BIOMARIN PHARMACEUTICAL INC

FORM 10-Q
(Quarterly Report)

Filed 10/29/10 for the Period Ending 09/30/10

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Industry	Biotechnology & Drugs
Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer ☒ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

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

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

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

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 102,497,125 shares of common stock, par value $0.001, outstanding as of October 22, 2010.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(In thousands, except for share and per share data)

	December 31, 2009 (1)	September 30, 2010 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 167,171	$ 127,539
Short-term investments	133,506	224,428
Accounts receivable, net	73,540	78,734
Inventory	78,662	91,741
Other current assets	14,848	31,747
Total current assets	467,727	554,189
Investment in BioMarin/Genzyme LLC	441	1,161
Long-term investments	169,849	88,955
Property, plant and equipment, net	199,141	213,755
Intangible assets, net	40,977	104,604
Goodwill	23,722	53,364
Other assets	15,306	228,505
Total assets	$ 917,163	$1,244,533
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable, accrued liabilities and other current liabilities	$ 78,068	$ 92,097
Deferred revenue	86	0
Total current liabilities	78,154	92,097
Convertible debt	497,083	497,083
Other long-term liabilities	19,741	69,689
Total liabilities	594,978	658,869
Stockholders' equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2009 and September 30, 2010; 100,961,922 and 102,464,509 shares issued and outstanding at December 31, 2009 and September 30, 2010, respectively	101	103
Additional paid-in capital	899,950	948,394
Company common stock held by Nonqualified Deferred Compensation Plan	(1,715)	(2,176)
Accumulated other comprehensive income (loss)	933	(1,581)
Accumulated deficit	(577,084)	(359,076)
Total stockholders' equity	322,185	585,664
Total liabilities and stockholders' equity	$ 917,163	$1,244,533

(1) December 31, 2009 balances were derived from the audited consolidated financial statements.

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three and Nine Months Ended September 30, 2009 and 2010
(In thousands, except for per share data, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Revenues:				
Net product revenues	$ 78,383	$ 96,559	$231,769	$ 271,224
Collaborative agreement revenues	648	130	2,025	507
Royalty and license revenues	1,776	1,061	3,780	2,922
Total revenues	80,807	97,750	237,574	274,653
Operating expenses:				
Cost of sales (excludes amortization of developed product technology)	14,970	18,003	49,180	49,816
Research and development	26,991	39,366	87,673	105,112
Selling, general and administrative	28,667	38,348	87,762	109,625
Intangible asset amortization and contingent consideration	46	3,972	2,914	6,206
Total operating expenses	70,674	99,689	227,529	270,759
Income (loss) from operations	10,133	(1,939)	10,045	3,894
Equity in the loss of BioMarin/Genzyme LLC	(680)	(639)	(1,773)	(2,194)
Interest income	1,012	968	4,051	3,193
Interest expense	(2,880)	(3,008)	(11,375)	(8,072)
Impairment loss on equity investments	0	0	(5,848)	0
Net gain from sale of investments	0	0	1,585	927
Income (loss) before income taxes	7,585	(4,618)	(3,315)	(2,252)
Provision for (benefit from) income taxes	945	(221,952)	1,884	(220,260)
Net income (loss)	$ 6,640	$ 217,334	$ (5,199)	$ 218,008
Net income (loss) per share, basic	$ 0.07	$ 2.13	$ (0.05)	$ 2.14
Net income (loss) per share, diluted	$ 0.07	$ 1.68	$ (0.05)	$ 1.74
Weighted average common shares outstanding, basic	100,331	102,110	100,098	101,660
Weighted average common shares outstanding, diluted	101,815	131,278	100,098	130,821

See accompanying notes to unaudited consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Nine Months Ended September 30, 2009 and 2010
(In thousands, unaudited)

	Nine Months Ended September 30,	
	2009	2010
Cash flows from operating activities:		
Net income (loss)	$ (5,199)	$ 218,008
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	16,114	19,806
Amortization of discount (premium) on investments	489	3,506
Imputed interest on acquisition obligation	2,577	0
Equity in the loss of BioMarin/Genzyme LLC	1,773	2,195
Stock-based compensation	26,649	28,527
Impairment loss on equity investments	5,848	0
Deferred income taxes	0	(223,065)
Net gain from sale of investments	(1,585)	(927)
Unrealized foreign exchange (gain) loss on forward contracts	4,327	(3,669)
Changes in the fair value of contingent acquisition consideration payable	0	4,596
Excess tax benefit from stock option exercises	(131)	(32)
Changes in operating assets and liabilities:		
Accounts receivable, net	(14,080)	(5,194)
Inventory	(2,279)	(13,079)
Other current assets	33,776	646
Other assets	(1,981)	(2,148)
Accounts payable, accrued liabilities and other current liabilities	620	4,404
Other long-term liabilities	1,506	1,040
Deferred revenue	(158)	(86)
Net cash provided by operating activities	68,266	34,528
Cash flows from investing activities:		
Purchase of property, plant and equipment	(67,180)	(38,720)
Maturities and sales of investments	373,062	135,739
Purchase of investments	(332,406)	(148,886)
Business acquisitions, net of cash acquired	0	(32,950)
Investments in BioMarin/Genzyme LLC	(1,380)	(2,915)
Investment in equity securities	(6,250)	0
Net cash provided by (used in) investing activities	(34,154)	(87,732)
Cash flows from financing activities:		
Proceeds from Employee Stock Purchase Plan (ESPP) and exercise of stock options	8,371	19,888
Excess tax benefit from stock option exercises	131	32
Repayment of acquisition obligation	(73,600)	0
Payment of contingent acquisition payable	0	(6,230)
Repayment of capital lease obligations	(136)	(118)
Net cash provided by (used in) financing activities	(65,234)	13,572
Net decrease in cash and cash equivalents	(31,122)	(39,632)
Cash and cash equivalents:		
Beginning of period	222,900	167,171
End of period	$ 191,778	$ 127,539
Supplemental cash flow disclosures:		
Cash paid for interest, net of interest capitalized into fixed assets	$ 6,935	$ 6,675
Cash paid for income taxes	1,066	2,904
Stock-based compensation capitalized into inventory	4,096	3,705
Depreciation capitalized into inventory	3,259	5,054
Supplemental non-cash investing and financing activities disclosures:		
Changes in accrued liabilities related to fixed assets	1,461	(7,606)
Changes in contingent acquisition consideration payable	0	4,596

See accompanying notes to unaudited consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2010
(Unaudited)

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

BioMarin Pharmaceutical Inc. (the Company or BioMarin ®) 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. Approved products include Naglazyme ® (galsulfase), Kuvan ® (sapropterin dihydrochloride), Aldurazyme ® (laronidase) and Firdapse ™ (amifampridine phosphate).

Through September 30, 2010, the Company had accumulated losses of approximately $359.1 million. Management believes that the Company's cash, cash equivalents and short-term and long-term investments at September 30, 2010 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 enter 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 net 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, Aldurazyme and Firdapse; 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

(a) Basis of Presentation

These unaudited condensed consolidated financial statements include the accounts of BioMarin and its wholly owned subsidiaries. All significant intercompany transactions have been eliminated. These unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP) for interim financial information and the Securities and Exchange Commission (SEC) requirements for interim reporting. However, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Management performed an evaluation of the Company's activities through the filing of this Quarterly Report on Form 10-Q and has concluded that there are no subsequent events requiring disclosure through that date.

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and related notes thereto for the year ended December 31, 2009, included in the Company's Annual Report on Form 10-K filed with the SEC on February 26, 2010.

(b) Investment in BioMarin/Genzyme LLC and Equity in the Loss of BioMarin/Genzyme LLC

Effective January 1, 2008, the Company restructured its relationship with Genzyme Corporation (Genzyme) (see Note 17 for further information). The Company accounts for its remaining investment in the joint venture between the Company and Genzyme (BioMarin/Genzyme LLC) using the equity method. Accordingly, the Company records an increase in its investment for contributions to the joint venture and a reduction in its investment for its 50% share of any losses of the joint venture or disbursements of profits from the joint venture. Equity in the loss of BioMarin/Genzyme LLC includes the Company's 50% share of the joint venture's loss for the period. The investment in BioMarin/Genzyme LLC includes the Company's share of the net equity of the joint venture.

In June 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 167, *Amendments to FASB Interpretation No. 46(R)* (SFAS 167). SFAS 167 was subsequently codified in December 2009 as Accounting Standards Update (ASU) No. 2009-17, *Improvements to Financial Reporting by Enterprises Involved With Variable Interest Entities* (ASU 2009-17), which is effective the first annual reporting period after November 15, 2009 and is effective for the Company in the fiscal year ending December 31, 2010. ASU 2009-17 amends FASB Accounting Standards Codification (ASC) Topic 810 to require revised evaluations of whether entities represent variable interest entities, ongoing assessments of control over such entities, and additional disclosures for variable interests. In accordance with the new guidance the Company is required to reassess its previous assertion that BioMarin was not the primary beneficiary of BioMarin/Genzyme LLC. Under the new guidance, the entity with the power to direct the activities that most significantly impact a variable interest entity's economic performance is the primary beneficiary. The Company has concluded that BioMarin/Genzyme LLC is a variable interest entity, but does not have a primary beneficiary because the power to direct the activities of BioMarin/Genzyme LLC that most significantly impact its performance, is shared equally between Genzyme and BioMarin through Genzyme's commercialization rights and BioMarin's manufacturing rights.

(c) Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income/loss by the weighted average shares of common stock outstanding during the period. Diluted net income (loss) per share reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock; however, potential common equivalent shares are excluded if their effect is anti-dilutive. Potential shares of common stock include shares issuable upon the exercise of outstanding employee stock option awards, common stock issuable under the Company's 2006 Employee Stock Purchase Plan (ESPP), restricted stock and contingent issuances of common stock related to convertible debt.

