

BIOMARIN PHARMACEUTICAL INC

FORM 10-Q (Quarterly Report)

Filed 08/04/10 for the Period Ending 06/30/10

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

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 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
(State or other jurisdiction of
incorporation or organization)

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

105 Digital Drive, Novato, California
(Address of principal executive offices)

94949
(Zip Code)

(415) 506-6700
Registrant's telephone number including area code:

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

Large accelerated filer 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: 102,058,660 shares of common stock, par value \$0.001, outstanding as of July 23, 2010.

Table of Contents

BIOMARIN PHARMACEUTICAL INC.

TABLE OF CONTENTS

	<u>Page</u>
PART I. FINANCIAL INFORMATION	3
Item 1. Consolidated Financial Statements (Unaudited)	3
Consolidated Balance Sheets	3
Consolidated Statements of Operations	4
Consolidated Statements of Cash Flows	5
Notes to Consolidated Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	30
Item 3. Quantitative and Qualitative Disclosures about Market Risk	40
Item 4. Controls and Procedures	40
PART II. OTHER INFORMATION	41
Item 1. Legal Proceedings	41
Item 1A. Risk Factors	41
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	41
Item 3. Defaults Upon Senior Securities	41
Item 4. (Removed and Reserved)	41
Item 5. Other Information	41
Item 6. Exhibits	41
SIGNATURE	43

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

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

	December 31, <u>2009 (1)</u>	June 30, <u>2010</u> (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 167,171	\$ 115,779
Short-term investments	133,506	221,894
Accounts receivable, net	73,540	77,682
Inventory	78,662	83,778
Other current assets	<u>14,848</u>	<u>22,775</u>
Total current assets	467,727	521,908
Investment in BioMarin/Genzyme LLC	441	351
Long-term investments	169,849	117,734
Property, plant and equipment, net	199,141	212,620
Intangible assets, net	40,977	77,985
Goodwill	23,722	40,360
Other assets	<u>15,306</u>	<u>14,558</u>
Total assets	<u>\$ 917,163</u>	<u>\$ 985,516</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable, accrued liabilities and other current liabilities	\$ 78,068	\$ 83,930
Deferred revenue	<u>86</u>	<u>0</u>
Total current liabilities	78,154	83,930
Convertible debt	497,083	497,083
Other long-term liabilities	<u>19,741</u>	<u>41,541</u>
Total liabilities	<u>594,978</u>	<u>622,554</u>
Stockholders' equity:		
Common stock, \$0.001 par value: 250,000,000 shares authorized at December 31, 2009 and June 30, 2010; 100,961,922 and 102,016,778 shares issued and outstanding at December 31, 2009 and June 30, 2010, respectively	101	102
Additional paid-in capital	899,950	931,361
Company common stock held by Nonqualified Deferred Compensation Plan	(1,715)	(2,315)
Accumulated other comprehensive income	933	10,224
Accumulated deficit	<u>(577,084)</u>	<u>(576,410)</u>
Total stockholders' equity	<u>322,185</u>	<u>362,962</u>
Total liabilities and stockholders' equity	<u>\$ 917,163</u>	<u>\$ 985,516</u>

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

See accompanying notes to unaudited consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2010	2009	2010
Revenues:				
Net product revenues	\$ 81,472	\$ 90,592	\$153,386	\$174,665
Collaborative agreement revenues	868	176	1,377	377
Royalty and license revenues	447	1,182	2,004	1,861
Total revenues	<u>82,787</u>	<u>91,950</u>	<u>156,767</u>	<u>176,903</u>
Operating expenses:				
Cost of sales (excludes amortization of developed product technology)	19,848	14,401	34,210	31,813
Research and development	26,324	35,649	60,682	65,746
Selling, general and administrative	30,527	37,277	59,095	71,277
Intangible asset amortization and contingent consideration	1,775	1,580	2,868	2,234
Total operating expenses	<u>78,474</u>	<u>88,907</u>	<u>156,855</u>	<u>171,070</u>
Income (loss) from operations	4,313	3,043	(88)	5,833
Equity in the loss of BioMarin/Genzyme LLC	(546)	(864)	(1,093)	(1,555)
Interest income	886	1,035	3,039	2,225
Interest expense	(4,404)	(2,635)	(8,496)	(5,064)
Impairment loss on equity investments	0	0	(5,848)	0
Net gain from sale of investments	1,585	0	1,585	927
Income (loss) before income taxes	1,834	579	(10,901)	2,366
Provision for income taxes	522	1,056	939	1,692
Net income (loss)	<u>\$ 1,312</u>	<u>\$ (477)</u>	<u>\$ (11,840)</u>	<u>\$ 674</u>
Net income (loss) per share, basic	<u>\$ 0.01</u>	<u>\$ (0.00)</u>	<u>\$ (0.12)</u>	<u>\$ 0.01</u>
Net income (loss) per share, diluted	<u>\$ 0.01</u>	<u>\$ (0.01)</u>	<u>\$ (0.12)</u>	<u>\$ 0.01</u>
Weighted average common shares outstanding, basic	<u>100,065</u>	<u>101,712</u>	<u>99,984</u>	<u>101,431</u>
Weighted average common shares outstanding, diluted	<u>101,217</u>	<u>101,834</u>	<u>100,075</u>	<u>104,347</u>

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Six Months Ended June 30, 2009 and 2010

(In thousands, unaudited)

