	0
Forward foreign currency exchange contract asset (3)	3,632	0	3,632	0
Total assets	$ 546,831	$ 62,575	$ 484,256	$ 0
Liabilities:				
Nonqualified Deferred Compensation Plan liability (4)	$ 13,667	$ 9,395	$ 4,272	$ 0
Forward foreign currency exchange contract liability (3)	791	0	791	0
Contingent acquisition consideration payable (5)	35,290	0	0	35,290
Asset retirement obligation (6)	3,406	0	0	3,406
Total liabilities	$ 53,154	$ 9,395	$ 5,063	$ 38,696

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	Fair Value Measurements at December 31, 2011			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents				
Overnight deposits	$ 44,212	$ 44,212	$ 0	$ 0
Money market instruments	2,060	0	2,060	0
Total cash and cash equivalents	$ 46,272	$ 44,212	$ 2,060	$ 0
Available-for-sale securities				
Short-term				
Certificates of deposit	$ 38,564	$ 0	$ 38,564	$ 0
Commercial paper	24,721	0	24,721	0
Corporate securities	85,535	0	85,535	0
Long-term				
Certificates of deposit	17,191	0	17,191	0
Corporate securities	44,112	0	44,112	0
U.S. Government agency securities	32,890	0	32,890	0
Greek government-issued bonds	192	0	192	0
Total available-for-sale securities	$ 243,205	$ 0	$ 243,205	$ 0
Nonqualified Deferred Compensation Plan assets (2)	3,505	0	3,505	0
Forward foreign currency exchange contract asset (3)	6,682	0	6,682	0
Total assets	$ 299,664	$ 44,212	$ 255,452	$ 0
Liabilities:				
Nonqualified Deferred Compensation Plan liability (4)	$ 9,450	$ 5,945	$ 3,505	$ 0
Forward foreign currency exchange contract liability (3)	220	0	220	0
Contingent acquisition consideration payable (5)	38,614	0	0	38,614
Asset retirement obligation (6)	2,991	0	0	2,991
Total liabilities	$ 51,275	$ 5,945	$ 3,725	$ 41,605

(1) At September 30, 2012, 63% and 37% of the restricted investments were included in other assets and other current assets, respectively. The restricted investments secure the Company s irrevocable standby letters of credit obtained in connection with the Company s new corporate facility lease agreements and certain other commercial arrangements. See Note 26 to the Consolidated Financial Statements

included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011 for additional discussion.

(2) At September 30, 2012 and December 31, 2011, 98% and 96%, respectively, of the Nonqualified Deferred Compensation Plan assets balance were included in other assets and the remainder of the balance was included in other current assets on the Condensed Consolidated Balance Sheets.

(3) See Note 9 for further information regarding the derivative instruments.

(4) At September 30, 2012 and December 31, 2011, 96% and 93%, respectively, of the Nonqualified Deferred Compensation Plan liability balance was included in other long-term liabilities and the remainder was included in accounts payable and accrued liabilities on the Condensed Consolidated Balance Sheets.

(5) At September 30, 2012 and December 31, 2011, 83% and 86%, respectively, of the contingent acquisition consideration payable was included in other long-term liabilities and 17% and 14%, respectively, was included in accounts payable and accrued liabilities.

(6) At September 30, 2012 and December 31, 2011, the asset retirement obligation liability was included in other long-term liabilities.

The Company s level 2 securities are valued using third-party pricing sources, which generally use observable market prices, interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing. 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, 2012 and December 31, 2011. See Note 5 for further information regarding the Company s financial instruments.

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The Company s level 3 liabilities are estimated using a probability-based income approach utilizing an appropriate discount rate. 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. 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.

During the three and nine months ended September 30, 2012, the fair value of the contingent acquisition consideration payable increased by $0.6 million and decreased $3.3 million, respectively, due to changes in estimated probability and estimated timing of attaining certain milestones.

See Notes 5, 6 and 7 to the Consolidated Financial Statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, for additional discussion related to business acquisitions and contingent acquisition consideration payable.

(12) STOCK-BASED COMPENSATION

On May 8, 2012, the Company s Board of Directors approved the 2012 Inducement Plan (2012 Inducement Plan), which provides for grants of up to 750,000 share-based awards to new employees to purchase common stock at fair value of such shares. The awards are substantially similar to those granted under the Company s 2006 Share Incentive Plan as amended and restated on March 22, 2010 (2006 Share Incentive Plan).

In addition to the 2012 Inducement Plan, the Company s stock-based compensation plans include the 2006 Share Incentive Plan, as amended and restated on March 22, 2010 (2006 Share Incentive Plan) and the Employee Stock Purchase Plan (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 18 to the Consolidated Financial Statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, for additional information related to 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, 2012. 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,	
	2012	2011	2012	2011
Expected volatility	46%	47%	45 46%	47 50%
Dividend yield	0.0%	0.0%	0.0%	0.0%

Expected life	6.5 years	6.4 years	6.5 years		6.3	6.4 years
Risk-free interest rate	0.9%	1.3%	0.8	1.1%	1.3	2.7%

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During the nine months ended September 30, 2012, the Company granted 2.2 million options with a weighted average option value of $37.35 per option.