The following represents a reconciliation from basic weighted shares outstanding to diluted weighted shares outstanding and the earnings per share for the three months ended September 30, 2009 and 2010, and for the nine months ended September 30, 2010 (in thousands, except per share data):

	Three Months Ended September 30,					
	2009			2010		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Net Income (Loss) Per Share:						
Net Income (Loss)	$ 6,640	100,331	$ 0.07	$ 217,334	102,110	$ 2.13
Effect of dilutive shares:						
Stock options using the treasury method	0	1,159		0	2,103	
Potentially issuable restricted common stock	0	32		0	171	
Potentially issuable common stock for ESPP purchases	0	293		0	551	
Common stock issuable under convertible debt	0	0		3,010	26,343	
Diluted Net Income (Loss) Per Share:						
Net Income (Loss)	$ 6,640	101,815	$ 0.07	$ 220,344	131,278	$ 1.68

	Nine Months Ended September 30, 2010		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Net Income Per Share:			
Net Income	$ 218,008	101,660	$ 2.14
Effect of dilutive shares:			
Stock options using the treasury method	0	2,095	
Potentially issuable restricted common stock	0	171	
Potentially issuable common stock for ESPP purchases	0	552	
Common stock issuable under convertible debt	9,029	26,343	
Diluted Net Income Per Share:			
Net Income	$ 227,037	130,821	$ 1.74

In addition to the equity instruments included in the table above, the table below presents potential shares of common stock were excluded from the computation as they were anti-dilutive for the three and nine months ended September 30, 2009 and 2010 using the treasury stock method: (i) stock options to purchase common stock using the treasury method, (ii) shares of common stock issuable under Company's convertible debt using the if-converted method whereby the related interest expense for the convertible debt is added to net income for the period, (iii) unvested restricted stock units, (iv) potentially issuable common stock for ESPP purchases and (v) Company common stock issued to the Nonqualified Deferred Compensation Plan (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30	
	2009	2010	2009	2010
Options to purchase common stock using the treasury method	2,335	13,561	14,155	13,569
Common stock issuable under convertible debt	26,343	0	26,343	0
Unvested restricted stock units	343	251	375	251
Potentially issuable common stock for ESPP purchases	0	0	279	0
Nonqualified Deferred Compensation Plan obligation using the treasury method	91	115	91	115
Total	29,112	13,927	41,243	13,935

(d) Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred taxes are determined based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded to reduce deferred tax assets to the amount that is more likely than not to be realized. There was a full valuation allowance against net deferred tax assets of $268.1 million at December 31, 2009. Historical earnings, future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. Adjustments to the valuation allowance increase or decrease net income/loss in the period such adjustment was made. Based on projected U.S. taxable income and other key operating factors, the Company concluded in the third quarter of 2010 that it is more likely than not that a significant portion of the benefit of these deferred tax assets would be realized. As a result, the amount of the valuation allowance related to the deferred tax assets that are expected to be realized was reversed, resulting in a net tax benefit of $223.1 million recognized during the third quarter of 2010. The financial projections supporting the Company's conclusion to release a portion of its valuation allowance contain significant assumptions and estimates of future operations. If such assumptions were to differ significantly, it may have a material impact on the Company's ability to realize its deferred tax assets. At the end of each period, the Company will reassess the ability to realize the deferred tax benefits. If it is more likely than not that the Company would not realize the deferred tax benefits, then all or a portion of the valuation allowance may need to be re-established, which will result in a charge to tax expense.

For the three and nine months ended September 30, 2010, the Company recognized income tax benefit of $222.0 million and $220.3 million, respectively, compared to the three and nine months ended September 30, 2009, when the Company recognized income tax expense of $0.9 million and $1.9 million, respectively. Income tax expense for the three and nine months ended September 30, 2009 was primarily related to income earned in certain of the Company's international subsidiaries, California state income tax and U.S. federal alternative minimum tax expense.

(e) Contingent Acquisition Consideration Payable

The Company determines the fair value of contingent acquisition consideration payable on the acquisition date using a probability-based income approach utilizing an appropriate discount rate. Contingent acquisition consideration payable is included in accrued expenses and other liabilities on the Company's consolidated balance sheet. Changes in the fair value of the contingent acquisition consideration payable are determined each period end and recorded in the Intangible asset amortization and contingent consideration expense line item on the consolidated statements of operations.

(f) Comprehensive Income (Loss) and Accumulated Other Comprehensive Income (Loss)

Comprehensive income (loss) includes net income/loss and certain changes in stockholders' equity that are excluded from net income/loss, such as changes in unrealized gains and losses on the Company's available-for-sale securities, unrealized gains/losses on foreign currency hedges and changes in the Company's cumulative foreign currency translation account. The tax provision (benefit) to the items included in other comprehensive income loss, assuming they were recognized in income would be approximately $1.1 million for both the three and nine months ended September 30, 2010. There were no tax effects allocated to any components of other comprehensive income for the three and nine months ended September 30, 2009.

During the three and nine months ended September 30, 2010, total comprehensive income was approximately $205.5 million and $215.5 million, respectively, compared to the three months ended September 30, 2009 when comprehensive income was $5.8 million and the nine months ended September 30, 2009 when comprehensive loss was $7.0 million. The fluctuation in accumulated other comprehensive income (loss) is comprised of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Net unrealized gain (loss) on available-for-sale securities	$ 573	$ 593	$ (265)	$ 539
Net unrealized gain (loss) on foreign currency hedges, net of taxes	(1,503)	(12,236)	(2,450)	(1,998)
Net unrealized loss on equity investments	125	(163)	899	(1,052)
Net foreign currency translation loss	0	1	6	(3)
Change in accumulated other comprehensive income (loss)	$ (805)	$ (11,805)	$ (1,810)	$ (2,514)

(g) Recent Accounting Pronouncements

In April 2010, the FASB issued ASU 2010-17, *Revenue Recognition—Milestone Method (Topic 605)*, (ASU 2010-17), which provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. ASU 2010-17 is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010 with early adoption permitted. ASU 2010-17 is effective for the Company on January 1, 2011 and is not expected to have a significant impact on the Company's consolidated financial statements.

In January 2010, the FASB issued ASU 2010-6, *Fair Value Measurements and Disclosures (Topic 820), Improving Disclosures about Fair Value Measurements* (ASU 2010-6) , which expands fair value disclosure requirements. Transition will be in two phases with expanded disclosures regarding activity for level 1 and 2 applicable to the Company on January 1, 2010 and expanded disclosures for level 3 activity effective on January 1, 2011.

In September 2009, the FASB issued ASU 2009-13, *Multiple Deliverable Revenue Arrangements* (ASU 2009-13), which amended the accounting standards for multiple element arrangements to:

- provide updated guidance on whether multiple deliverables exist, how the elements in an arrangement should be separated and how the consideration should be allocated;
- require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of each element if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and
- eliminate the use of the residual method and require a vendor to allocate revenue using the relative selling price method.

ASU 2009-13 is effective for fiscal years beginning after June 15, 2010, which for the Company will be January 1, 2011, with early application permitted. The Company is currently evaluating the impact, if any, ASU 2009-13 will have on the Company's consolidated financial statements.

(h) Reclassifications and Adjustments

Certain items in the prior year's consolidated financial statements have been reclassified to conform to the current presentation.

(3) STOCK-BASED COMPENSATION

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 ESPP. These plans are administered by the Compensation Committee of the Board, which selects persons to receive awards and determines the number of shares subject to each award and the terms, conditions, performance measures and other provision of the award. See Note 3 of the Company's consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 26, 2010, and the Company's Definitive Proxy Statement on Schedule 14A, which was filed with the SEC on March 26, 2010, 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, 2010. The expected volatility of stock options is based upon proportionate weightings 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. During the nine months ended September 30, 2010, the Company granted 3.3 million options with a weighted average option value of $11.16 per option. The assumptions used to estimate the per share fair value of stock options granted and stock purchase rights granted under the Company's 2006 Share Incentive Plan and ESPP for the three and nine months ended September 30, 2009 and 2010, respectively, are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Stock Option Valuation Assumptions	**2009**	**2010**	**2009**	**2010**
Weighted average fair value of common stock per share	$ 15.66	$ 21.70	$ 14.23	$ 21.39
Expected volatility	54%	52%	54%	52%
Dividend yield	0%	0%	0%	0%
Expected life	6.1 years	6.2 years	6.0 – 6.1 years	6.2 years
Risk-free interest rate	2.5%	1.8%	1.9 – 2.5%	1.8 – 2.7%

	Nine Months Ended September 30,	
Employee Stock Purchase Plan Valuation Assumptions	**2009**	**2010**
Fair value of common stock on grant date	$ 13.69	$ 22.76
Expected volatility	55%	52%
Dividend yield	0%	0%
Expected life	6-24 months	6-24 months
Risk-free interest rate	0.3 – 0.9%	0.3 – 1.0%

Restricted Stock Units

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, 2010, the Company granted 209,236 RSUs with a weighted average fair market value of $21.16 per share.

Stock Option Grants to Non-Employees

During the third quarter of 2009, the Company granted 54,000 stock options to non-employees. The non-employee grants vest over periods from nine months to two years depending on the grant. The unvested portion of the stock options will be re-measured at each reporting period. Total stock-based compensation expense for non-employee stock option grants for the three and nine months ended September 30, 2009 was approximately $0.1 million. Total stock-based compensation expense for non-employee stock option grants for the three months ended September 30, 2010 was insignificant and was approximately $0.1 million for the nine months ended September 30, 2010.

Stock-based Compensation Expense

The compensation expense that has been included in the Company's consolidated statements of operations for stock-based compensation arrangements for the three and nine months ended September 30, 2009 and 2010, respectively, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Cost of sales	$1,192	$1,044	$ 3,179	$ 2,852
Research and development expense	3,408	3,621	8,488	10,244
Selling, general and administrative expense	4,321	5,292	14,064	14,578
Total stock-based compensation expense	$8,921	$9,957	$25,731	$27,674

Stock-based compensation of $4.1 million and $3.7 million was capitalized into inventory during the first nine months of 2009 and 2010, respectively. Capitalized stock-based compensation is recognized into cost of sales when the related product is sold.

(4) GOODWILL

The following table represents the changes in goodwill for the quarter ended September 30, 2010 (in thousands):

Balance at December 31, 2009	$23,722
Goodwill related to the acquisition of LEAD Therapeutics, Inc. (LEAD) (See Note 6)	16,638
Goodwill related to the acquisition of ZyStor Therapeutics, Inc. (ZyStor) (See Note 5)	13,004
Balance at September 30, 2010	$53,364

The $16.6 million of LEAD goodwill represents $14.0 million of goodwill recognized in connection with the deferred tax liability associated with the indefinite-lived intangible assets acquired and $2.6 million of excess purchase price. See Note 6 for additional discussion.

The $13.0 million of ZyStor Therapeutics, Inc. (ZyStor) goodwill represents $10.7 million of goodwill recognized in connection with the deferred tax liability associated with the indefinite-lived intangible assets acquired and $2.3 million of excess purchase price. See Note 5 for additional discussion.

(5) ACQUISITION OF ZYSTOR THERAPEUTICS, INC.

On August 17, 2010, the Company acquired all of the capital stock of ZyStor, a privately held biotechnology company, pursuant to a securities purchase agreement dated August 17, 2010 between the Company, ZyStor, the holders of outstanding capital stock and rights to acquire capital stock of ZyStor and the representative of such holders. ZyStor is developing enzyme replacement therapies for the treatment of lysosomal storage disorders. ZyStor's lead product candidate is ZC-701, a novel fusion of insulin-like growth factor 2 and alpha glucosidase in development for Pompe disease.