	<u>Six Months Ended June 30,</u>	
	<u>2009</u>	<u>2010</u>
Cash flows from operating activities:		
Net income (loss)	\$ (11,840)	\$ 674
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	11,273	11,987
Amortization of discount (premium) on investments	(341)	2,501
Imputed interest on acquisition obligation	2,859	0
Equity in the loss of BioMarin/Genzyme LLC	1,093	1,555
Stock-based compensation	17,494	18,233
Impairment loss on equity investments	5,848	0
Net gain from sale of investments	(1,585)	(927)
Unrealized foreign exchange (gain) loss on forward contracts	3,323	(1,475)
Changes in the fair value of contingent acquisition consideration payable	0	1,453
Excess tax benefit from stock option exercises	(131)	(13)
Changes in operating assets and liabilities:		
Accounts receivable, net	(18,278)	(4,142)
Inventory	326	(5,116)
Other current assets	31,904	1,287
Other assets	(1,674)	(2,646)
Accounts payable, accrued liabilities and other current liabilities	(2,183)	1,839
Other long-term liabilities	1,122	347
Deferred revenue	622	(86)
Net cash provided by operating activities	<u>39,832</u>	<u>25,471</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment	(40,621)	(29,348)
Maturities and sales of investments	326,703	50,682
Purchase of investments	(271,119)	(89,472)
Business acquisitions, net of cash acquired	0	(14,124)
Investments in BioMarin/Genzyme LLC	(640)	(1,465)
Investment in equity securities	(6,250)	0
Net cash provided by (used in) investing activities	<u>8,073</u>	<u>(83,727)</u>
Cash flows from financing activities:		
Proceeds from Employee Stock Purchase Plan (ESPP) and exercise of stock options	2,805	13,166
Excess tax benefit from stock option exercises	131	13
Repayment of acquisition obligation	(73,600)	0
Payment of contingent acquisition payable	0	(6,230)
Repayment of capital lease obligations	(91)	(85)
Net cash provided by (used in) financing activities	<u>(70,755)</u>	<u>6,864</u>
Net decrease in cash and cash equivalents	(22,850)	(51,392)
Cash and cash equivalents:		
Beginning of period	<u>222,900</u>	<u>167,171</u>
End of period	<u>\$ 200,050</u>	<u>\$ 115,779</u>
Supplemental cash flow disclosures:		
Cash paid for interest, net of interest capitalized into fixed assets	\$ 4,959	\$ 4,524
Cash paid for income taxes	813	1,183
Stock-based compensation capitalized into inventory	2,672	2,324
Depreciation capitalized into inventory	1,339	3,009
Supplemental non-cash investing and financing activities disclosures:		
Changes in accrued liabilities related to fixed assets	1,480	5,790
Changes in contingent acquisition consideration payable	0	1,453

See accompanying notes to unaudited consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

June 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[®] (aronidase) and Firdapse[™] (amifampridine phosphate).

Through June 30, 2010, the Company had accumulated losses of approximately \$576.4 million. Management believes that the Company's cash, cash equivalents and short-term and long-term investments at June 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 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, as well as other changes in the health care industry.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

These unaudited consolidated financial statements include the accounts of BioMarin and its wholly owned subsidiaries. All significant intercompany transactions have been eliminated. These unaudited 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 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.

(c) Cash and Cash Equivalents

The Company treats liquid investments with original maturities of three months or less when purchased as cash and cash equivalents.

Table of Contents

(d) Investments

The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and reevaluates such designations at each balance sheet date. All of the Company's securities are classified as either held-to-maturity or available-for-sale and reported in short-term investments or long-term investments. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investments are recorded at fair market value, with unrealized gains or losses included in accumulated other comprehensive income or loss, exclusive of other-than-temporary impairment losses, if any. Short-term and long-term investments are comprised of corporate securities, commercial paper, U.S. federal government agency securities, money market funds, equity securities and certificates of deposit. As of June 30, 2010, the Company had no held-to-maturity investments.

(e) Inventory

The Company values inventory at the lower of cost or net realizable value. The Company determines the cost of inventory using the average-cost method. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of sales in the consolidated statements of operations.

Manufacturing costs for product candidates are expensed as research and development expenses. The Company considers regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory. When regulatory approval is obtained, the Company begins capitalizing inventory at the lower of cost or net realizable value.

Stock-based compensation capitalized into inventory for the six months ended June 30, 2009 and 2010, was \$2.7 million and \$2.3 million, respectively.

(f) 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 will be 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.

Table of Contents

(g) Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the related estimated useful lives, except for leasehold improvements, which are depreciated over the shorter of the useful life of the asset or the lease term. Significant additions and improvements are capitalized, while repairs and maintenance are charged to expense as incurred. Property and equipment purchased for specific research and development projects with no alternative uses are expensed as incurred. See Note 10 for further information on property, plant and equipment balances as of December 31, 2009 and June 30, 2010.

Certain of the Company's operating lease agreements include scheduled rent escalations over the lease term, as well as tenant improvement allowances. Scheduled increases in rent expense are recognized on a straight-line basis over the lease term. The difference between rent expense and rent paid is recorded as deferred rent and included in other liabilities in the accompanying consolidated balance sheets. The tenant improvement allowances and free rent periods are recognized as a reduction of rent expense over the lease term on a straight-line basis.

(h) Revenue Recognition

The Company recognizes revenue in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopics ASC 605-15, *Revenue Recognition—Products* and ASC 605-25, *Revenue Recognition—Multiple-Element Arrangements*. The Company's revenues consist of net product revenues from its commercial products, revenues from its collaborative agreement with Merck Serono and other license and royalty revenues. Milestone payments are recognized in full when the related milestone performance goal is achieved and the Company has no future performance obligations related to that payment.

Net Product Revenues —The Company recognizes net product revenue when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. Product sales transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes related to Naglazyme and Firdapse sales in foreign jurisdictions, are presented on a net basis in the Company's consolidated statements of operations, in that taxes billed to customers are not included as a component of net product revenues.

The Company receives a 39.5% to 50% royalty on worldwide net Aldurazyme sales by Genzyme depending on sales volume, which is included in net product revenues in the consolidated statements of operations. 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 that 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 will eventually be deducted from the calculated royalty rate when the product is sold by Genzyme. The Company records the Aldurazyme royalty revenue based on net sales information provided by Genzyme and records product transfer revenue based on the fulfillment of Genzyme purchase orders in accordance with the terms of the related agreements with Genzyme and when the title and risk of loss for the product is transferred to Genzyme. As of December 31, 2009 and June 30, 2010, accounts receivable included \$20.3 million and \$18.0 million, respectively, of unbilled accounts receivable related to net incremental Aldurazyme product transfers to Genzyme.