The Company did not grant any new stock purchase rights under the ESPP during the three months ended September 30, 2012.

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, 2012, the Company granted 0.6 million RSUs with a weighted average fair market value of $37.57 per share.

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

Pursuant to the Board of Directors approval, the Company granted 140,000 RSU awards with performance and market-based vesting conditions during the nine months ended September 30, 2012. The awards were granted to two executive officers in the amounts of 40,000 and 100,000 on September 5, 2012 and May 29, 2012, respectively. The terms of the 2012 grants are consistent with the terms of the 875,000 RSU awards granted under the 2006 Share Incentive Plan on June 1, 2011. These awards provide for a base award of 1,015,000 RSUs (Base RSUs). The grant date fair value of the Base RSUs was $43.26, $46.01 and $32.61 per RSU award on September 5, 2012, May 29, 2012 and June 1, 2011, respectively.

The vesting of the Base RSUs under these specific grants is contingent upon the achievement of multiple performance conditions, as follows:

Strategic Performance Goals	Percentage of Base RSUs to Vest Upon Achievement of Goal	Base Number of RSUs Granted Before TSR Multiplier
Product Goals		
Approval of GALNS in the U.S. or EU prior to December 31, 2015	35%	355,250
Approval of PEG-PAL or any other non-GALNS product in the U.S. or EU prior to December 31, 2015	25%	253,750
Financial Goal		
Total revenues of at least $775.0 million in fiscal 2015	40%	406,000
		1,015,000

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 (TSR) multiplier which could range from 75% to 125% to determine the number of earned RSUs. The TSR multiplier will be determined based on the Company s TSR percentile ranking relative to the TSR of the NASDAQ Biotechnology Index on December 31, 2015. TSR is calculated based on the 20-trading day average prices before the beginning and end of the

performance period of the Company s common stock and each comparator company in the NASDAQ Biotechnology Index. The measurement period for the performance and TSR conditions is from June 1, 2011 through December 31, 2015, subject to certain change of control provisions (the Performance Period). The Company s TSR percentile ranking within the NASDAQ Biotechnology Index will result in a TSR multiplier ranging from 75% to 125%. The RSUs earned at the end of the Performance Period will vest on the filing date of the Company s Annual Report on Form 10-K for the 2015 fiscal year, subject to certain holding periods.

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The Company utilized a Monte Carlo simulation model to estimate the TSR multiplier and determined the grant date fair value on each of the grant dates. The assumptions used to estimate the fair value of the RSUs with performance and market vesting conditions were as follows:

	Grant Date		
	September 5, 2012	May 29, 2012	June 1, 2011
Fair value of the Company s common stock on grant date	$ 37.45	$ 39.06	$ 28.11
Expected volatility	31.73%	44.87%	47.95%
Risk-free interest rate	0.37%	0.52%	1.42%
Dividend yield	0.0%	0.0%	0.0%

The Monte Carlo simulation model also assumed correlations of returns of the stock prices of the Company s common stock and the common stock of a peer group of companies and historical stock price volatilities of the peer group of companies. The valuation model also used terms based on the length of the performance period and compound annual growth rate goals for total stockholder return based on the provisions of the award.

Stock-based compensation expense for this award will be recognized over the remaining service period beginning in the period the Company determines the strategic performance goal or goals is probable of achievement. Accordingly, because the Company s management has not yet determined the goals are probable of achievement as of September 30, 2012, no compensation expense has been recognized for these awards for the three and nine month periods ended September 30, 2012 and 2011.

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,	
	2012	2011	2012	2011
Cost of sales	$ 1,327	$ 1,334	$ 3,535	$ 3,864
Research and development	5,060	4,372	15,351	12,070
Selling, general and administrative	5,752	5,912	17,021	16,673
Total stock-based compensation expense	$ 12,139	$ 11,618	$ 35,907	$ 32,607

Stock-based compensation of $3.0 million and $4.0 million was capitalized into inventory for the nine months ended September 30, 2012 and 2011, respectively. Capitalized stock-based compensation is recognized as cost of sales when the related product is sold.

(13) EARNINGS (LOSS) PER SHARE

Potential 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:

	Three Months Ended September 30,		Nine Months Ended September 30	
	2012	2011	2012	2011
Options to purchase common stock	15,998	16,674	15,998	16,674
Common stock issuable under convertible debt	17,370	17,372	17,370	17,372
Unvested restricted stock units	1,297	1,033	1,256	1,001
Potentially issuable common stock for ESPP purchases	263	326	254	312
Common stock held by the Nonqualified Deferred Compensation Plan	233	173	233	173
Total	35,161	35,578	35,111	35,532

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(14) 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 were to 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,	
	2012	2011	2012	2011
Region:				
United States	53%	53%	50%	49%
Europe	21%	21%	22%	23%
Latin America	14%	16%	15%	15%
Rest of world	12%	10%	13%	13%
Total net product revenue	100%	100%	100%	100%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Customer A	14%	16%	15%	17%
Customer B (1)	18%	21%	15%	18%
Customer C	11%	13%	12%	12%
Total	43%	50%	42%	47%

(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, 2012 and December 31, 2011 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 two largest customers accounted for 43% and 12% of the September 30, 2012 accounts receivable balance, respectively, compared to December 31, 2011 when the two largest customers accounted for 49% and 14% of the accounts receivable balance, respectively. As of September 30, 2012 and December 31, 2011, accounts receivable for the Company s largest customer balance included $31.8 million and $31.0 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 performs 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, 2012, approximately 4% of the Company s net product revenues were from these countries. Additionally, approximately 9% of the Company s outstanding accounts receivable at September 30, 2012 related to such countries.