In connection with its acquisition of ZyStor, the Company paid $20.3 million, net of transaction costs, upfront for all of the outstanding common stock of ZyStor. Additionally at the closing, the Company held back $2.0 million of the purchase price. The purpose of the holdback of the purchase price is to satisfy any obligations of the former ZyStor stockholders to pay any indemnification claims to BioMarin. The Company has also agreed to pay ZyStor stockholders additional consideration in future periods up to $93.0 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and development milestones are met. The fair value of the contingent acquisition consideration payments on the acquisition date was $15.6 million and was estimated by applying a probability-based income approach utilizing an appropriate discount rate. This estimation was based on significant inputs that are not observable in the market, referred to as level 3 inputs. Key assumptions include: (1) a discount rate of 5.6%; and (2) various probability factors. As of September 30, 2010, the range of outcomes and assumptions used to develop these estimates have not changed (see Note 15 for additional discussion regarding fair value measurements of the contingent acquisition payable).

The following table presents the allocation of the purchase consideration, including the contingent acquisition consideration payable, based on fair value (in thousands):

Upfront cash payments	$ 20,250
Present value of cash held back at closing	1,890
Contingent consideration payable	15,560
Transaction costs included in General & Administrative (G&A) expense	(1,751)
Total consideration	$ 35,949
Cash and cash equivalents	$ 13
Other assets	14
Property, plant and equipment	54
Acquired deferred tax assets	7,600
Intangible assets – In Process Research & Development (IPR&D)	27,600
Total identifiable assets acquired	$ 35,281
Accounts payable and accrued expenses	(1,644)
Deferred tax liability	(10,692)
Total liabilities assumed	$(12,336)
Net identifiable assets acquired	22,945
Goodwill	13,004
Net assets acquired	$ 35,949

Intangible Assets

A substantial portion of the assets acquired consisted of intangible assets related to ZyStor's lead product candidate ZC-701. The Company determined that the estimated acquisition-date fair values of the intangible assets related to the lead product candidate were $25.0 million. See Note 9 for further discussion related to intangible assets.

Deferred Tax Assets and Deferred Tax Liabilities

The $7.6 million of deferred tax assets resulting from the acquisition was primarily related to federal and state net operating loss and tax credit carryforwards. The $10.7 million of deferred tax liabilities resulting from the acquisition was primarily related to the difference between the book basis and tax basis of the intangible assets related to IPR&D projects. The deferred tax liability relates to the tax impact of future amortization or possible impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes.

Goodwill

The excess of the consideration transferred over the fair values assigned to the assets acquired and liabilities assumed was $2.3 million, which represents the amount of goodwill resulting from the acquisition. The Company believes that the goodwill primarily represents the synergies and economies of scale expected from combining the Company's operations with ZyStor's. None of the goodwill is expected to be deductible for income tax purposes. The Company recorded the goodwill in the Company's consolidated balance sheet as of the acquisition date. Goodwill is tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the goodwill below its carrying amount.

Acquisition-Related Transaction Costs and Restructuring Expenses

The Company recognized $1.8 million of acquisition-related transaction costs in selling, general and administrative expenses during the three and nine months ended September 30, 2010, which consisted primarily of investment banker fees, legal fees and transaction bonuses to former ZyStor employees related to the acquisition.

Results of Operations

The results of operations of ZyStor since August 17, 2010 have been included in the Company's consolidated statements of operations. This includes net loss from operations of $0.3 million for the three and nine months ended September 30, 2010, respectively.

Pro Forma Information

The following unaudited consolidated pro forma financial information presents the combined results of operations of the Company and ZyStor for the three and nine months ended September 30, 2009 and 2010 as if the acquisition had occurred as of January 1, 2009 and 2010. The unaudited pro forma financial information is not necessarily indicative of what the Company's consolidated results of operations actually would have been had the acquisition been completed as of January 1, 2009. In addition, the unaudited pro forma financial information does not attempt to project the future results of operations of the Company combined with ZyStor.

Unaudited Pro Forma Consolidated Information (in thousands, except per share data):	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Revenue	$ 80,807	$ 97,750	$237,574	$274,653
Net income (loss)	$ 5,726	$218,702	$ (10,089)	$218,059
Net income (loss) per share, basic	$ 0.05	$ 2.14	$ (0.10)	$ 2.14
Net income (loss) per share, diluted	$ 0.05	$ 1.69	$ (0.10)	$ 1.74
Weighted average common shares outstanding, basic	100,331	102,110	100,098	101,660
Weighted average common shares outstanding, diluted	101,815	131,278	100,098	130,821

(6) ACQUISITION OF LEAD THERAPEUTICS, INC.

On February 10, 2010, the Company acquired LEAD Therapeutics, Inc. (LEAD), a small private drug discovery and early stage development company with a key compound LT-673, now referred to as BMN-673, an orally available poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of patients with rare, genetically defined cancers for a total purchase price of $39.1 million.

In connection with its acquisition of LEAD, the Company paid $18.6 million in cash for all of the outstanding common stock of LEAD. The Company has also agreed to pay LEAD stockholders additional consideration in future periods up to $68.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met. The fair value of the contingent acquisition consideration payments was $20.5 million and was estimated by applying a probability-based income approach utilizing an appropriate discount rate. This estimation was based on significant inputs that are not observable in the market, referred to as level 3 inputs. Key assumptions include: (1) a discount rate of 6.4%; and (2) various probability factors. As September 30, 2010, the range of outcomes and assumptions used to develop these estimates have not changed (see Note 15 for additional discussion regarding fair value measurements of the contingent acquisition payable).

The following table presents the allocation of the purchase consideration, including the contingent acquisition consideration payable, based on fair value (in thousands):

Cash and cash equivalents	$ 1,187
Prepaid expenses	40
Property, plant and equipment	26
Acquired deferred tax assets	7,788
Intangible assets – IPR&D	36,089
Total identifiable assets acquired	$ 45,130
Accounts payable and accrued expenses	(891)
Deferred tax liability	(13,981)
Valuation allowance for acquired deferred tax assets	(7,788)
Total liabilities assumed	$(22,660)
Net identifiable assets acquired	22,470
Goodwill	16,638
Net assets acquired	$ 39,108

The deferred tax liability relates to the tax impact of future amortization or possible impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes. The $16.6 million of goodwill reflects the $14.0 million deferred tax liability recognized in connection with the LEAD acquisition and $2.6 million of goodwill attributable to the synergies expected from the acquisition and other benefits that do not qualify for separate recognition as acquired intangible assets.

LEAD's results of operations prior to and since the acquisition date were insignificant compared to the Company's consolidated financial statements.

See Note 8 for further discussion of the acquired intangible assets.

(7) ACQUISITION OF HUXLEY PHARMACEUTICALS, INC.

On October 23, 2009, the Company acquired Huxley Pharmaceuticals, Inc. (Huxley), which had rights to a proprietary form of 3,4-diaminopyridine (3,4-DAP), amifampridine phosphate, which the Company has branded Firdapse, for the rare autoimmune disease Lambert Eaton Myasthenic Syndrome (LEMS) for a total purchase price of $37.2 million. As a result of the acquisition, the Company was the first to market an approved treatment for LEMS in Europe. The Company launched Firdapse on a country by county basis in April 2010.

In connection with its acquisition of Huxley, the Company paid $15.0 million upfront for all of the outstanding common stock of Huxley. The Company has also agreed to pay Huxley stockholders additional consideration in future periods up to $42.9 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and development milestones are met. The fair value of the contingent acquisition consideration payments on the acquisition date was $22.2 million and was estimated by applying a probability-based income approach utilizing an appropriate discount rate. This estimation was based on significant inputs that are not observable in the market, referred to as level 3 inputs. Key assumptions include: (1) a discount rate of 6.3%; and (2) various probability factors. As of September 30, 2010, the range of outcomes and assumptions used to develop these estimates have not changed (see Note 15 for additional discussion regarding fair value measurements of the contingent acquisition payable). In November 2009, the U.S. Food and Drug Administration (FDA) granted Firdapse U.S. orphan status, resulting in a payment of $1.0 million to the former Huxley stockholders. In December 2009, the European Medicines Agency (EMEA) granted marketing approval for Firdapse, which resulted in a payment of $6.5 million in the second quarter of 2010 to the former Huxley stockholders.

The following table presents the allocation of the purchase consideration, including the contingent acquisition consideration payable, based on fair value (in thousands):

Cash and cash equivalents	$ 483
Intangible assets - IPR&D	36,933
Other assets	179
Total identifiable assets	$37,595
Accounts payable and accrued expenses	(387)
Deferred tax liability	(2,460)
Total liabilities assumed	(2,847)
Net identifiable assets acquired	$34,748
Goodwill	2,460
Net assets acquired	$37,208

Huxley’s results of operations prior to and since the acquisition date were insignificant compared to the Company’s consolidated financial statements.

The deferred tax liability relates to the tax impact of future amortization or possible impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes. The $2.5 million of goodwill represents the assets recognized in connection with the deferred tax liability and did not result from excess purchase price. In April 2010, the Company and the former Huxley stockholders executed an amendment to the acquisition agreements, which resulted in a $1.0 million reduction to certain of the future milestone payments.

See Note 8 for further discussion of the acquired intangible assets.

(8) INTANGIBLE ASSETS

As of December 31, 2009 and September 30, 2010, intangible assets consisted of the following (in thousands):

	December 31, 2009	September 30, 2010
Intangible assets:		
Finite-lived intangible assets	$ 5,016	$ 37,242
Indefinite-lived intangible assets	36,933	70,396
Gross intangible assets:	41,949	107,638
Less: Accumulated amortization	(972)	(3,034)
Net carrying value	$ 40,977	$ 104,604

Finite-Lived Intangible Assets

The following table summarizes the annual amortization of the finite-lived intangible assets through 2018 (in thousands):

	Net Balance at September 30, 2010	Remaining Life	Annual Amortization
European Union (EU) marketing rights for Firdapse	$ 30,615	9.5 years	$ 3,223
License payment for Kuvan FDA Approval	1,759	5.3 years	332
License payment for Kuvan EMEA Approval	1,834	6.8 years	269
Total	$ 34,208		$ 3,824

The Firdapse intangible assets consist of the Firdapse product technology purchased as part of the Huxley acquisition in the fourth quarter of 2009. As of December 31, 2009, the gross and net carrying value of the Firdapse product technology was comprised of $30.2 million and $6.7 million related to marketing rights in Europe and the U.S., respectively, which were both in-process research and development assets with indefinite lives as of the purchase date. Subsequently, in December 2009, the EMEA granted marketing approval for Firdapse in the EU. As a result, the Company assigned a useful life of 10 years to the European product technology, which corresponds to the period of market exclusivity conferred through the orphan drug protection. The EMEA did not enable the commercial launch of Firdapse until April 2010, at which time the Company began amortizing the European product technology at an annual rate of $3.2 million. The increase in the Firdapse intangible assets relates to license payments of $2.0 million made to a third party as a result of the EMEA approval of Firdapse.