The Company sells Naglazyme worldwide, Kuvan in the U.S. and Canada and Firdapse in the EU. In the U.S., Naglazyme and Kuvan are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. The Company also sells Kuvan to Merck Serono at a price near its manufacturing cost, and Merck Serono resells the product to end users outside the U.S., Canada and Japan. The royalty earned from Kuvan product sold by Merck Serono in the EU is included as a component of net product revenues in the period earned and approximates 4%. Outside the U.S., Naglazyme and Firdapse are sold to the Company's authorized distributors or directly to government purchasers or hospitals, which act as the end-users. The Company records reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product revenues are recorded. The Company's reserve calculations require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. The Company updates its estimates and assumptions each quarter and records any necessary adjustments to its reserves. The Company records fees paid to distributors as a reduction of revenue.

The Company records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including market exclusivity of the products based on their orphan drug status, the patient population, the customers' limited return rights and the Company's experience with returns. Because of the pricing of Naglazyme, Kuvan and Firdapse, the limited number of patients and the customers' limited return rights, most Naglazyme and Kuvan customers and retailers carry a limited inventory.

Table of Contents

However, certain international customers, usually government entities, tend to purchase larger quantities of product less frequently. Although such buying patterns may result in revenue fluctuations from quarter to quarter, the Company has not experienced any increased product returns or risk of product returns. The Company relies on historical return rates to estimate returns for Aldurazyme, Naglazyme and Kuvan. Genzyme's contractual return rights for Aldurazyme are limited to defective product. The Company's products are comparable in nature and sold to similar customers with limited return rights; therefore the Company relies on historical return rates for Aldurazyme, Naglazyme and Kuvan to estimate returns for Firdapse, which has a limited history of product returns. Based on these factors, management has concluded that product returns will be minimal, and the Company has not experienced significant product returns to date. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

The Company maintains a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of June 30, 2010, the Company has experienced no significant bad debts and the recorded allowance for doubtful accounts was insignificant.

Collaborative Agreement Revenues —Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue under the Company's agreement with Merck Serono, which was executed in May 2005. Nonrefundable up-front license fees where the Company has continuing involvement through research and development collaboration are initially deferred and recognized as collaborative agreement license revenue over the estimated period for which the Company continues to have a performance obligation. The Company's recognition of license revenue from Merck Serono was completed in 2008. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related expenses are incurred. Contract research revenue included in collaborative agreement revenues represents Merck Serono's share of Kuvan development costs under the Merck Serono agreement, which are recorded as research and development expenses in the consolidated statements of operations. Allowable costs during the development period must have been included in the pre-approved annual budget in order to be subject to reimbursement or must be separately approved by both parties.

Collaborative agreement revenues totaled \$0.2 million and \$0.4 million during the three and six months ended June 30, 2010, respectively, compared to the three and six months ended June 30, 2009 when collaborative revenues totaled \$0.9 million and \$1.4 million, respectively. Collaborative agreement revenues for the three and six month periods ended June 30, 2009 and 2010 were comprised of reimbursable development costs for Kuvan.

Royalty and License Revenues —Royalty revenue includes royalties on net sales of products with which the Company has no direct involvement and is recognized based on data reported by licensees or sublicensees. Royalties are recognized as earned in accordance with the contract terms at the time the royalty amount is fixed or determinable based on information received from the sublicensee and at the time collectibility is reasonably assured.

Due to the significant role the Company plays in the operations of Aldurazyme and Kuvan, primarily the manufacturing and regulatory activities, as well as the rights and responsibilities to deliver the products to Genzyme and Merck Serono, respectively, the Company elected not to classify the Aldurazyme and Kuvan royalties earned as other royalty revenues and instead to include them as a component of net product revenues.

Royalty and license revenues for the three and six months ended June 30, 2010 include \$0.9 million and \$1.4 million, respectively, of Orapred product royalties, a product that the Company acquired in 2004 and sublicensed in 2006, and \$0.3 million and \$0.5 million, respectively of royalty revenues for 6R-BH4, the active ingredient in Kuvan, sold in Japan. Royalty and license revenues for the three and six months ended June 30, 2009 included \$0.2 million and \$1.6 million, respectively, of Orapred product royalties and \$0.2 million and \$0.4 million of royalty revenue for 6R-BH4.

(i) Research and Development

Research and development expenses include expenses associated with contract research and development provided by third parties, product manufacturing prior to regulatory approval, clinical and regulatory costs, and internal research and development costs. In instances where the Company enters into agreements with third parties for research and development activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the vendors that perform the activities.

Table of Contents

The Company believes that regulatory approval of its product candidates is uncertain and does not assume that products manufactured prior to regulatory approval will be sold commercially. As a result, inventory costs for product candidates are expensed as research and development until regulatory approval is obtained in a major market, at which time inventory is capitalized at the lower of cost or net realizable value.

(j) 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, contingent issuances of common stock related to convertible debt and through the first quarter of 2009, the portion of acquisition costs that was payable in shares of the Company's common stock at the Company's option.