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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, 2012.

	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	2,515	258	0	2,773	0
Portugal	0	0	0	0	0
Greece	0	0	341	341	341
Total	$ 2,515	$ 258	$ 341	$ 3,114	$ 341

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.

(15) COMMITMENTS AND CONTINGENCIES

The Company is also subject to contingent payments totaling approximately $357.6 million as of September 30, 2012, which are due upon achievement of certain regulatory and licensing milestones if they occur before certain dates in the future.

(16) SUBSEQUENT EVENT

In October 2012, the Company entered into agreements with a third party to license the North American rights to market Firdapse. As part of the arrangement with the third-party licensee, the Company invested $5.0 million in the third-party and in exchange received an unsecured, non-interest bearing convertible promissory note.

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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, pote 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. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these statements, which speak only as of the date that they were made. These cautionary 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. 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 the 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,	
	2012	2011	2012	2011
Total net product revenues	$ 126.3	$ 112.9	$ 365.5	$ 331.6
Cost of sales	24.6	22.4	65.3	62.5
Research and development expense	66.2	58.6	217.9	156.5
Selling, general and administrative expense	46.3	44.9	143.1	127.0
Net loss	(5.4)	(17.7)	(61.3)	(27.1)
Stock-based compensation expense	12.1	11.6	35.9	32.6

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).

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 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, 2012, totaled $62.5 million and $193.9 million, respectively, compared to $55.9 million and $176.8 million, respectively, for the three and nine months ended September 30, 2011.

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. Kuvan net product revenues for the three and nine months ended September 30, 2012 totaled $36.4 million and $103.1 million, respectively, compared to $30.5 million and $86.0 million, respectively, for the three and nine months ended September 30, 2011, respectively.

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

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 the three and nine months ended September 30, 2012 totaled $3.6 million and $10.8 million, respectively, compared to $3.5 million and $9.8 million, respectively, for the three and nine months ended September 30, 2011.

Aldurazyme (laronidase), which was developed in collaboration with Genzyme Corporation (Genzyme), was approved in 2003 for marketing in the U.S., the EU and subsequently in other countries for patients with mucopolysaccharidosis I (MPS I). Aldurazyme net product revenues for the three and nine months ended September 30, 2012 totaled $23.8 million and $57.7 million, respectively, compared to $23.0 million and $59.0 million, respectively for the three and nine months ended September 30, 2011.

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

- 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; and
- BMN-111, a peptide therapeutic for the treatment of achondroplasia, the leading cause of dwarfism.

We are conducting preclinical development of several other product candidates for genetic and other metabolic diseases, including BMN-190 for late infantile neuronal ceroid lipofuscinosis (LINCL), a lysosomal storage disorder primarily affecting the brain.

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 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, audit and legal fees.

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 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 and changes in assumed discount periods and rates.

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

Our cash, cash equivalents, short-term investments and long-term investments totaled $533.2 million as of September 30, 2012, compared to $289.5 million as of December 31, 2011. We have historically financed our operations primarily through 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. 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 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 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.

There have been no significant changes to our critical accounting policies and estimates during the nine months ended September 30, 2012, 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, 2011, which was filed with the SEC on February 22, 2012.

Recent Accounting Pronouncements

See Note 3 of the 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 and nine months ended September 30, 2012 was $5.4 million and $61.3 million, respectively, compared to net loss of $17.7 million and $27.1 million, respectively, for the three and nine months ended September 30, 2011. 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, 2011	$ (17.7)	$ (27.1)
Increased gross profit from product sales	11.2	31.1
Increased research and development expense	(7.6)	(61.4)
Increased selling, general and administrative expense	(1.5)	(16.2)
Decreased (increased) intangible asset amortization and contingent consideration expense	1.6	0.9
Absence of debt conversion expense	1.9	1.9

Impairment loss on intangible assets	0	(6.7)
Decreased income tax expense	4.3	13.4
Other individually insignificant fluctuations	2.4	2.8
Net loss for the period ended September 30, 2012	$ (5.4)	$ (61.3)

The increase in gross profit from product sales during the three and nine months ended September 30, 2012, as compared to the three and nine months ended September 30, 2011 was primarily a result of additional Naglazyme patients initiating therapy 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 GALNS, PEG-PAL, BMN-701 and BMN-673 programs. The increase in selling, general and administrative expense was primarily due to increased facility and employee related costs and the continued international expansion of Naglazyme.