The Kuvan intangible assets relate to license payments made to third parties as a result of the FDA approval of Kuvan in December 2007 and the EMEA approval in December 2008, which resulted in a $2.7 million addition to the Kuvan intangible assets. At December 31, 2009 and September 30, 2010, Kuvan intangible assets totaled a gross value of $5.0 million. In each of the third quarters and first nine months of 2009 and 2010, the Company recognized amortization expense related to the Kuvan intangible assets of $0.2 million and $0.5 million, respectively, as a component of cost of sales in the consolidated statements of operations.

Indefinite-Lived Intangible Assets

A substantial portion of the assets acquired in the Huxley, LEAD and ZyStor acquisitions consisted of in-process research and development assets related to both early and late stage drug product candidates. The Company determined that the estimated acquisition-date fair values of the intangible assets related to rights to develop and commercialize the acquired assets as of December 31, 2009 and September 30, 2010, respectively, were as follows (in thousands):

	December 31, 2009	September 30, 2010
In-Process Research and Development		
EU marketing rights for Firdapse	$ 30,223	$ 0
U.S. marketing rights for Firdapse	6,710	6,707
BMN-673 compound acquired through LEAD	0	36,089
BMN-701 acquired through ZyStor	0	25,010
Other pre-clinical compounds acquired through LEAD	0	2,590
Net carrying value	$ 36,933	$ 70,396

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. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. In estimating fair value of the IPR&D assets, the Company compensated for the differing phases of development of each asset by probability-adjusting its estimation of the expected future cash flows associated with each asset. The Company then determined the present value of the expected future cash flows. The projected cash flows from the IPR&D assets were based on key assumptions such as estimates of revenues and operating profits related to the feasibility and timing of achievement of development, regulatory and commercial milestones, expected costs to develop the IPR&D into commercially viable products and future expected cash flows from product sales. As discussed above, the EU marketing rights for Firdapse were assigned a useful life of 10 years when the EMEA granted approval for Firdapse.

(9) SHORT-TERM AND LONG-TERM INVESTMENTS

At December 31, 2009, the principal amounts of short-term and long-term investments by contractual maturity are summarized in the table below (in thousands):

	Contractual Maturity Date For the Years Ending December 31,					
	2010	2011	2012	Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
Certificates of deposit	$ 30,924	$ 18,833	$ 0	$ 49,757	$ (120)	$ 49,637
Corporate securities	57,973	64,735	38,096	160,804	461	161,265
Commercial paper	7,981	0	0	7,981	12	7,993
Equity securities	701	0	0	701	1,052	1,753
U.S. Government agency securities	34,861	47,724	0	82,585	122	82,707
Total	$132,440	$131,292	$38,096	$301,828	$ 1,527	$303,355

At September 30, 2010, the principal amounts of short-term and long-term investments by contractual maturity are summarized in the table below (in thousands):

	Contractual Maturity Date For the Years Ending December 31,						
	2010	2011	2012	2013	Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
Certificates of deposit	$12,231	$ 30,433	$10,914	$ 46	$ 53,624	$ (25)	$ 53,599
Corporate securities	20,422	65,915	44,394	0	130,731	877	131,608
Commercial paper	10,240	9,956	0	0	20,196	23	20,219
Equity securities	179	0	0	0	179	0	179
U.S. Government agency securities	26,374	61,077	18,153	2,000	107,604	174	107,778
Total	$69,446	$167,381	$73,461	$2,046	$312,334	$ 1,049	$313,383

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of September 30, 2010. The investments are placed in financial institutions with strong credit ratings and management expects full recovery of the amortized costs.

At December 31, 2009, the aggregate amounts of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands). All investments were classified as available-for-sale at December 31, 2009.

	Less Than 12 Months To Maturity		12 Months or More To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	$ 23,744	$ (55)	$14,358	$ (69)	$ 38,102	$ (124)
Corporate securities	12,265	(16)	45,488	(186)	57,753	(202)
U.S. Government agency securities	5,325	(1)	20,010	(93)	25,335	(94)
Total	$ 41,334	$ (72)	$79,856	$ (348)	$121,190	$ (420)

At September 30, 2010, the aggregate amounts of unrealized losses and related fair value of investments with unrealized losses were as

follows (in thousands). All investments were classified as available-for-sale at September 30, 2010.

	Less Than 12 Months To Maturity		12 Months or More To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	$ 20,084	$ (26)	$ 3,115	$ (13)	$23,199	$ (39)
Corporate securities	12,873	(13)	0	0	12,873	(13)
U.S. Government agency securities	4,004	(1)	13,636	(17)	17,640	(18)
Total	$ 36,961	$ (40)	$16,751	$ (30)	$53,712	$ (70)

(10) SUPPLEMENTAL BALANCE SHEET INFORMATION

As of December 31, 2009 and September 30, 2010, inventory consisted of the following (in thousands):

	December 31, 2009	September 30, 2010
Raw materials	$ 7,692	$ 9,196
Work in process	40,416	49,693
Finished goods	30,554	32,852
Total inventory	$ 78,662	$ 91,741

As of December 31, 2009 and September 30, 2010, other current assets consisted of the following (in thousands):

	December 31, 2009	September 30, 2010
Non-trade receivables	$ 7,083	$ 4,710
Prepaid expenses	5,202	9,923
Deferred cost of sales	2,232	2,478
Foreign currency forward contracts	83	970
Short-term deferred tax asset	0	13,433
Other	248	233
Total other current assets	$ 14,848	$ 31,747

As of December 31, 2009 and September 30, 2010, other assets consisted of the following (in thousands):

	December 31, 2009	September 30, 2010
Deferred debt offering costs	$ 8,791	$ 7,560
Long-term portion of investments held in the Company's nonqualified deferred compensation plan	1,699	2,303
Deposits	4,575	2,349
Long-term portion of deferred tax asset	0	216,092
Other	241	201
Total other current assets	$ 15,306	$ 228,505

As of December 31, 2009 and September 30, 2010, accounts payable, accrued liabilities and other current liabilities consisted of the following (in thousands):

	December 31, 2009	September 30, 2010
Accounts payable	$ 7,567	$ 7,184
Accrued accounts payable	28,353	22,535
Accrued vacation	4,652	5,436
Accrued compensation	14,544	14,737
Accrued interest and taxes	2,859	3,107
Accrued royalties	4,740	5,480
Other accrued expenses	1,525	5,513
Accrued rebates	4,786	3,863
Short-term portion of contingent acquisition consideration payable	8,124	18,998

VAT payable	0	2,630
Short-term portion of forward contract liability	795	1,714
Other	123	900
Total accounts payable and accrued liabilities	$ 78,068	$ 92,097

As of December 31, 2009 and September 30, 2010, other long-term liabilities consisted of the following (in thousands):

	December 31, 2009	September 30, 2010
Long-term portion of deferred rent	$ 983	$ 937
Long-term portion of contingent acquisition consideration payable	13,089	36,327
Long-term portion of deferred compensation liability	3,124	4,644
Deferred tax liabilities	2,460	27,137
Other	85	644
Total other long-term liabilities	$ 19,741	$ 69,689

(11) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2009 and September 30, 2010 consisted of the following (in thousands):

Category	December 31, 2009	September 30, 2010	Estimated Useful Lives
Leasehold improvements	$ 38,059	$ 39,171	Shorter of life of asset or lease term
Building and improvements	69,564	135,511	20 years
Manufacturing and laboratory equipment	34,228	57,075	5 to 15 years
Computer hardware and software	28,695	34,737	3 to 5 years
Office furniture and equipment	5,529	6,149	5 years
Land	10,056	10,056	Not applicable
Construction-in-progress	74,914	9,475	Not applicable
Total property, plant and equipment, gross	$ 261,045	$ 292,174	
Less: Accumulated depreciation	(61,904)	(78,419)	
Total property, plant and equipment, net	$ 199,141	$ 213,755	

Depreciation expense for three and nine months ended September 30, 2010 was $6.3 million and $16.4 million, respectively, of which $2.0 million and $5.1 million was capitalized into inventory, respectively. Depreciation expense for the three and nine months ended September 30, 2009 was $4.3 million and $11.6 million, respectively, of which $1.2 million and $3.3 million was capitalized into inventory, respectively. During the third quarter of 2010, the Company completed the improvements to its manufacturing facilities and placed them into service.

Capitalized interest related to the Company's property, plant and equipment purchases for the three and nine months ended September 30, 2010 was insignificant and $0.7 million, respectively, compared to the three and nine months ended September 30, 2009 when capitalized interest totaled $0.2 million and $0.4 million, respectively.

(12) INVESTMENT IN LA JOLLA PHARMACEUTICAL COMPANY

On January 4, 2009, the Company entered into a co-exclusive worldwide (excluding Asia Pacific) licensing agreement with La Jolla Pharmaceutical Company (La Jolla) to develop and commercialize Riquent, La Jolla's investigational drug for lupus nephritis. The Company paid La Jolla $7.5 million for the license rights and an additional $7.5 million for 339,104 shares of La Jolla's Series B Preferred Stock. The initial equity investment represents the acquisition of the La Jolla Series B Preferred shares with a fair value of $6.2 million. The $1.3 million paid in excess of the fair value of the shares acquired was allocated to the license fee using the residual method and expensed in the first quarter of 2009, as the license acquired did not have an alternative future use. Research and development expense related to the Company's agreements with La Jolla in the first quarter of 2009 approximated $8.8 million, and is comprised of the $7.5 million up-front license fee and the $1.3 million premium paid in excess of the preferred stock's fair value.

On February 12, 2009, the results of the first interim efficacy analysis for the Phase 3 study of Riquent were announced, and the Independent Data Monitoring Board determined that the continuation of the trial was futile. Based on the results of this interim efficacy analysis, the Company and La Jolla decided to stop the study.

On March 27, 2009, the licensing agreement with La Jolla terminated in accordance with its terms, triggering the preferred stock's automatic conversion feature at a rate of one preferred share to thirty shares of common stock. Thus, as of the conversion date, the Company held approximately 10.2 million shares of common stock, or approximately 15.5% of La Jolla's outstanding common stock. The Company accounted for the converted La Jolla shares, which were traded on the NASDAQ Stock Exchange, as an available-for-sale investment. The investment was classified as available-for-sale, with changes in the fair value reported as a component of accumulated other comprehensive income/loss, exclusive of other-than-temporary impairment losses, if any. Losses determined to be other-than-temporary were reported in earnings in the period in which the impairment occurs.

In March 2009, the Company recognized an impairment charge of $4.5 million, for the decline in the La Jolla investment's value, which was determined to be other-than-temporary. The determination that the decline was other-than-temporary was, in part, subjective and influenced by several factors, including: the length of time and the extent to which the market value of La Jolla's common stock had been less than the value on the date of purchase, La Jolla's financial condition and near-term prospects, including any events which may influence its operations, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for the anticipated recovery in market value. Based on the then current market conditions, La Jolla's current financial condition and its business prospects, the Company determined that its investment in La Jolla was other-than-temporarily impaired and adjusted the recorded amount of the investment to the stock's market price on March 31, 2009. In June 2009, the Company sold its 10.2 million shares of La Jolla common stock through a series of open market trades, ranging in gross proceeds to the Company of $0.17 to $0.22 per share. In connection with the sale of the La Jolla common stock, the Company recognized a loss of $66,000 on the sale of the equity investment during the second quarter of 2009.