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

	Three Months Ended June 30, 2009			Six Months Ended June 30, 2009		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount	Net Loss (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Net Income (Loss) Per Share:						
Net Income (Loss)	\$ 1,312	100,065	\$ <u>0.01</u>	\$ (11,840)	99,984	\$ <u>(0.12)</u>
Effect of dilutive shares:						
Stock options using the treasury method		839			0	
Potentially issuable common stock for ESPP purchases		222			0	
Common stock held in the Nonqualified Deferred Compensation Plan using the treasury method	(116)	91		(111)	91	
Diluted Net Income (Loss) Per Share:						
Net Income (Loss)	\$ <u>1,196</u>	<u>101,217</u>	\$ <u>0.01</u>	\$ <u>(11,951)</u>	<u>100,075</u>	\$ <u>(0.12)</u>
	Three Months Ended June 30, 2010			Six Months Ended June 30, 2010		
	Net (Loss) (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 Loss	\$ (477)	101,712	\$ <u>(0.00)</u>	\$ 674	101,431	\$ <u>0.01</u>
Effect of dilutive shares:						
Stock options using the treasury method		0			2,156	
Potentially issuable restricted common stock		0			110	
Potentially issuable common stock for ESPP purchases		0			528	
Common stock held in the Nonqualified Deferred Compensation Plan using the treasury method	(324)	122		(49)	122	
Diluted Net Loss Per Share:						
Net Loss	\$ <u>(801)</u>	<u>101,834</u>	\$ <u>(0.01)</u>	\$ <u>625</u>	<u>104,347</u>	\$ <u>0.01</u>

Table of Contents

In addition to the equity instruments included in the table above, the following potential shares of common stock were excluded from the computation as they were anti-dilutive for the three and six months ended June 30, 2009 and 2010 using the treasury stock method: (i) out-of-the-money options to purchase common stock, (ii) potentially issuable restricted stock, (iii) shares of common stock underlying the 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 and for the three and six months ended June 30, 2010, and (iv) Company common stock issued to the Nonqualified Deferred Compensation Plan (in thousands):

	Three Months Ended		Six Months Ended	
	June 30,		June 30	
	2009	2010	2009	2010
Options to purchase common stock	11,593	16,046	14,668	13,890
Common stock issuable under convertible debt	26,343	26,343	26,343	26,343
Unvested restricted stock units	400	426	400	316
Potentially issuable common stock for ESPP purchases	0	530	242	0
Total	<u>38,336</u>	<u>43,345</u>	<u>41,653</u>	<u>40,549</u>

(k) Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model to determine the fair value of stock options and ESPP awards. The determination of the fair value of stock-based payment awards using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of complex and subjective variables. Stock-based compensation expense is recognized on a straight-line basis over the requisite service period for each award. Further, stock-based compensation expense recognized in the consolidated statements of operations is based on awards expected to vest and therefore the amount of expense has been reduced for estimated forfeitures, which are based on historical experience. If actual forfeitures differ from estimates at the time of grant they will be revised in subsequent periods.

If factors change and different assumptions are employed in determining the fair value of stock-based awards, the stock-based compensation expense recorded in future periods may differ significantly from what was recorded in the current period (see Note 3 for further information).

(l) Nonqualified Deferred Compensation Plan

The Company's Nonqualified Deferred Compensation Plan allows eligible employees, including management and certain highly-compensated employees as designated by the plan's administrative committee and members of the Company's Board of Directors (the Board), to make voluntary deferrals of compensation to specified dates, retirement or death. Participants are permitted to defer portions of their salary, annual cash bonus and restricted stock. The Company is not allowed to make additional direct contributions to the Nonqualified Deferred Compensation Plan on behalf of the participants without further action by the Board.

Other current assets and other non-current assets include \$1.8 million and \$2.4 million, of investments held in trust related to the Company's Nonqualified Deferred Compensation Plan for certain employees and directors as of December 31, 2009, and June 30, 2010, respectively. All of the investments held in the Nonqualified Deferred Compensation Plan are classified as trading securities and recorded at fair value with changes in the investments' fair values recognized in earnings in the period they occur. Restricted stock issued into the Nonqualified Deferred Compensation Plan is accounted for similarly to treasury stock in that the value of the employer stock is determined on the date the restricted stock vests and the shares are issued into the Nonqualified Deferred Compensation Plan. The restricted stock issued into the Nonqualified Deferred Compensation Plan is recorded in equity and changes in the fair value of the corresponding liability are recognized in earnings as incurred. The corresponding liability for the Nonqualified Deferred Compensation Plan is included in other current liabilities and other long-term liabilities.

(m) 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

Table of Contents

net deferred tax assets of \$268.1 million at December 31, 2009. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. An adjustment to the valuation allowance would increase or decrease net income/loss in the period such adjustment was made or additional paid-in-capital. For the three and six months ended June 30, 2010, the Company recognized income tax expense of \$1.1 million and \$1.7 million, respectively, compared to the three and six months ended June 30, 2009 when the Company recognized income tax expense of \$0.5 million and \$0.9 million, respectively. Income tax expense for the three and six months ended June 30, 2009 and 2010 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.

(n) Foreign Currency and Other Hedging Instruments

The Company has transactions denominated in foreign currencies and, as a result, is exposed to changes in foreign currency exchange rates. The Company manages some of these exposures on a consolidated basis, which results in the netting of certain exposures to take advantage of natural offsets and through the use of foreign currency forward contracts. Gains or losses on net foreign currency hedges are intended to offset gains or losses on the underlying net exposures in an effort to reduce the earnings and cash flow volatility resulting from fluctuating foreign currency exchange rates.

The Company accounts for its derivative instruments as either assets or liabilities on the balance sheet and measures them at fair value. Derivatives that are not defined as hedging instruments are adjusted to fair value through earnings. Gains and losses resulting from changes in fair value are accounted for depending on the use of the derivative and whether it is designated and qualifies for hedge accounting (see Note 14 for further information).

(o) Fair Value of Financial Instruments

The Company discloses the fair value of financial instruments for assets and liabilities for which the value is practicable to estimate. The carrying amounts of all cash equivalents, investments and forward exchange contracts approximate fair value based upon quoted market prices or discounted cash flows. The fair value of trade accounts receivables, accounts payable and other financial instruments approximates carrying value due to their short-term nature.

(p) 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.

(q) 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. There were no tax effects allocated to any components of other comprehensive income (loss) during the three and six months ended June 30, 2009 and 2010.