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

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,		
	2012	2011	Change	2012	2011	Change
Naglazyme	$ 62.5	$ 55.9	$ 6.6	$ 193.9	$ 176.8	$ 17.1
Kuvan	36.4	30.5	5.9	103.1	86.0	17.1
Firdapse	3.6	3.5	0.1	10.8	9.8	1.0
Aldurazyme	23.8	23.0	0.8	57.7	59.0	(1.3)
Total net product revenues	$ 126.3	$ 112.9	$ 13.4	$ 365.5	$ 331.6	$ 33.9

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Naglazyme	$ 53.4	$ 46.4	$ 7.0	$ 165.6	$ 146.9	$ 18.7
Kuvan	30.7	25.5	5.2	86.6	71.9	14.7
Firdapse	2.9	2.9	0	8.8	8.2	0.6
Aldurazyme	14.7	15.7	(1.0)	39.2	42.1	(2.9)
Total gross profit	$ 101.7	$ 90.5	$ 11.2	$ 300.2	$ 269.1	$ 31.1

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Aldurazyme revenue reported by Genzyme	$ 48.3	$ 46.3	$ 2.0	$ 140.0	$ 136.4	$ 3.6
Royalties due from Genzyme	$ 19.7	$ 19.0	$ 0.7	$ 56.6	$ 53.0	$ 3.6
Incremental (previously recognized) Aldurazyme product transfer revenue	4.1	4.0	0.1	1.1	6.0	(4.9)
Total Aldurazyme net product revenues	$ 23.8	$ 23.0	$ 0.8	$ 57.7	$ 59.0	$ (1.3)

Naglazyme net product revenues for the three and nine months ended September 30, 2012 totaled $62.5 million and $193.9 million, respectively, of which $54.1 million and $168.5 million, respectively, was earned from customers based outside the U.S. The impact of foreign currency exchange rates on Naglazyme sales denominated in currencies other than the U.S. dollar was negative by $0.2 million and negative by $1.4 million for the three and nine months ended September 30, 2012, respectively. Naglazyme gross margins for the three and nine months ended September 30, 2012 were 85% in both periods, compared to the three and nine months ended September 30, 2011 when Naglazyme gross margins were 83% in both periods. The increased Naglazyme gross margins for the three and nine months ended September 30, 2012 were consistent with expectations for the three and nine months ended September 30, 2012 as a result of our purchase of the Naglazyme royalty rights from SA Pathology in November 2011 and the price increase in the U.S. and Latin America that occurred in March 2012. Prior to the purchase, we licensed the intellectual property from SA Pathology to whom we paid a five percent royalty on net sales of Naglazyme. For additional

discussion of the transaction see Note 10 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2011.

Net product revenue for Kuvan for the three and nine months ended September 30, 2012 was $36.4 million and $103.1 million, respectively, compared to $30.5 million and $86.0 million for the three and nine months ended September 30, 2011, respectively. Kuvan gross margins for the three and nine months ended September 30, 2012 were 84% in both periods, compared to the three and nine months ended September 30, 2011 when gross margins were 83% and 84%, respectively. Cost of goods sold for the three and nine months ended September 30, 2012 and 2011 reflect royalties paid to third-parties of 10%. Kuvan gross margins for the three and nine months ended September 30, 2012 were consistent with expectations and are not expected to fluctuate significantly in the future. The four percent royalties earned from Merck Serono s net sales of Kuvan during the three and nine months ended September 30, 2012 were $0.5 million and $1.5 million, respectively, compared to $0.4 million and $1.2 million for the three and nine months ended September 30, 2011, respectively.

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

Net product revenue for Firdapse during the three and nine months ended September 30, 2012 was $3.6 million and $10.8 million, respectively, compared to $3.5 million and $9.8 million for the three and nine months ended September 30, 2011, respectively. Firdapse gross margins for the three and nine months ended September 30, 2012 were 82% and 81%, respectively, compared to the three and nine months ended September 30, 2011 when gross margins were 83% in both periods. Cost of goods sold for the periods presented reflect royalties paid to third-parties of approximately 8%. Firdapse gross margins for the three and nine months ended September 30, 2012 decreased, compared to the three and nine months ended September 30, 2011 due to increased manufacturing costs and the depletion of previously expensed inventory. Firdapse gross margins for the three and nine months ended September 30, 2012 were consistent with expectations and are not expected to fluctuate significantly in the future.

During the three and nine months ended September 30, 2012, Aldurazyme gross margins were 62% and 68%, respectively, compared to 68% and 71% for the three and nine months ended September 30, 2011, 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, 2012 was $24.6 million and $65.3 million, respectively, compared to $22.4 million and $62.5 million, respectively, for the three and nine months ended September 30, 2011. The increase in cost of sales was primarily attributed to the increase in product sales, and the amortization of the cost of the Naglazyme royalty rights purchased in the fourth quarter of 2011 and the shift in Aldurazyme revenue mix between royalty revenue and net product revenues. Additionally, Aldurazyme cost of goods sold during the nine months ended September 30, 2012 included a $0.8 million write-off of finished goods inventory in the first quarter of 2012.