(13) CONVERTIBLE DEBT

In April 2007, the Company sold approximately $324.9 million of senior subordinated convertible notes due 2017. 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 Company 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 April 2007 debt, the Company paid approximately $8.5 million in offering costs, which have been deferred and are included in other assets. In each of the three and nine months ended September 30, 2009 and 2010, 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 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 Company 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 March 2006 debt, the Company paid approximately $5.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt, and the Company recognized amortization of expense of $0.2 million and $0.6 million, in each of the three and nine months ended September 30, 2009 and 2010, respectively.

Interest expense on the convertible debt for each of the three and nine months ended September 30, 2009 and 2010 was $2.6 million and $7.8 million, respectively.

(14) DERIVATIVE INSTRUMENTS AND HEDGING STRATEGIES

The Company uses hedging contracts to manage the risk of its overall exposure to fluctuations in foreign currency exchange rates. All of the Company's designated hedging instruments are considered to be cash flow hedges.

Foreign Currency Exposure

The Company uses forward foreign exchange contracts to hedge certain operational exposures resulting from changes in foreign currency exchange rates. Such exposures result from portions of its forecasted revenues being denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound.

The Company designates certain of these foreign currency forward contract hedges as hedging instruments and enters into some foreign currency forward contracts that are considered to be economic hedges that are not designated as hedging instruments. Whether designated or undesignated, these forward contracts protect against the reduction in value of forecasted foreign currency cash flows resulting from Naglazyme and Aldurazyme revenues and net asset or liability positions designated in currencies other than the U.S. dollar. The fair values of foreign currency agreements are estimated using current interest rates and taking 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 fluctuations follow below. See Note 15 for additional discussion regarding the fair value of forward contracts.

At September 30, 2010, the Company had 115 foreign currency forward contracts outstanding to sell a total of 80.1 million Euros with expiration dates ranging from October 29, 2010 through June 29, 2012. These hedges were entered into to protect against the fluctuations in Euro denominated Naglazyme and Aldurazyme revenues. The Company has formally designated these contracts as cash flow hedges and expects them to be highly effective within the meaning of ASC Subtopic 815-30, *Derivatives and Hedging- Cash Flow Hedges* , in offsetting fluctuations in revenues denominated in Euros related to changes in the foreign currency exchange rates.

The Company also enters into forward foreign currency contracts that are not designated as hedges for accounting purposes. The changes in fair value of these foreign currency hedges are included as a part of selling, general and administrative expenses in the consolidated statements of operations. At September 30, 2010, the Company had two outstanding foreign currency contracts to sell 15.8 million Euros and 1.3 million British Pounds that were not designated as a hedge for accounting purposes.

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 foreign currency forward contracts is through June 29, 2012. Over the next twelve months, the Company expects to reclassify $0.8 million from accumulated other comprehensive income to earnings as related forecasted revenue transactions occur.

At December 31, 2009 and September 30, 2010, the fair value carrying amount of the Company's derivative instruments were recorded as follows (in thousands):

	Asset Derivatives December 31, 2009		Liability Derivatives December 31, 2009	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 77	Other current liabilities	$ 768
Total		$ 77		$ 768
Derivatives not designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 6	Other current liabilities	$ 27
Total		$ 6		$ 27
Total derivative contracts		$ 83		$ 795

	Asset Derivatives September 30, 2010		Liability Derivatives September 30, 2010	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 970	Other current liabilities	$ 1,645
Foreign currency forward contracts	Other assets	12	Other liabilities	677
Total		$ 982		$ 2,322
Derivatives not designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 0	Other current liabilities	$ 69
Total		$ 0		$ 69
Total derivative contracts		$ 982		$ 2,391

The effect of derivative instruments on the consolidated statements of operations for the three and nine months ended September 30, 2009 and 2010 was as follows (in thousands):

	Foreign Currency Forward Contracts Three Months Ended September 30,		Foreign Currency Forward Contracts Nine Months Ended September 30,	
	2009	2010	2009	2010
Derivatives Designated as Hedging Instruments				
Net gain (loss) recognized in OCI (1)	$ (1,499)	$ (11,095)	$ (2,426)	$ (858)
Net gain (loss) reclassified from accumulated OCI into income (2)	(733)	1,693	1,212	3,802
Net gain (loss) recognized in income (3)	51	197	(212)	517
Derivatives Not Designated as Hedging Instruments				
Net gain (loss) recognized in income (4)	$ (496)	$ (2,370)	$ (1,569)	$ 892

(1) Net change in the fair value of the effective portion classified in other comprehensive income (OCI)

(2) Effective portion classified as product revenue
(3) Ineffective portion and amount excluded from effectiveness testing classified in selling, general and administrative expense
(4) Classified in selling, general and administrative expense

At December 31, 2009 and September 30, 2010, accumulated other comprehensive income associated with foreign currency forward contracts qualifying for hedge accounting treatment was a loss of $0.7 million and $1.5 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.

(15) FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income, other equity securities and foreign currency derivatives. The tables below present the fair value of these financial assets and liabilities determined using the following inputs at December 31, 2009 and September 30, 2010 (in thousands).

	Fair Value Measurements at December 31, 2009			
	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	$ 18,761	$ 18,761	$ 0	$ 0
Money market instruments	148,410	0	148,410	0
Total cash and cash equivalents	$167,171	$ 18,761	$ 148,410	$ 0
Available-for-sale securities				
Certificates of deposit (1)	$ 49,637	$ 0	$ 49,637	$ 0
Corporate securities (2)	161,265	0	161,265	0
Government agency securities (2)	82,707	0	82,707	0
Commercial paper (2)	7,993	0	7,993	0
Equity securities (3)	1,753	1,361	392	0
Total available-for-sale securities	$303,355	$ 1,361	$ 301,994	$ 0
Deferred compensation asset (4)	$ 1,791	$ 0	$ 1,791	$ 0
Foreign currency derivatives (5)	83	0	83	0
Total	$472,400	$ 20,122	$ 452,278	$ 0
Liabilities:				
Deferred compensation liability (6)	$ 3,505	$ 1,714	$ 1,791	$ 0
Foreign currency derivatives (7)	795	0	795	0
Contingent acquisition consideration payable (8)	21,213	0	0	21,213
Total	$ 25,513	$ 1,714	$ 2,586	$ 21,213

	Fair Value Measurements at September 30, 2010			
	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	$ 57,105	$ 57,105	$ 0	$ 0
Money market instruments	70,434	0	70,434	0
Total cash and cash equivalents	$127,539	$ 57,105	$ 70,434	$ 0
Available-for-sale securities				
Certificates of deposit (1)	$ 53,599	$ 0	$ 53,599	$ 0
Corporate securities (2)	131,608	0	131,608	0
Commercial paper (2)	20,219	0	20,219	0
Equity securities (3)	179	0	179	0
Government agency securities (2)	107,778	0	107,778	0
Total available-for-sale securities	$313,383	$ 0	$ 313,383	$ 0
Deferred compensation asset (4)	$ 2,387	$ 0	$ 2,387	$ 0
Foreign currency derivatives (5)	982	0	982	0
Total	$444,291	$ 57,105	$ 387,186	$ 0
Liabilities:				
Deferred compensation liability (6)	$ 4,952	$ 2,565	$ 2,387	$ 0
Foreign currency derivatives (7)	2,391	0	2,391	0
Contingent acquisition consideration payable (8)	55,325	0	0	55,325
Total	$ 62,668	$ 2,565	$ 4,778	$ 55,325

(1) At December 31, 2009 and September 30, 2010, 62% and 73% are included in short-term investments in the Company's consolidated balance sheets, respectively. The remaining balances are included in long-term investments.

(2) These amounts are included in short-term investments and long-term investments in the Company's consolidated balance sheet. At December 31, 2009, 64% of corporate securities and 58% of government agencies are included in long-term investments and the remaining balances are included in short-term investments. At September 30, 2010, 41% of corporate securities and 19% of government agencies are included in long-term investments and the remaining balances are included in short-term investments.

(3) These amounts are included in short-term investments and long-term investments in the Company's consolidated balance sheet. At December 31, 2009 and September 30, 2010, 22% and 0%, respectively, are included in long-term investments and the remaining balances are included in short-term investments.

(4) At December 31, 2009 and September 30, 2010, 95% and 96%, respectively of this balance is included in other assets and the remainder of the balance is included in other current assets on the Company's consolidated balance sheet.

(5) These amounts are included in other current assets and other assets on the Company's consolidated balance sheet. At December 31, 2009 foreign currency derivatives included forward foreign exchange contracts for the Euro and are included in other current assets. At September 30, 2010, foreign currency derivatives included forward foreign exchange contracts for the Euro and British Pound of which 99% are included in other current assets and 1% is included in other assets.

(6) At December 31, 2009 and September 30, 2010, 89% and 94%, respectively, are included in other long-term liabilities and the remainder is included in accounts payable and accrued liabilities on the Company's consolidated balance sheet.

(7) At December 31, 2009 and September 30, 2010, 100% and 72% of these amounts are included in accounts payable and accrued liabilities on the Company's consolidated balance sheet. The remainder of the balances are included in other liabilities on the Company's consolidated balance sheet.

(8) At December 31, 2009 and September 30, 2010, 62% and 66% of these amounts are included in other long-term liabilities, respectively, and 38% and 35% are included in accrued expenses, respectively. See Notes 5, 6 and 7 for additional discussion.

The Company's level 2 securities are valued using third-party pricing sources, which generally use interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing. See Note 9 for further information regarding the Company's financial instruments.

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 will be recorded in the "Intangible asset and contingent consideration" expense line item in the consolidated statements of operations under operating expenses. During the three and nine months ended September 30, 2010, the fair value of the contingent acquisition consideration payable increased by $18.7 million and $34.1 million, respectively. The following table represents the changes in the Company's level 3 liabilities for the quarter ended September 30, 2010 (in thousands):

	Contingent Acquisition Payable
Fair value at December 31, 2009	$ 21,213
Contingent acquisition consideration payable resulting from the LEAD acquisition	20,456
Change in valuation of contingent consideration payable to former Huxley stockholders	654
Fair value at March 31, 2010	$ 42,323
Change in valuation of contingent consideration payable to former Huxley stockholders	593
Change in valuation of contingent consideration payable to former LEAD stockholders	206
Payments related to EMEA approval of Firdapse to former Huxley stockholders	(6,500)
Fair value at June 30, 2010	36,622
Change in valuation of contingent consideration payable to former Huxley stockholders	440
Change in valuation of contingent consideration payable to former LEAD stockholders	2,703
Contingent acquisition consideration payable resulting from the ZyStor acquisition	15,560
Fair value at September 30, 2010	$ 55,325

As discussed in Notes 5, 6 and 7, the Company acquired intangible assets as a result of ZyStor, LEAD, and Huxley acquisitions. The estimated fair value of these long-lived assets was measured using level 3 inputs.