During the three and six months ended June 30, 2010, total comprehensive income was approximately \$5.3 million and \$10.0 million, respectively, compared to the three and six months ended June 30, 2009 when comprehensive net loss totaled \$0.7 million and \$12.8 million, respectively. The fluctuation in accumulated other comprehensive income (loss) is comprised of the following (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2009</u>	<u>2010</u>	<u>2009</u>	<u>2010</u>
Net unrealized gain (loss) on available-for-sale securities	\$ (205)	\$ (337)	\$ (838)	\$ (55)
Net unrealized gain (loss) on foreign currency hedges	(2,877)	6,180	(945)	10,237
Net unrealized loss on equity investments	1,112	(23)	774	(889)
Net foreign currency translation loss	<u>2</u>	<u>(1)</u>	<u>4</u>	<u>(2)</u>
Change in accumulated other comprehensive income (loss)	<u>\$ (1,968)</u>	<u>\$ 5,819</u>	<u>\$ (1,005)</u>	<u>\$ 9,291</u>

Table of Contents

(r) Restricted Cash

The Company's balance of restricted cash amounted to \$2.0 million and \$2.8 million at December 31, 2009 and June 30, 2010, respectively. Restricted cash is primarily comprised of investments held by the Company's Nonqualified Deferred Compensation Plan totaling \$1.8 million and \$2.4 million as of December 31, 2009 and June 30, 2010, respectively, which are included in other current assets and other non-current assets.

Table of Contents

(s) 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. The Company is currently evaluating the impact, if any, ASU 2010-17 will have 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.

(t) 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 June 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 six months ended

Table of Contents

June 30, 2010, the Company granted 3.1 million options with a weighted average option value of \$11.15 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 six months ended June 30, 2009 and 2010, respectively, are as follows:

<u>Stock Option Valuation Assumptions</u>	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2009</u>	<u>2010</u>	<u>2009</u>	<u>2010</u>
Weighted average fair value of common stock per share	\$ 14.34	\$ 21.46	\$ 14.20	\$ 21.37
Expected volatility	54%	52%	54%	52%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected life	6.1 years	6.1 years	6.0 – 6.1 years	6.2 years
Risk-free interest rate	2.0%	2.6%	1.9 – 2.0%	2.7%

<u>Employee Stock Purchase Plan Valuation Assumptions</u>	<u>Six Months Ended June 30,</u>	
	<u>2009</u>	<u>2010</u>
Fair value of common stock on grant date	\$ 13.69	\$ 22.76
Expected volatility	55%	52%
Dividend yield	0.0%	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 six months ended June 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 months ended June 30, 2010 was insignificant and was approximately \$0.1 million for the six months ended June 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 six months ended June 30, 2009 and 2010, respectively, was as follows (in thousands):

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30,</u>	<u>June 30,</u>	<u>June 30,</u>	<u>June 30,</u>
	<u>2009</u>	<u>2010</u>	<u>2009</u>	<u>2010</u>
Cost of sales	\$ 1,423	\$ 781	\$ 1,987	\$ 1,809
Research and development expense	2,605	3,442	5,080	6,623
Selling, general and administrative expense	4,986	4,943	9,743	9,279
Total stock-based compensation expense	\$ 9,014	\$ 9,166	\$16,810	\$17,711

There was no income tax benefit associated with stock-based compensation for the three and six months ended June 30, 2009 and 2010 because any deferred tax asset resulting from stock-based compensation was offset by additional valuation allowance.

Stock-based compensation of \$2.7 million and \$2.3 million was capitalized into inventory during the first six months of 2009 and 2010, respectively. Capitalized stock-based compensation is recognized into cost of sales when the related product is sold.

Table of Contents

(4) GOODWILL

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

Balance at December 31, 2009	\$23,722
Goodwill related to the acquisition of LEAD Therapeutics, Inc. (LEAD) (See Note 6)	<u>16,638</u>
Balance at June 30, 2010	<u>\$40,360</u>

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.

(5) 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) a probability adjusted contingency. As of June 30, 2010, the range of outcomes and assumptions used to develop these estimates have not changed. 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 (EMA) 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 - In Process Research & Development (IPR&D)	36,933
Other assets	<u>179</u>
Total identifiable assets	<u>\$37,595</u>
Accounts payable and accrued expenses	(387)
Deferred tax liability	<u>(2,460)</u>
Total liabilities assumed	<u>(2,847)</u>
Net identifiable assets acquired	\$34,748
Goodwill	<u>2,460</u>
Net assets acquired	<u>\$37,208</u>

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 7 for further discussion of the acquired intangible assets.

Table of Contents

(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) a probability adjusted contingency. As June 30, 2010, the range of outcomes and assumptions used to develop these estimates have not changed (see Note 14 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	<u>\$ 45,130</u>
Accounts payable and accrued expenses	(891)
Deferred tax liability	(13,981)
Valuation allowance for acquired deferred tax assets	(7,788)
Total liabilities assumed	<u>\$(22,660)</u>
Net identifiable assets acquired	22,470
Goodwill	16,638
Net assets acquired	<u>\$ 39,108</u>

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 7 for further discussion of the acquired intangible assets.

Table of Contents

(7) INTANGIBLE ASSETS

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

	December 31, 2009	June 30, 2010
Intangible assets:		
Finite-lived intangible assets	\$ 5,016	\$37,241
Indefinite-lived intangible assets	36,933	42,799
Gross intangible assets:	41,949	80,040
Less: Accumulated amortization	(972)	(2,055)
Net carrying value	<u>\$ 40,977</u>	<u>\$77,985</u>

Finite-Lived Intangible Assets

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

	Net Balance at June 30, 2010	Remaining Life	Annual Amortization
EU marketing rights for Firdapse	\$ 31,443	9.8 years	\$ 3,223
License payment for Kuvan FDA Approval	1,480	4.5 years	332
License payment for Kuvan EMEA Approval	2,263	8.5 years	269
Total	<u>\$ 35,186</u>		<u>\$ 3,824</u>

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 June 30, 2010, Kuvan intangible assets totaled a gross value of \$5.0 million. In each of the second quarters and first six months of 2009 and 2010, the Company recognized amortization expense related to the Kuvan intangible assets of \$0.2 million and \$0.3 million, respectively, as a component of cost of sales in the consolidated statements of operations.