Research and Development

Research and development expense increased to $66.2 million for the three months ended September 30, 2012, from $58.6 million for the three months ended September 30, 2011. Research and development expense increased to $217.9 million for the nine months ended September 30, 2012, from $156.5 million for the nine months ended September 30, 2011. The increases in research and development expense were primarily a result of the following (in millions):

	Three Months	Nine Months
Research and development expense for the period ended September 30, 2011	$ 58.6	$ 156.5
Increased GALNS for MPS IV A development expenses	8.4	33.9
Increased BMN-190 development expenses	3.3	7.3
Increased BMN-701 development expenses	0.4	6.7
Increased BMN-673 development expenses	0.7	2.8
Decreased BMN-111 development expenses	(3.4)	0
Decreased PEG-PAL development expenses	(3.5)	(0.3)
Decreased development expense related to commercial products	(1.9)	(0.7)
Increased stock-based compensation expense related to research and development	0.7	3.3
Decreased development expenses on early development stage programs	(0.8)	(1.9)
Increase in non-allocated research and development expenses and other net changes	3.7	10.3
Research and development expense for the period ended September 30, 2012	$ 66.2	$ 217.9

The increase in GALNS development expenses was attributed to increased clinical trial and manufacturing activities related to the product candidate. We expect research and development expense for our GALNS program to decrease in the remainder of 2012 as manufacturing activities were substantially completed in July 2012. The decrease in GALNS manufacturing costs will be partially offset by increased cost of the ongoing clinical trials. The increase BMN-673 and BMN-701 development expense was attributed to increased clinical trial activities related

to these product candidates. The increase in BMN-190 development expense was attributed to increased pre-clinical activities related to this product candidate. The decrease in PEG-PAL development expense was attributed to the timing of purchases of materials to produce the drug substance for the clinical trial. The decrease in BMN-111 development expense was attributed to a decrease in pre-clinical activities related to this product candidate. The increase in stock-based compensation expense is a result of an increased number of options outstanding due to an increased number of employees. The increase in non-allocated research and development expense primarily includes increased research and development personnel costs that are not allocated to specific programs. We expect spending to increase as our GALNS, PEG-PAL, BMN-673, BMN-701, BMN-111 and BMN-190 programs progress through clinical trials and as pre-clinical and clinical activities for our early development stage programs increase. 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 related to our approved products.

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Selling, General and Administrative

Selling, general and administrative expense increased to $46.3 million for the three months ended September 30, 2012, from $44.9 million for the three months ended September 30, 2011. Selling, general and administrative expense increased to $143.1 million for the nine months ended September 30, 2012, from $127.0 million for the nine months ended September 30, 2011. The increases in selling, general and administrative expenses were primarily a result of the following (in millions):

	Three Months	Nine Months
Selling, general and administrative expense for the period ended September 30, 2011	$ 44.9	$ 127.0
Net increase in corporate support and other administrative expenses	2.2	13.0
Increased sales and marketing expenses related to commercial products	1.7	4.3
(Decreased) increased GALNS pre-commercial expenses	(0.3)	1.0
Increased foreign exchange losses on unhedged transactions	(2.2)	(1.3)
Absence of bad debt expense	0	(0.9)
Selling, general and administrative expense for the period ended September 30, 2012	$ 46.3	$ 143.1

The increase in corporate support and other administrative costs was primarily comprised of increased employee related costs and facility costs. The increase in employee related costs was attributed to the increase in headcount. The increase in facility costs was primarily driven by the occupation of our new corporate headquarters in San Rafael, California. 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 and the administrative support of our expanding operations.

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 on intangible assets. Changes in the fair value of contingent acquisition consideration payable result from updates to the assumed probability of achievement or 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,		
	2012	2011	Change	2012	2011	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	6.7	0	6.7
Changes in the fair value of contingent acquisition consideration payable	0.6	2.2	(1.6)	(3.3)	(2.4)	(0.9)
Total intangible asset amortization and contingent consideration	$ 1.4	$ 3.0	$ (1.6)	$ 5.8	$ 0	$ 5.8

In the first quarter of 2012, we recorded an impairment charge of $6.7 million related to the U.S. Firdapse in-process research and development (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 change in the contingent consideration amount was due to changes in the fair value of contingent acquisition consideration payable resulting

from changes in estimated probability and the estimated timing of when certain milestones may be achieved.

For additional discussion see Note 7 to the accompanying Condensed Consolidated Financial Statements.

Equity in the Loss of BioMarin/Genzyme LLC

Equity in the income/loss of BioMarin/Genzyme LLC includes our 50% share of the joint venture s income/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 $0.3 million for the three months ended September 30, 2012 compared to $0.6 million for the three months ended September 30, 2011. Equity in the loss of the joint venture for the nine months ended September 30, 2012 and 2011 was $1.0 million and $1.8 million, respectively.

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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 $0.8 million and $1.8 million for the three and nine months ended September 30, 2012, compared to $0.7 million and $2.3 million for the three and months ended September 30, 2011, respectively. The reduced interest income during the nine months ended September 30, 2012, as compared to the three and nine months ended September 30, 2011 was primarily due to lower market interest rates. We expect that interest income will increase during the remainder of 2012 as compared to 2011 due to higher cash and investment balances resulting from the net proceeds received from the sale of 6.5 million shares of our common stock in June 2012.