(16) REVENUE AND CREDIT CONCENTRATIONS

The Company considers there to be revenue concentration risks for regions where net product revenue exceeds 10% of consolidated net product revenue. The concentration of the Company's revenue within the regions below may expose the Company to a material adverse effect if sales in the respective regions were to experience difficulties. The table below summarizes product revenue concentrations based on patient location for Naglazyme, Kuvan and Firdapse and Genzyme's location for Aldurazyme for the three and nine months ended September 30, 2009 and 2010.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Region:				
United States	53%	52%	53%	52%
Europe	25%	25%	25%	25%
Latin America	12%	13%	11%	12%
Rest of World	10%	10%	11%	11%
Total Net Product Revenue	100%	100%	100%	100%

The following table illustrates the percentage of the Company's consolidated net product revenue attributed to the Company's four largest customers for the three and nine months ended September 30, 2009 and 2010.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Customer A	20%	17%	19%	18%
Customer B	19%	17%	23%	18%
Customer C	10%	13%	10%	11%
Customer D	10%	9%	8%	9%
Total	59%	56%	60%	56%

The accounts receivable balances at December 31, 2009 and September 30, 2010 are 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 17% of the September 30, 2010 accounts receivable balance, compared to December 31, 2009 when the two largest customers accounted for 49% and 18% of the accounts receivable balance. As of December 31, 2009 and September 30, 2010,

accounts receivable included $20.3 million and $17.8 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.

(17) JOINT VENTURE

Effective January 2008, the Company and Genzyme restructured BioMarin/Genzyme LLC. Under the revised structure, the operational responsibilities for the Company and Genzyme did not significantly change, as Genzyme continues to globally market and sell Aldurazyme and the Company continues to manufacture Aldurazyme. The restructuring had two significant business purposes. First, since each party now has full control over its own operational responsibilities, without the need to obtain the approval of the other party, and the parties do not need to review and oversee the activities of the other, it reduces management's time and effort and therefore improves overall efficiencies. Second, since each party will realize 100% of the benefit of their own increased operational efficiencies, it increases the incentives to identify and implement cost saving measures. Under the previous 50/50 structure, each company shared 50% of the expense associated with the other's inefficiencies and only received 50% of the benefit of its own efficiencies. Specifically, the Company will be able to realize the full benefit of any manufacturing cost reductions and Genzyme will be able to realize the full benefit of any sales and marketing efficiencies.

Genzyme records sales of Aldurazyme to third party customers and pays the Company a tiered payment ranging from approximately 39.5% to 50% of worldwide net product sales depending on sales volume, which is recorded by the Company as product revenue. The Company recognizes a portion of this amount as product transfer revenue when product is released to Genzyme because all of the Company's performance obligations are fulfilled at this point and title to, and risk of loss for, the product has transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay the Company if the product is unsold by Genzyme. The amount of product transfer revenue is deducted from the calculated royalty rate when the product is sold by Genzyme. Genzyme's contractual return rights for Aldurazyme are limited to defective product. Certain research and development activities and intellectual property related to Aldurazyme continue to be managed in the joint venture with the costs shared equally by the Company and Genzyme.

The Company presents the related cost of sales and its Aldurazyme-related operating expenses as operating expenses in the consolidated statements of operations. Equity in the loss of BioMarin/Genzyme LLC subsequent to the restructuring includes the Company's 50% share of the net income/loss of BioMarin/Genzyme LLC related to intellectual property management and ongoing research and development activities.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined under securities laws. Many of these statements can be identified by the use of terminology such as "believes," "expects," "anticipates," "plans," "may," "will," "projects," "continues," "estimates," "potential," "opportunity" and 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 our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the Securities and Exchange Commission (SEC) on February 26, 2010 as well as those discussed elsewhere in 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 our unaudited consolidated financial statements and notes to those statements 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. Our product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme, Aldurazyme, Kuvan and Firdapse.

Naglazyme 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 third quarter and first nine months of 2010 were $51.7 million and $147.5 million, respectively, compared to $42.1 million and $124.3 million in the third quarter and first nine months of 2009, respectively.

Aldurazyme, which was developed in collaboration with Genzyme Corporation (Genzyme), has been approved for marketing in the U.S., EU and other countries. Pursuant to our arrangement with Genzyme, Genzyme sells Aldurazyme to third parties and we recognize royalty revenue on net sales by Genzyme. We recognize a portion of the royalty as product transfer revenue when product is released to Genzyme because all obligations related to the transfer have been fulfilled at that point and title to, and risk of loss for, the product has been transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalties earned when the product is sold by Genzyme. Aldurazyme net product revenues for the third quarter and first nine months of 2010 were $16.5 million and $48.2 million, respectively, compared to $14.6 million and $53.4 million in the third quarters and first nine months of 2009, respectively.

Kuvan was granted marketing approval in the U.S. and EU in December 2007 and December 2008, respectively. Kuvan net product revenues for the third quarter and first nine months of 2010 totaled $26.2 million and $72.1 million, respectively, compared to $21.7 million and $54.1 million in the third quarter and first nine months of 2009, respectively.

In December 2009, the EMEA granted marketing approval for Firdapse. We launched this product on country by country basis in Europe in April 2010. Firdapse net product revenues in the third quarter and first nine months of 2010 were $2.2 million and $3.4 million, respectively. We also continue to develop Firdapse for the possible treatment of LEMS in the U.S. and expect to initiate a Phase 3 clinical trial in early 2011.

We are conducting clinical trials on several investigational product candidates for the treatment of genetic diseases, including: GALNS, an enzyme replacement therapy for the treatment of Mucopolysaccharidosis Type IV or Morquio Syndrome Type A (MPS IV A), and PEG-PAL, an enzyme substitution therapy for the treatment of phenylketonurics (PKU) for patients who do not respond well to Kuvan. In the first nine months of 2009, we initiated a Phase 1/2 clinical trial of GALNS. We have completed enrollment in this clinical trial and reported results in April 2010. We recently met with regulatory authorities and are incorporating their input into our final protocol and expect to initiate a Phase 3 trial in the first quarter of 2011. In September 2009, we initiated a Phase 2 clinical

trial to evaluate PEG-PAL in PKU patients. Initial results from this clinical trial were presented in August 2010. These preliminary results showed that of the seven patients who received at least one milligram per kilogram per week of PEG-PAL for at least four weeks, six patients have achieved phe levels below 600 micromoles per liter. Mild to moderate self limiting injection site reactions are the most commonly reported toxicity. We expect to announce final results from this clinical trial in the fourth quarter of 2010. Additionally, in August 2010, we initiated a Phase 3b study to evaluate the effects of Kuvan on neurophychiatric symptoms in patients with PKU and expect results from this clinical trial in the second quarter of 2011. In addition to GALNS and PEG-PAL, we also expect to begin clinical trials for two new investigational product candidates in the fourth quarter of 2010 and the first quarter of 2011. We expect to initiate a Phase 1/2 clinical trial of BMN-701, an enzyme replacement therapy for Pompe disease, a glycogen storage disorder, in the fourth quarter of 2010. We expect to file an investigational new drug (IND) application with the FDA for BMN-673, an orally available poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of patients with rare, genetically defined cancers in the fourth quarter of 2010 and initiate a Phase 1 trial of BMN-673 in December 2010 or January 2011.

Key components of our results of operations for the three and nine months ended September 30, 2009 and 2010 include the following (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Total net product revenues	$78.4	$ 96.6	$231.8	$ 271.2
Cost of sales	15.0	18.0	49.2	49.8
Research and development expense	27.0	39.4	87.7	105.1
Selling, general and administrative expense	28.7	38.3	87.8	109.6
Provision for (benefit from) income taxes	0.9	(222.0)	1.9	(220.3)
Net income	6.6	217.3	(5.2)	218.0
Stock-based compensation expense	8.9	10.0	25.7	27.7

See " *Results of Operations* " below for a discussion of the detailed components and analysis of the amounts above. Our cash, cash equivalents, short-term investments and long-term investments totaled $440.9 million as of September 30, 2010, compared to $470.5 million as of December 31, 2009. See " *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 the valuation and impairment reviews of long-lived assets, revenue recognition and related reserves, income taxes, inventory, research and development expenses, stock-based compensation and business combinations 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 polices have not differed materially from actual results.

Except for our critical accounting policy for the valuation of our contingent acquisition consideration payable and deferred tax asset valuation noted below, there have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2010, 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, 2009, which was filed with the SEC on February 26, 2010.

Valuation of Contingent Acquisition Consideration Payable

Each period we revalue the contingent acquisition consideration payable associated with certain acquisitions to their then fair value and record increases in the fair value as contingent consideration expense and record decreases in the fair value as a reduction of contingent consideration expense. Increases or decreases in the fair value of the contingent acquisition consideration payable can result from changes in assumed discount periods and rates, changes in the assumed timing of when milestones will be achieved and amount of revenue and expense estimates and changes in assumed probability adjustments with respect to regulatory approval. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, future business and economic conditions, as well as changes in any of the assumptions described above, can materially impact the amount of contingent consideration expense that we record in any given period.

Deferred Tax Asset Valuation

Our balance sheet reflects a net deferred tax asset that represents the tax benefit of net operating loss and credit carryforwards and timing differences between book and tax recognition of certain revenue and expense items, net of a valuation allowance. When it is more likely than not that all or some portion of deferred tax assets may not be realized, we establish a valuation allowance for the amount that may not be realized. Each quarter, we evaluate the need to retain all or a portion of the valuation allowance on our net deferred tax assets. During the three months ended September 30, 2010, we determined that it is more likely than not that the majority of our deferred tax assets, including net operating losses (NOLs) and tax credit carryforwards, will be realized. In making this determination, we analyzed our recent history of earnings, forecasts of future earnings and cumulative U.S. earnings for the last twelve quarters. The reversal of the valuation allowance in the U.S. resulted in an income tax benefit of $223.1 million and an increase in the current and non-current deferred tax assets on the consolidated balance sheet as of September 30, 2010.

We continue to maintain a valuation allowance against certain deferred tax assets totaling $6.9 million. We continually review the adequacy and necessity of the valuation allowance. Changes in tax laws and rates could also affect recorded deferred tax assets in the future. Management is not aware of any such changes that would have a material effect on our consolidated financial statements.