Table of Contents

Indefinite-Lived Intangible Assets

A substantial portion of the assets acquired in the Huxley and LEAD 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 June 30, 2010, respectively, were as follows (in thousands):

	December 31,	June 30,
	2009	2010
In-Process Research and Development		
EU marketing rights for Firdapse	\$ 30,223	\$ 0
U.S. marketing rights for Firdapse	6,710	6,710
BMN-673 compound acquired through LEAD	0	35,150
Other pre-clinical compounds acquired through LEAD	0	939
Net carrying value	<u>\$ 36,933</u>	<u>\$42,799</u>

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.

(8) 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,			Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
	2010	2011	2012			
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	<u>\$132,440</u>	<u>\$131,292</u>	<u>\$38,096</u>	<u>\$301,828</u>	<u>\$ 1,527</u>	<u>\$303,355</u>

Table of Contents

At June 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,			Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
	2010	2011	2012			
Certificates of deposit	\$ 22,165	\$ 28,183	\$ 3,131	\$ 53,479	\$ (37)	\$ 53,442
Corporate securities	70,828	77,910	40,359	189,097	450	189,547
Commercial paper	20,219	0	0	20,219	(6)	20,213
Equity securities	204	0	0	204	163	367
U.S. Government agency securities	6,407	57,568	12,019	75,994	65	76,059
Total	<u>\$119,823</u>	<u>\$163,661</u>	<u>\$55,509</u>	<u>\$338,993</u>	<u>\$ 635</u>	<u>\$339,628</u>

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of June 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	<u>\$ 41,334</u>	<u>\$ (72)</u>	<u>\$ 79,856</u>	<u>\$ (348)</u>	<u>\$121,190</u>	<u>\$ (420)</u>

At June 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 June 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	\$ 25,668	\$ (38)	\$ 7,123	\$ (27)	\$ 32,791	\$ (65)
Corporate securities	39,532	(143)	9,651	(43)	49,183	(186)
Commercial paper	12,469	(11)	0	0	12,469	(11)
U.S. Government agency securities	0	0	32,034	(57)	32,034	(57)
Total	<u>\$ 77,669</u>	<u>\$ (192)</u>	<u>\$ 48,808</u>	<u>\$ (127)</u>	<u>\$126,477</u>	<u>\$ (319)</u>

Table of Contents

(9) SUPPLEMENTAL BALANCE SHEET INFORMATION

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

	December 31, 2009	June 30, 2010
Raw materials	\$ 7,692	\$ 8,002
Work in process	40,416	37,674
Finished goods	30,554	38,102
Total inventory	<u>\$ 78,662</u>	<u>\$83,778</u>

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

	December 31, 2009	June 30, 2010
Non-trade receivables	\$ 7,083	\$ 6,093
Prepaid expenses	5,202	6,496
Deferred cost of sales	2,232	1,354
Foreign currency forward contracts	83	8,262
Other	248	570
Total other current assets	<u>\$ 14,848</u>	<u>\$22,775</u>

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

	December 31, 2009	June 30, 2010
Accounts payable	\$ 7,567	\$ 9,708
Accrued accounts payable	28,353	23,481
Accrued vacation	4,652	5,625
Accrued compensation	14,544	12,596
Accrued interest and taxes	2,859	2,768
Accrued royalties	4,740	5,013
Other accrued expenses	1,525	1,849
Accrued rebates	4,786	5,094
Short-term portion of contingent acquisition consideration payable	8,124	16,576
Other	918	1,220
Total accounts payable and accrued liabilities	<u>\$ 78,068</u>	<u>\$83,930</u>

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

	December 31, 2009	June 30, 2010
Long-term portion of deferred rent	\$ 983	\$ 948
Long-term portion of capital lease liability	85	0
Long-term portion of contingent acquisition consideration payable	13,089	20,046
Long-term portion of deferred compensation liability	3,124	4,106
Deferred tax liabilities	2,460	16,441
Total other long-term liabilities	<u>\$ 19,741</u>	<u>\$41,541</u>

Table of Contents

(10) PROPERTY, PLANT AND EQUIPMENT

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

Category	December 31,		Estimated Useful Lives
	2009	June 30, 2010	
Leasehold improvements			Shorter of life of asset or
	\$ 38,059	\$ 38,802	lease term
Building and improvements	69,564	74,573	20 years
Manufacturing and laboratory equipment	34,228	41,008	5 years
Computer hardware and software	28,695	33,197	3 to 5 years
Office furniture and equipment	5,529	5,906	5 years
Land	10,056	10,056	Not applicable
Construction-in-progress	74,914	81,070	Not applicable
Total property, plant and equipment, gross	\$ 261,045	\$284,612	
Less: Accumulated depreciation	(61,904)	(71,992)	
Total property, plant and equipment, net	<u>\$ 199,141</u>	<u>\$212,620</u>	

Depreciation expense for three and six months ended June 30, 2010 was \$5.2 million and \$10.1 million, respectively, of which \$1.5 million and \$3.0 million was capitalized into inventory, respectively. Depreciation expense for the three and six months ended June 30, 2009 was \$4.5 million and \$8.6 million, respectively, of which \$0.7 million and \$1.3 million was capitalized into inventory, respectively.

Capitalized interest related to the Company's property, plant and equipment purchases for the three and six months ended June 30, 2010 was \$0.3 million and \$0.7 million, respectively, compared to the three and six months ended June 30, 2009 when capitalized interest totaled \$0.1 million and \$0.2 million, respectively.

(11) INVESTMENT IN SUMMIT CORPORATION PLC

In July 2008, the Company entered into an exclusive worldwide licensing agreement with Summit Corporation plc (Summit) related to Summit's preclinical drug candidate SMT C1100 and follow-on molecules (2008 Summit License), which are being developed for the treatment of Duchenne muscular dystrophy. The Company paid Summit \$7.1 million for an equity investment in Summit shares and licensing rights to SMT C1100. The initial equity investment represented the acquisition of approximately 5.1 million Summit shares with a fair value at the time of acquisition of \$5.7 million, based on public market quotes. The Company's investment in Summit represents less than 10% of Summit's outstanding shares.