Interest Expense

We incur interest expense on our convertible debt. Interest expense for the three and nine months ended September 30, 2012 was $1.8 million and $5.7 million, respectively, compared to $2.2 million and $6.5 million for the three and nine months ended September 30, 2011, respectively. The decrease in interest expense was attributed to the early conversion of $29.2 million in aggregate principal of our 2013 Notes in September 2011. We expect interest expense for the remainder of 2012 and the first quarter of 2013 to be approximately $1.7 million per quarter based on the amount of our outstanding debt at September 30, 2012. See Note 15 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2011 for additional discussion.

Provision for (Benefit from) Income Taxes

During the three and nine months ended September 30, 2012 we recognized an income tax benefit of $6.4 million and $6.8 million, respectively, compared to an income tax benefit of $2.1 million and income tax expense of $6.6 million during the three and nine months ended September 30, 2011, respectively. The provision for income taxes for the three and nine months ended September 30, 2012 and 2011 consisted of state, federal and foreign current tax expense and deferred tax expense related to the utilization of our federal net operating loss carryforwards and a portion of our credit carryforwards. Our overall tax expense during the three and nine months ended September 30, 2012 was offset by deferred tax benefits from federal orphan drug credits earned during the periods. The current period provision was further reduced by the benefit related to stock option exercises during the nine months ended September 30, 2012. See Note 22 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2011 for additional discussion of the components of income tax expense.

Financial Position, Liquidity and Capital Resources

We have historically financed our operations primarily through the issuance of common stock and convertible debt and by relying on equipment and other commercial financing. In June 2012, we sold 6,500,000 shares our common stock at a price of $36.28 per share in an underwritten public offering pursuant to an effective registration statement. We received net cash proceeds of $235.5 million from the public offering. 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. 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.

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Our financial condition as of September 30, 2012 and December 31, 2011 was as follows (in millions):

	September 30, 2012	December 31, 2011	Change
Cash and cash equivalents	$ 181.3	$ 46.3	$ 135.0
Short-term investments	245.1	148.8	96.3
Long-term investments	106.8	94.4	12.4
Cash, cash equivalents and investments	$ 533.2	$ 289.5	$ 243.7
Current assets	$ 719.4	$ 469.8	$ 249.6
Current liabilities	134.9	94.1	40.8
Working capital	$ 584.5	$ 375.7	$ 208.8
Convertible debt	$ 348.3	$ 348.3	$ 0

Our cash flows for each of the nine months ended September 30, 2012 and 2011 is summarized as follows (in millions):

	2012	2011	Change
Cash and cash equivalents at the beginning of the period	$ 46.3	$ 88.1	$ (41.8)
Net cash provided by operating activities	5.6	18.9	(13.3)
Net cash used in investing activities	(143.3)	(54.6)	(88.7)
Net cash provided by financing activities	272.7	18.9	253.8
Cash and cash equivalents at the end of the period	$ 181.3	$ 71.3	$ 110.0
Short-term and long-term investments	351.9	298.7	53.2
Cash, cash equivalents and investments	$ 533.2	$ 370.0	$ 163.2

Working Capital

Working capital was $584.5 million at September 30, 2012, an increase of $208.8 million from working capital of $375.7 million at December 31, 2011. The increase was primarily attributed to increases of $231.3 million in cash, cash equivalents and short-term investments resulting from net proceeds of $235.5 million from the public offering of our common stock in June 2012, $12.5 million in accounts receivable and $15.1 million in other current assets, offset by a decrease in inventory of $9.3 million, an increase of $17.4 million in accounts payable and accrued liabilities and the classification of the 2013 Notes as a current liability from long-term convertible debt based on their maturity in March 2013.

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, 2012, approximately 9% of our outstanding accounts receivable relate to such countries. See Note 14 of the accompanying Condensed Consolidated Financial Statements for additional discussion.

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Cash Provided by Operating Activities

Cash provided by operating activities during the nine months ended September 30, 2012 was $5.6 million, compared to cash provided by operating activities of $18.9 million during the nine months ended September 30, 2011. The decrease in cash provided by operating activities was primarily related to increased research and development expense that drove the increase in our net loss of $61.3 million, adjusted for non-cash items such as $33.4 million of depreciation and amortization expenses, $35.4 million of stock-based compensation expense, $6.7 million of impairment loss on intangible assets, $3.3 million decrease in the fair value of contingent acquisition consideration payable, $10.6 million decrease in deferred income taxes and $4.8 million of unrealized foreign exchange gain on forward foreign currency exchange contracts.

Cash Used in Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2012 was $143.3 million, compared to net cash used in investing activities of $54.6 million during the nine months ended September 30, 2011. Our investing activities have consisted primarily of purchases and sales and maturities of investments and capital expenditures. The increase in net cash used in investing activities during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily due to increased net purchases of investment securities of $123.2 million, offset by a $33.9 million decrease in capital expenditures.

Cash Provided by Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2012 was $272.7 million, compared to net cash provided by financing activities of $18.9 million during the nine months ended September 30, 2011. During the nine months ended September 30, 2012, our financing activities primarily included the June 2012 sale of our common stock and proceeds from the ESPP and stock option exercises. The net proceeds from the June 2012 public offering of our common stock were $235.5 million and proceeds from stock option exercises and ESPP contributions amounted to $37.7 million. See Note 4 to the accompanying Condensed Consolidated Financial Statements for additional discussion.