Recent Accounting Pronouncements

See Note 2(g) of our accompanying unaudited 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 Income (Loss)

Our net income for the three and nine months ended September 30, 2010 was $217.3 million and $218.0 million, respectively, compared to net income of $6.6 million and net loss of $5.2 million for the three and nine months ended September 30, 2009, respectively with the change primarily a result of the following (in millions):

	Three Months Ended September 30,	Nine Months Ended September 30,
Net income (loss) for the period ended September 30, 2009	$ 6.6	$ (5.2)
Benefit from reversal of deferred tax asset valuation allowance	223.1	223.1
Increased Naglazyme gross profit	9.7	22.3
Increased Kuvan gross profit	3.4	14.8
Increased Firdapse gross profit	1.8	2.7
Decreased impairment loss on equity investments	0	5.9
Increased research and development expense	(12.4)	(17.4)
Increased selling, general and administrative expense	(9.7)	(21.9)
Increased amortization of acquired intangible assets and contingent consideration	(3.9)	(3.3)
Increased (Decreased) Aldurazyme gross profit	0.3	(1.0)
Decreased collaborative revenues	(0.5)	(1.5)
Decreased Orapred royalty revenue	(0.8)	(1.0)
(Increased) Decreased interest expense	(0.1)	3.3
Decreased gain on the sale of equity investments	0	(0.7)
Other individually insignificant fluctuations	(0.2)	(2.1)
Net income for the period ended September 30, 2010	$ 217.3	$ 218.0

During the third quarter of 2010, we determined that it is more likely than not that the majority of our deferred tax assets, including NOLs, will be realized, resulting in the reversal of the valuation allowance and an income tax benefit of $223.1 million. The increase in Naglazyme gross profit in the third quarter and first nine months of 2010 as compared to the same periods in 2009 is primarily a result of additional patients initiating therapy. The increase in Kuvan gross profit in the third quarter and first nine months of 2010 as compared to the same periods in 2009 is primarily a result of additional patients initiating therapy in the U.S. The increase in research and development expense is primarily attributed to increased development expenses for our GALNS, PEG-PAL, LEMS and PARP programs. The increase in selling, general and administrative expense in the third quarter and first nine months of 2010 is primarily due to increased facility and employee related costs and the continued international expansion of Naglazyme and commercialization of Firdapse in Europe. The increase in amortization of acquired intangible assets and contingent consideration is attributed to the amortization of the Firdapse EU marketing rights and the change in the fair values of contingent consideration payable to the former Huxley Pharmaceuticals, Inc. (Huxley) and LEAD Therapeutics, Inc. (LEAD) stockholders. The decrease in Aldurazyme gross profit in 2010 as compared to 2009 is primarily attributed to fewer shipments of Aldurazyme to Genzyme.

Net Product Revenues, Cost of Sales and Gross Profit

The following table shows a comparison of net product revenues for the three and nine months ended September 30, 2009 and 2010 (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2010	Change	2009	2010	Change
Naglazyme	$ 42.1	$ 51.7	$ 9.6	$ 124.3	$ 147.5	$ 23.2
Kuvan	21.7	26.2	4.5	54.1	72.1	18.0
Aldurazyme	14.6	16.5	1.9	53.4	48.2	(5.2)
Firdapse	0	2.2	2.2	0	3.4	3.4
Total Net Product Revenues	$ 78.4	$ 96.6	$ 18.2	$ 231.8	$ 271.2	$ 39.4

Net product revenues for Naglazyme in the third quarter and first nine months of 2010 totaled $51.7 million and $147.5 million, respectively, of which $43.4 million and $125.4 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 positive $0.1 million for the third quarter of 2010 and negative $1.4 million for the nine months ended September 30, 2010. Gross profit from Naglazyme sales in the third quarter and first nine months of 2010 was $42.8 million and $120.9 million, respectively, representing gross margins of 83% and 82%, respectively. Gross profits from Naglazyme sales in the third quarter and first nine months of 2009 were $33.1 million and $98.6 million, respectively, representing gross margins of approximately 79% in both periods. The slight increase in gross margins during the third quarter and first nine months of 2010 as compared to the third quarter and first nine months of 2009 is primarily due to the impact of improved manufacturing yields.

Net product revenue for Kuvan during the third quarter and first nine months of 2010 was $26.2 million and $72.1 million, respectively, compared to $21.7 million and $54.1 million during the third quarter and first nine months of 2009. With the commercial launch of Kuvan in the EU during the first nine months of 2009, we began receiving a royalty of approximately 4% on net sales of Kuvan from Merck Serono. During the third quarter and first nine months of 2010, we earned $0.3 million and $0.7 million in royalties from Merck Serono on net sales of $6.3 million and $16.9 million, respectively. Royalties earned from Merck Serono during both the third quarter and first nine months of 2009 were insignificant. Gross profit from Kuvan in the third quarter and first nine months of 2010 was approximately $21.6 million and $59.7 million, respectively, representing gross margins of approximately 82% and 83%, respectively, compared to the third quarter and first nine months of 2009 when gross profit totaled $18.2 million and $44.9 million, respectively, representing gross margins of approximately 84% and 83%, respectively. All periods reflect royalties paid to third parties of 11%.

Pursuant to our relationship with Genzyme, we record a 39.5% to 50% royalty on worldwide net product sales of Aldurazyme. We also recognize product transfer revenue when product is released to Genzyme and all of our obligations have been fulfilled. Genzyme's contractual return rights for Aldurazyme are limited to defective product. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will be deducted from the calculated royalty rate when the product is sold by Genzyme.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2010	Change	2009	2010	Change
Aldurazyme revenue reported by Genzyme	$ 40.3	$ 40.8	$ 0.5	$ 116.4	$ 124.3	$ 7.9
Royalties due from Genzyme	15.9	16.5	0.6	46.0	50.2	4.2
Incremental (previously recognized) Aldurazyme product transfer revenue	(1.3)	0	1.3	7.4	(2.0)	(9.4)
Total Aldurazyme net product revenues	$ 14.6	$ 16.5	$ 1.9	$ 53.4	$ 48.2	$ (5.2)
Gross profit	$ 12.1	$ 12.4	$ 0.3	$ 39.1	$ 38.1	$ (1.0)

In the third quarter and first nine months of 2010, Aldurazyme gross margins were 75% and 79%, respectively, compared to 82% and 73% in the third quarter and first nine months of 2009, respectively. Aldurazyme gross margins reflect the profit earned on royalty revenue and net incremental product transfer revenue. The change in gross margins is attributed to a shift in revenue mix between royalty revenue and net product transfer revenues. In the future, to the extent that Genzyme's Aldurazyme inventory quantities on hand remain flat, we expect that our total Aldurazyme revenues will approximate the 39.5% to 50% royalties on net product sales by Genzyme. 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 a lower gross profit.

Total cost of sales in the third quarter and first nine months of 2010 was $18.0 million and $49.8 million, respectively, compared to $15.0 million and $49.2 million in the third quarter and first nine months of 2009, respectively. The increase in cost of sales for the three and nine months ended September 30, 2010 compared to the same periods in 2009 is primarily attributed to the increase in Naglazyme and Kuvan product sales.

Collaborative Agreement Revenues

Collaborative agreement revenues for the first quarters of 2009 and 2010 are comprised of contract research revenue under our agreement with Merck Serono, which was executed in May 2005. Contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. As shared development spending increases or decreases, contract research revenues will also change proportionately. Reimbursable revenues are expected to increase if PEG-PAL successfully completes Phase 2 clinical trials and Merck Serono exercises its right to co-develop it. The related costs are included in research and development expenses.

Collaborative agreement revenue in the third quarter and first nine months of 2010 were $0.1 million and $0.5 million, respectively, compared to $0.6 million and $2.0 million in the third quarter and first nine months of 2009, respectively. In all periods collaborative agreement revenue was comprised solely of reimbursable Kuvan development costs.

Royalty and License Revenues

The following table details the components of royalty and license revenues for the three and nine months ended September 30, 2009 and 2010 (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2010	Change	2009	2010	Change
Orapred product royalties	$ 1.6	$ 0.8	$ (0.8)	$ 3.2	$ 2.2	$ (1.0)
6R-BH4 royalty revenues	0.2	0.3	0.1	0.6	0.8	0.2
Total	$ 1.8	$ 1.1	$ (0.7)	$ 3.8	$ 3.0	$ (0.8)

Royalty and license revenues include Orapred product royalties, a product we acquired in 2004 and sublicensed in 2006, and 6R-BH4 royalty revenues for product sold in Japan. There is no cost of sales associated with the royalty and license revenues recorded during the periods and no related costs are expected in future periods.

Research and Development Expense

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates and products. These research and development costs primarily include preclinical and clinical studies, manufacturing of our product candidates prior to regulatory approval, quality control and assurance and other product development expenses, such as regulatory costs.

Research and development expense increased by $12.4 million and $17.4 million, to $39.4 million and $105.1 million during the third quarter and first nine months of 2010, respectively, from $27.0 million and $87.7 million in the third quarter and first nine months of 2009, respectively. The change in research and development expense for the three and nine months ended September 30, 2010 was primarily a result of the following (in millions):

	Three Months Ended September 30,	Nine Months Ended September 30,
Research and development expense for period ended September 30, 2009	$ 27.0	$ 87.7
Absence of license payment related to collaboration with La Jolla Pharmaceutical Company	0	(8.8)
Decreased 6R-BH4 development expenses for indications other than PKU	(0.7)	(4.0)
Increased PARP & non-PARP development expenses	3.8	7.8
Increased development expenses related to commercial products	4.3	6.3
Increased GALNS for Morquio Syndrome Type A development expense	2.4	5.0
Increased PEG-PAL development expenses	0.8	4.2
Increased research and development expenses on early development stage programs	1.0	2.4
Increased stock-based compensation expense	0.2	1.8
Increased (Decreased) Duchenne muscular dystrophy program development expense	(0.5)	0.6
Increased ZC-701 development expenses	0.4	0.4
Increase in non-allocated research and development expenses and other net changes	0.7	1.7
Research and development expense for the period ended September 30, 2010	$ 39.4	$ 105.1

During the first quarter of 2009, we paid La Jolla an up-front license fee for the rights to develop and commercialize La Jolla's investigational drug, Riquent. We terminated the license agreement with La Jolla in 2009 and there will not be any additional development expense for Riquent. The decrease in 6R-BH4 development expense expenses for indications other than PKU is primarily due to a decline in clinical studies in the first nine months of 2010 compared to the same period in 2009. The increase in PARP and non-PARP development expense relates to pre-clinical activities related to the product candidate acquired from LEAD during the first quarter of 2010. The increase in research and development expenses related to commercial products is primarily attributed to long-term Kuvan and Firdapse clinical activities related to post-approval regulatory commitments in the U.S. and EU, respectively. The increase in GALNS and PEG-PAL development expense is attributed to increased clinical trial activities related to the product candidates. 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 ZC-701 development expense relates to pre-clinical activities related to the product candidate acquired from ZyStor Therapeutics, Inc. (ZyStor) during the third quarter of 2010. The increase in non-allocated research and development expense primarily includes increases in general research costs and research and development personnel costs that are not allocated to specific programs. 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 products and spending on our GALNS, PEG-PAL, Firdapse and PARP programs and our other product candidates.

Selling, General and Administrative Expense

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support our commercialized products and product development programs. These selling, general and administrative costs include: corporate facility operating expenses and depreciation; marketing and sales operations; human resources; finance; legal and support personnel expenses and other external corporate costs such as insurance, audit and legal fees.