In March 2009, the Company entered into an asset purchase agreement with Summit. Pursuant to the terms of the asset purchase agreement, the Company purchased certain of Summit's assets which included the rights, title to and interest in Summit's preclinical drug candidate SMT C1100, thus terminating the 2008 Summit License. These assets were acquired by issuing a secured promissory note and assuming \$56,000 in related liabilities. The promissory note is secured by all of the assets acquired from Summit. The value of the assumed liabilities was expensed in the first quarter of 2009, as the asset acquired does not have an alternative use. Under the secured promissory note, the Company is obligated to make up to \$50.0 million in future development and regulatory milestone payments contingent on achieving certain development and regulatory milestones, as well as tiered royalties based on future net sales.

The Company accounts for the Summit shares, which are traded on the London Stock Exchange, as an available-for-sale investment, 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 are reported in earnings in the period in which the impairment occurs.

As of June 30, 2010, the Company has recognized cumulative impairment charges of \$5.5 million for the decline in the investment's value determined to be other-than-temporary. The impairment charges are comprised of \$4.1 million and \$1.4 million recognized in December 2008 and March 2009, respectively. The determination that the decline was other-than-temporary is, in part, subjective and influenced by several factors, including: the length of time and the extent to which the market value had been less than the value on the date of purchase, Summit's financial condition and near-term prospects, including any events that 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.

Table of Contents

(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 26, 2009, the Company terminated its licensing agreement with La Jolla, 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. There is not a call provision included 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 six months ended June 30, 2009 and 2010, the Company recognized amortization of expense of \$0.2 million and \$0.4 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. There is not a call provision included 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.

Table of Contents

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 \$0.4 million, in each of the three and six months ended June 30, 2009 and 2010, respectively. Interest expense on the convertible debt for each of the three and six months ended June 30, 2009 and 2010 was \$2.6 million and \$5.2 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 as described in Note 15, taking into consideration current interest rates and 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.

At June 30, 2010, the Company had 70 foreign currency forward contracts outstanding to sell a total of 73.0 million Euros with expiration dates ranging from July 30, 2010 through December 31, 2011. 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 June 30, 2010, the Company had two outstanding foreign currency contracts to sell 15.4 million Euros and 1.6 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 December 31, 2011. Over the next twelve months, the Company expects to reclassify \$8.2 million from accumulated other comprehensive income to earnings as related forecasted revenue transactions occur.

Table of Contents

At December 31, 2009 and June 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 June 30, 2010		Liability Derivatives June 30, 2010	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments				
Foreign currency forward contracts	Other current assets	\$ 8,173	Other current liabilities	\$ 0
Foreign currency forward contracts	Other assets	1,274	Other liabilities	0
Total		\$ 9,447		\$ 0
Derivatives not designated as hedging instruments				
Foreign currency forward contracts	Other current assets	\$ 88	Other current liabilities	\$ 0
Total		\$ 88		\$ 0
Total derivative contracts		\$ 9,535		\$ 0

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

	Foreign Currency Forward Contracts Three Months Ended June 30,		Foreign Currency Forward Contracts Six Months Ended June 30,	
	2009	2010	2009	2010
Derivatives Designated as Hedging Instruments				
Net gain (loss) recognized in OCI (1)	\$ (2,903)	\$ 6,178	\$ 927	\$ 10,236
Net gain (loss) reclassified from accumulated OCI into income (2)	761	1,835	1,945	2,109
Net gain (loss) recognized in income (3)	(54)	234	(263)	320
Derivatives Not Designated as Hedging Instruments				
Net gain (loss) recognized in income (4)	\$ (2,179)	\$ 1,946	\$ (1,073)	\$ 3,263

(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 June 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 gain of \$9.5 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.

Table of Contents

(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 June 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	<u>\$167,171</u>	<u>\$ 18,761</u>	<u>\$ 148,410</u>	<u>\$ 0</u>
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	<u>\$303,355</u>	<u>\$ 1,361</u>	<u>\$ 301,994</u>	<u>\$ 0</u>
Deferred compensation asset (4)	\$ 1,791	\$ 0	\$ 1,791	\$ 0
Foreign currency derivatives (5)	83	0	83	0
Total	<u>\$472,400</u>	<u>\$ 20,122</u>	<u>\$ 452,278</u>	<u>\$ 0</u>
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	<u>\$ 25,513</u>	<u>\$ 1,714</u>	<u>\$ 2,586</u>	<u>\$ 21,213</u>

Table of Contents

	Fair Value Measurements at June 30, 2010			
		Quoted Price in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
	Total	(Level 1)	(Level 2)	(Level 3)
Assets:				
Cash and cash equivalents				
Overnight deposits	\$ 23,145	\$ 23,145	\$ 0	\$ 0
Money market instruments	92,634	0	92,634	0
Total cash and cash equivalents	<u>\$115,779</u>	<u>\$ 23,145</u>	<u>\$ 92,634</u>	<u>\$ 0</u>
Available-for-sale securities				
Certificates of deposit (1)	\$ 53,442	\$ 0	\$ 53,442	\$ 0
Corporate securities (2)	189,547	0	189,547	0
Commercial paper (2)	20,213	0	20,213	0
Equity securities (3)	367	0	367	0
Government agency securities (2)	76,059	0	76,059	0
Total available-for-sale securities	<u>\$339,628</u>	<u>\$ 0</u>	<u>\$ 339,628</u>	<u>\$ 0</u>
Deferred compensation asset (4)	\$ 2,394	\$ 0	\$ 2,394	\$ 0
Foreign currency derivatives (5)	9,535	0	9,535	0
Total	<u>\$467,336</u>	<u>\$ 23,145</u>	<u>\$ 444,191</u>	<u>\$ 0</u>
Liabilities:				
Deferred compensation liability (6)	\$ 4,708	\$ 2,313	\$ 2,395	\$ 0
Contingent acquisition consideration payable (8)	36,622	0	0	36,622
Total	<u>\$ 41,330</u>	<u>\$ 2,313</u>	<u>\$ 2,395</u>	<u>\$ 36,622</u>