Other Information

In March 2006, we sold approximately $172.5 million of senior subordinated convertible notes due March 2013 (the 2013 Notes) of which $23.4 million remains outstanding at September 30, 2012. The debt was issued at face value and bears interest at the rate of 2.5% per annum, payable semi-annually in cash. The debt does not contain a call provision included and we are unable to unilaterally redeem the remaining debt prior to maturity in 2013. The remaining $23.4 million of the 2013 Notes is 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 $16.58 per share, subject to adjustment in certain circumstances. However, we must repay the remaining debt prior to maturity if there is a qualifying change in control or termination of trading of our common stock.

In April 2007, we sold approximately $324.9 million of senior subordinated convertible notes due April 2017 (the 2017 Notes). 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, 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. See Note 10 to our accompanying Condensed Consolidated Financial Statements for additional discussion. Our $348.3 million of total convertible debt as of September 30, 2012 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.

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 cash, cash equivalents and short-term and long-term investments will meet our operating and capital requirements for the foreseeable future based on our current long-term business plans and assuming that we are able to achieve our long-term goals. 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.

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

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. In October 2012, we paid the former LEAD stockholders $6.0 million for the attainment of a clinical milestone.

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 $20.9 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 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.

Funding Commitments

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, 2012 and 2011 and during the period since inception (March 1997 for the portion not allocated to any major program) were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Program Inception
	2012	2011	2012	2011	
GALNS for MPS IV A	$ 21.5	$ 13.1	$ 75.0	$ 41.1	$ 189.8
Naglazyme	2.7	2.7	8.4	7.7	160.9
Kuvan	3.3	3.6	11.1	9.2	137.8
Firdapse	0.8	2.4	4.6	8.3	24.9
BMN-673	2.7	2.0	8.1	5.3	23.8
BMN-701	5.1	4.7	17.2	10.5	37.2
BMN-111	2.3	5.7	10.1	10.1	29.9
BMN-190	3.5	0.2	7.9	0.6	14.5
PEG-PAL	5.3	8.8	21.3	21.6	107.7
Not allocated to specific major current projects	19.0	15.4	54.2	42.1	Not meaningful
Totals	$ 66.2	$ 58.6	$ 217.9	$ 156.5	

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 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;

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;

if we are unable to successfully develop 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.

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

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 market and commercialize Aldurazyme;
- the progress, timing, scope and results 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 time and cost necessary to respond to technological and market developments;
- 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.

We are also subject to contingent payments related to various development activities totaling approximately $357.6 million as of September 30, 2012, which are due upon achievement of certain development and commercial milestones, and if they occur before certain dates in the future.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks during the nine months ended September 30, 2012 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, 2011, which was filed with the SEC on February 22, 2012.

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.

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, 2011 filed with the SEC on February 22, 2012.

Risk Related to Our Business

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. If we fail to obtain regulatory approval for our product candidates, 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.

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

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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, 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, are regulated by the FDA as biologics under the Federal Food, Drug and Cosmetics 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.

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*** 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 increases 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.

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 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 and 2011. 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 2012 and may operate at an annual net loss beyond 2012. Our future profitability depends on our marketing and selling of Naglazyme, Kuvan and Firdapse, the successful 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 have been approved by the FDA, the European Commission (EC), and health agencies in other countries for the manufacture of Aldurazyme and Naglazyme. 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.

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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.**

In June 2012, we sold 6,500,000 shares of our common stock at a price of $36.28 per share in an underwritten public offering pursuant to an effective registration statement previously filed with the SEC. We received cash proceeds of approximately $235.5 million from the public offering. During the nine months ended September 30, 2012, we also received net proceeds of $37.7 million from stock option exercises and ESPP stock purchases. 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 stock purchase agreements with the former stockholders of Huxley, LEAD Therapeutics, Inc. (LEAD) and ZyStor 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 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.

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Improvements in manufacturing processes typically are very difficult to achieve and are often very expensive and may require extended periods of time to develop and may require us to complete clinical trials to receive regulatory approval of any manufacturing improvements. 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, 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 and Aldurazyme, 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 and Aldurazyme 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 and Aldurazyme or our third-party manufacturer s ability to manufacture Kuvan or Firdapse.

Our Galli Drive facility located in Novato, California is our only manufacturing facility for Naglazyme and Aldurazyme. 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, 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 and Aldurazyme, or to have Kuvan or Firdapse manufactured, could be seriously, or potentially completely impaired, and our Naglazyme, Kuvan, Aldurazyme and Firdapse commercialization efforts and revenue from the sale of Naglazyme, Kuvan, Aldurazyme and Firdapse 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;

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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 some of our products are small, we must achieve significant market share and maintain high per-patient prices for our products to achieve profitability.

Naglazyme, Aldurazyme, Kuvan and Firdapse all 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, we believe that we will need to continue to 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 Naglazyme, Kuvan, Aldurazyme and Firdapse 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 negotiation process in some countries can 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. 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.