Selling, general and administrative expenses increased by $9.6 million and $21.8 million to $38.3 million and $109.6 million for the third quarter and first nine months of 2010, respectively, from $28.7 million and $87.8 million for the third quarter and first nine months of 2009, respectively. The components of the change for the three and nine months ended September 30, 2010 primarily include the following (in millions):

The increase in Naglazyme sales and marketing expenses in the third quarter and first nine months of 2010 is attributed to continued expansion of our international activities. We continue to incur spending related to the European commercialization of Firdapse which launched in April 2010. Transactions costs related to the Zy

Equity in the Loss of BioMarin/Genzyme LLC

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

Equity in the loss of the joint venture totaled $0.6 million and $2.2 million, respectively, for the third quarter and first nine months of 2010, compared to $0.7 million and $1.8 million for the third quarter and first nine months of 2009, respectively.

Interest Income

We invest our cash, short-term and long-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income totaled $1.0 million and $3.2 million in the third quarter and first nine months of 2010, respectively, compared to $1.0 million and $4.1 million in the third quarter and first nine months of 2009, respectively. The reduced interest yield during the third quarter and first nine months of 2010 was due to lower market interest rates and decreased levels of cash and investments. We expect that interest income will decline during the remainder of 2010 as compared to 2009 due to reduced interest yields and lower cash and investment balances.

Interest Expense

We incur interest expense on our convertible debt. Interest expense also includes imputed interest expense on the discounted acquisition obligation for the Ascent Pediatrics transaction. Interest expense during the third quarter and first nine months of 2010 was $3.0 million and $8.1 million, respectively, compared to $2.9 million and $11.4 million in the third quarter and first nine months of 2009, respectively. Interest expense in the first nine months of 2009 included imputed interest of $2.6 million. Imputed interest has not been incurred in periods subsequent to September 2009 as the Medicis obligation was paid in full in June 2009.

Changes in Financial Position

September 30, 2010 Compared to December 31, 2009

From December 31, 2009 to September 30, 2010, our cash, cash equivalents and short-term and long-term investments decreased by $29.6 million, primarily as a result the upfront cash payments of $14.5 million and $18.5 million to acquire LEAD in the first quarter of 2010 and ZyStor in the third quarter of 2010, respectively, a $6.5 million milestone payment to the former Huxley stockholders and capital expenditures, offset by cash flows from operating activities and proceeds from ESPP contributions and stock option exercises. Our accounts receivable increased by $5.2 million due to increased sales of Naglazyme, Kuvan, Firdapse and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. Our net property, plant and equipment increased by approximately $14.6 million from December 31, 2009 to September 30, 2010, primarily as a result of continued expansion and improvements to our facilities during the period. Intangible assets, goodwill and other long-term liabilities increased by approximately $63.6 million, $29.6 million and $50.0 million, respectively, primarily as a result of the LEAD acquisition. Other current assets and other assets increased by $16.9 million and $213.2 million, respectively, due to the release of our income tax valuation allowance in the third quarter of 2010. Due to several ongoing facility improvement projects completed in 2010, we expect depreciation expense to increase as the assets are placed into service.

Liquidity and Capital Resources

Cash and Cash Flow

As of September 30, 2010, our combined cash, cash equivalents, short-term and long-term investments totaled $440.9 million, a decrease of $29.6 million, from $470.5 million at December 31, 2009.

The decrease in our combined cash, cash equivalents, short-term investments and long-term investments during the first nine months of 2010 was $29.6 million, which was $40.0 million less than the net decrease in the first nine months of 2009 of $69.6 million. The primary items contributing to the decrease in net cash outflow in the first nine months of 2010 were as follows (in millions):

Absence of Orapred acquisition payments, primarily the early settlement of the Medicis obligation	$ 73.6
Absence of milestone payment received for Kuvan EMEA approval	(30.0)
Business acquisitions net of cash acquired	(33.0)
Increased contingent acquisition payments	(6.2)
Increased proceeds from ESPP and stock option exercises	11.5
Decreased investments in equity securities	6.3
Decreased capital asset purchases	28.5
Increased investments in BioMarin/Genzyme LLC	(1.2)
Net decrease in cash provided by operating activities, including net payments for working capital, and other	(9.5)
Total increase in net cash outflow	$ 40.0

The net decrease in cash provided by operating activities includes increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, partially offset by increases in cash receipts from net revenue, as discussed in *"Results of Operations"* above. Decreased capital purchases reflect the substantial completion of our manufacturing facilities at our Novato, California campus in the second half of 2009. Net payments for working capital in the first nine months of 2010 primarily includes increased inventory build of $10.8 million and decreased accounts receivable build of $8.9 million and other current assets build of $33.1 million.

On October 23, 2009, we acquired Huxley, which has rights to a proprietary form of 3,4-diaminopyridine (3,4-DAP), amifampridine phosphate for the treatment of the rare autoimmune disease LEMS for a total purchase price of $37.2 million, of which $15.0 million was paid in cash and $22.2 million is contingent acquisition consideration payable, of which $1.0 million was paid in the fourth quarter of 2009 and $6.5 million was paid in April 2010. In connection with the acquisition, we agreed to pay 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.

On February 10, 2010, we acquired LEAD, which has the key compound, LT-673, an orally available PARP inhibitor for the treatment of patients with rare, genetically defined cancers for a total purchase price of $39.1 million, of which $18.6 million was paid in cash and $20.5 million is 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 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.

On August 17, 2010, we acquired ZyStor, which is developing enzyme replacement therapies for the treatment of lysosomal storage disorders for a total purchase price of $35.9 million, of which $20.3 million was paid in cash, $2.0 million was held back and $15.6 million is contingent acquisition consideration payable. The purpose of the holdback of the purchase price is to satisfy any obligations of the former Zystor stockholders to pay any indemnification claims to BioMarin. 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.

We expect that our net cash outflow in 2010 related to capital asset purchases will decrease significantly compared to 2009. The expected decrease in capital asset purchases primarily reflects the substantial completion of our manufacturing facility and the related spending on manufacturing and laboratory equipment.

We have historically financed our operations primarily by the issuance of common stock and convertible debt and by relying on equipment and other commercial financing. During 2010, and for the foreseeable future, we will be highly dependent on our net product revenue to supplement our current liquidity and fund our operations. 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, in the future we may choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities.

Funding Commitments

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.

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 for the third quarter and first nine months of 2009 and 2010 and for the period since inception (March 1997 for the portion not allocated to any major program) represent the following (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Program
	2009	2010	2009	2010	Inception
Naglazyme	$ 2.3	$ 2.6	$ 7.4	$ 6.7	$ 139.1
Kuvan	2.9	3.7	8.7	10.2	111.5
GALNS for Morquio Syndrome Type A	5.3	7.7	13.2	18.2	52.3
6R-BH4 for indications other than PKU	0.7	0	4.3	0.2	46.7
PEG-PAL	3.4	4.2	8.1	12.3	54.7
Not allocated to specific major current projects	12.4	21.2	46.0	57.5	308.7
Total	$27.0	$39.4	$87.7	$105.1	$ 713.0

We cannot estimate the cost to complete any of our product development programs. Additionally, except as disclosed under *"Overview"* above, we cannot 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* " in our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 26, 2010, for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in such Annual Report on Form 10-K " *—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. "*

We may elect to increase our spending above our current long-term plans and may be unable to achieve our long-term goals. This could increase our capital requirements, including: costs associated with the commercialization of our products; additional clinical trials and 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; general corporate purposes; and working capital.

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 financial position or results of operations.

Borrowings and Contractual Obligations

In April 2007, we sold approximately $324.9 million of senior subordinated convertible notes due April 2017. 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. In March 2006, we sold approximately $172.5 million of senior subordinated convertible notes due 2013. The debt was issued at face value and bears interest at the rate of 2.5% per annum, payable semi-annually in cash. There is a no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2013. 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 $16.58 per share, subject to adjustment in certain circumstances. However, we must repay the debt prior to maturity if there is a qualifying change in control or termination of trading of our common stock. Our $497.1 million of convertible debt will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayments of the debt.

We have contractual and commercial obligations under our debt, operating leases and other obligations related to research and development activities, purchase commitments, licenses and sales royalties with annual minimums. Information about these obligations as of September 30, 2010 is presented in the table below (in thousands).

	Payments Due by Period					
	2010	2011	2012 -2013	2014-2015	2016 and Thereafter	Total
Convertible debt and related interest	$ 3,046	$10,401	$190,853	$12,183	$334,012	$550,495
Operating leases	1,093	4,365	7,439	2,841	4,548	20,286
Research and development and purchase commitments	12,782	24,719	11,392	6,222	5,811	60,926
Total	$16,921	$39,485	$209,684	$21,246	$344,371	$631,707

We are also subject to contingent payments related to various development activities totaling approximately $263.5 million, which are due upon achievement of certain development and commercial milestones, and if they occur before certain dates in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 2010 have not materially changed from those in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 26, 2010.

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 filed 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 Rule 13a-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

In the three months ended September 30, 2010, there have not been any material changes from the risk factors previously disclosed in Part 1, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009, which was filed with the SEC on February 26, 2010 and Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarters ended March 31, 2010, and June 30, 2010 which were filed with the SEC on May 3, 2010 and August 4, 2010, respectively.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. (Removed and Reserved).

Item 5. Other Information.

None.

Item 6. Exhibits.

10.1#	Securities Purchase Agreement dated August 17, 2010 by and among BioMarin Pharmaceutical Inc., ZyStor Therapeutics Inc., the holders of outstanding capital stock and rights to acquire capital stock of ZyStor Therapeutics Inc. and George G. Arida as the representative of such holders, previously filed with the Commission on August 17, 2010 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated by reference herein.
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

The SEC granted confidential treatment with respect to certain portions of this document. Omitted portions have been filed separately with the SEC.

* 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). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.

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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, 2010

By /s/ JEFFREY H. COOPER

Jeffrey H. Cooper,
Senior Vice President, Chief Financial Officer
(On behalf of the registrant and as principal financial officer)

Exhibit Index

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Exhibit 31.1

CERTIFICATION

I, Jean-Jacques Bienaimé, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioMarin Pharmaceutical Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2010

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

Exhibit 31.2

CERTIFICATION

I, Jeffrey H. Cooper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioMarin Pharmaceutical Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2010

/s/ JEFFREY H. COOPER
Jeffrey H. Cooper
Senior Vice President, Chief Financial Officer

Exhibit 32.1

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

We, Jean-Jacques Bienaimé and Jeffrey H. Cooper, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that BioMarin Pharmaceutical Inc.'s Quarterly Report on Form 10-Q for the period ended September 30, 2010, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

October 29, 2010

/s/ JEFFREY H. COOPER
Jeffrey H. Cooper
Senior Vice President, Chief Financial Officer

October 29, 2010