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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 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 expands the 340B drug discount program (excluding orphan drugs), including the creation of new penalties for non-compliance; includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or donut hole, and imposes 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. Substantial new provisions affecting compliance also have been added, which may require us to modify our business practices with health care practitioners. For example, beginning in 2013, drug manufacturers will be required to 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. Although the statute requires reporting by March 31, 2013 of payments and other transfers of value made in calendar year 2012, the CMS has proposed not to require manufacturers to begin collecting required information until 90 days after publication of a final rule which has not yet been issued, and has also published a notice stating that manufacturers will not be required to begin collecting required information before January 1, 2013.

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The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the CMS and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products or product candidates. We will continue to evaluate the PPACA, as amended, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially have an impact on our business over time. The cost of implementing more detailed record keeping systems and otherwise complying with these regulations could substantially increase our costs. The changes to the way our products are reimbursed by the CMS could reduce our revenues. Both of these situations could adversely affect our results of operations.

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. In addition, the state of California and several other states have passed laws that require pharmaceutical companies to comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals.

Neither the government nor the courts have provided definitive guidance on the application of some of these laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we are required to pay a penalty or are suspended or excluded from participation in federal or state health care programs and our business, financial condition and results of operation may be adversely affected.

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:

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- 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 and 3,4-DAP 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. 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. For example, we may not have developed a method for treating a disease before others developed identical or similar methods, in which case we may not receive a granted patent.
- 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. In litigation, a competitor could claim that our issued patents are not valued 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 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 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.

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In addition, competition 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 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, 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.
- 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 or consultants may unintentionally or willfully disclose our information 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 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.

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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.

Our strategic alliance with Merck Serono may be terminated at any time by Merck Serono, and if it is terminated, our expenses could increase and our operating performance could be adversely affected.

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. Through the agreement, as amended in 2007, Merck Serono acquired exclusive rights to market these products in all territories outside the U.S., Canada and Japan, and we retained exclusive rights to market these products in the U.S. and Canada. Merck Serono may terminate the agreement forming our strategic alliance with them at any time by giving 90 days prior written notice if such termination occurs prior to the commercialization of any of the products licensed under our agreement, or by giving 180 days prior written notice if such termination occurs after the commercialization of such a product. Either Merck Serono or we may terminate our strategic alliance under certain circumstances, including if the other party is in material breach of the agreement and does not remedy the breach within a specified period of time, or has suffered certain financial difficulties, including filing for bankruptcy or making an assignment for the benefit of creditors. Although we are not currently in breach of the agreement and we believe that Merck Serono is not currently in breach of the agreement, there is a risk that either party could breach the agreement in the future. Upon a termination of the agreement by Merck Serono by giving notice or by us for a material breach by Merck Serono, all rights licensed to us under the agreement become irrevocable and fully-paid except in those countries where restricted by applicable law or for all intellectual property that Merck Serono does not own.

Upon a termination of the agreement by Merck Serono for a material breach by us or based on our financial difficulty, or upon the expiration of the royalty term of the products licensed under the agreement, all rights licensed to Merck Serono under the agreement become irrevocable and fully-paid upon the payment of amounts due by Merck Serono to us which accrued prior to the expiration of the royalty term, except in those countries where restricted by applicable law or for all intellectual property that we do not own and for which we do not have a royalty-free license. Upon a termination of the agreement for a material breach by us or for our financial difficulty, all rights and licenses granted by Merck Serono to us under or pursuant to the agreement will automatically terminate. If the agreement is terminated by either Merck Serono or us, and we continue the development and commercialization of products related to that agreement, we would be responsible for 100% of future development costs and all costs relating to the assumption of commercial responsibility for the marketing and selling of products related to that agreement, and accordingly our expenses would increase and our operating performance may be adversely affected.

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.

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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 equivalency 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 is preparing 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 patent rights. Upon receipt of this 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 such a suit is commenced, 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 and costly and may result in generic competition if such patent(s) are not upheld or if the generic competitor does not infringe such patent(s). However, generic versions of Kuvan would be prohibited until the expiration of orphan drug exclusivity in 2014 or 2015, depending on 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 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 and financial and administrative systems. Our

staff, financial resources, systems, procedures or controls may be inadequate to support our operations and our management may be unable to manage successfully future market opportunities or our relationships with customers and other third-parties.

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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, GALNS, BMN-701, BMN-673 or BMN-111 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.

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For the nine months ended September 30, 2012, approximately 4% of our net product revenues were from the Southern European countries of Italy, Spain, Portugal and Greece. Approximately, 9% of our total accounts receivable as of September 30, 2012 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;
- 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., the EU or in other parts of the world;
- actual or anticipated fluctuations in our operating results; and
- changes in our 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.

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 additional shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders, which would allow our Board of Directors to implement a stockholder rights plan without any 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.

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Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures
None.

Item 5. Other Information.
None.

Item 6. Exhibits.

10.1^	Employment Agreement with Jeffery R. Ajer dated September 5, 2012, previously filed with the Commission on September 5, 2012 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.2^	Severance Agreement and Release of All Claims with Stephen Aselage, dated September 4, 2012, previously filed with the Commission on September 5, 2012 as Exhibit 10.2 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.
Furnished herewith and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
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, 2012 and December 31, 2011, (ii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2012 and 2011, (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011, and (iv) Notes to Condensed Consolidated Financial Statements.

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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 29, 2012

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

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