- (1) At December 31, 2009 and June 30, 2010, 62% and 75% 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 June 30, 2010, 33% of corporate securities and 54% 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 June 30, 2010, 22% and 100%, respectively, are included in long-term investments and the remaining balances are included in short-term investments.
- (4) At December 31, 2009 and June 30, 2010, 95% and 87%, 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 June 30, 2010, foreign currency derivatives included forward foreign exchange contracts for the Euro and British Pound of which 87% are included in other current assets and 13% are included in other assets.
- (6) At December 31, 2009 and June 30, 2010, 89% and 87%, 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) These amounts are included in accounts payable and accrued liabilities on the Company's consolidated balance sheet.
- (8) At December 31, 2009 and June 30, 2010, 62% and 55% of these amounts are included in other long-term liabilities, respectively, and 38% and 45% are included in accrued expenses, respectively. See Notes 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 8 for further information regarding the fair value of the Company's financial instruments.

Table of Contents

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 six months ended June 30, 2010, the fair value of the contingent acquisition consideration payable increased by \$0.8 million and \$1.5 million, respectively. The following table represents the changes in the Company's level 3 liabilities for the quarter ended June 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	<u>\$ 36,622</u>

As discussed in Notes 6 and 7, the Company acquired intangible assets as a result of Huxley and LEAD 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 six months ended June 30, 2009 and 2010.

Region:	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2010	2009	2010
United States	54%	53%	53%	52%
Europe	25%	26%	25%	24%
Latin America	10%	10%	11%	11%
Rest of World	11%	11%	11%	13%
Total Net Product Revenue	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>

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 six months ended June 30, 2009 and 2010.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2010	2009	2010
Customer A	20%	19%	19%	18%
Customer B	27%	19%	25%	18%
Customer C	8%	8%	9%	10%
Total	<u>55%</u>	<u>46%</u>	<u>53%</u>	<u>46%</u>

The accounts receivable balances at December 31, 2009 and June 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 45% and 18% of the June 30, 2010 accounts receivable balance,

Table of Contents

compared to December 31, 2009 when the two largest customers accounted for 49% and 18% of the accounts receivable balance. 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.

See Note 2(f) above for additional discussion.

Table of Contents

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 second quarter and first six months of 2010 were \$47.3 million and \$95.9 million, respectively, compared to \$42.9 million and \$82.3 million in the second quarter and first six 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 second quarter and first six months of 2010 were \$17.5 million and \$31.7 million, respectively, compared to \$21.6 million and \$38.7 million in the second quarters and first six 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 second quarter and first six months of 2010 totaled \$24.7 million and \$45.9 million, respectively, compared to \$17.0 million and \$32.5 million in the second quarter and first six 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 second quarter and first six months of 2010 were \$1.1 million and \$1.2 million, respectively. We also continue to develop Firdapse for the possible treatment of LEMS in the U.S.

Table of Contents

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), PEG-PAL, an enzyme substitution therapy for the treatment of phenylketonurics (PKU) for patients who do not respond well to Kuvan. 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. In the first six 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 January 2011. In January 2010, we initiated a Phase 1 clinical trial of our small molecule for the treatment of Duchenne muscular dystrophy. Due to pharmaceutical and pharmacokinetic challenges, we have decided not to pursue further development of the small molecule for the treatment of Duchenne muscular dystrophy.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2010	2009	2010
Total net product revenues	\$ 81.5	\$ 90.6	\$153.4	\$174.7
Cost of sales	19.8	14.4	34.2	31.8
Research and development expense	26.3	35.6	60.7	65.7
Selling, general and administrative expense	30.5	37.3	59.1	71.3
Net income (loss)	1.3	(0.5)	(11.8)	0.7
Stock-based compensation expense	9.0	9.2	16.8	17.7

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 \$455.4 million as of June 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 policies have not differed materially from actual results.

Except for our critical accounting policy for the valuation of our contingent acquisition consideration payable noted below, there have been no significant changes in our critical accounting policies and estimates during the six months ended June 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

Table of Contents

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.

Recent Accounting Pronouncements

See Note 2(s) 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 loss for the second quarter of 2010 was \$0.5 million and our net income for the six months ended June 30, 2010 was \$0.7 million, respectively, compared to net income of \$1.3 million and net loss of \$11.8 million for the three and six months ended June 30, 2009, respectively with the change primarily a result of the following (in millions):

	Three Months Ended	Six Months Ended
	June 30,	June 30,
Net income (loss) for the period ended June 30, 2009	\$ 1.3	\$ (11.8)
Increased Naglazyme gross profit	4.6	12.7
Increased Kuvan gross profit	6.7	11.4
Decreased impairment loss on equity investments	0	5.8
Decreased interest expense	1.8	3.4
Increased selling, general and administrative expense	(6.8)	(12.2)
Increased research and development expense	(9.3)	(5.1)
Increased (Decreased) Aldurazyme gross profit	2.3	(1.3)
Increased Firdapse gross profit	0.9	0.9
Decreased collaborative revenues	(0.7)	(1.0)
Increased (Decreased) Orapred royalty revenue	0.7	(0.2)
Decreased gain on the sale of equity investments	(1.6)	(0.7)
Other individually insignificant fluctuations	(0.4)	(1.2)
Net income (loss) for the period ended June 30, 2010	<u>\$ (0.5)</u>	<u>\$ 0.7</u>

The increase in Naglazyme gross profit in the second quarter and first six months of 2010 as compared to the same periods in 2009 is primarily a result of additional patients initiating therapy outside the U.S. The increase in Kuvan gross profit in the second quarter and first six 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 selling, general and administrative expense in the second quarter and first six 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 research and development expense is primarily attributed to increased development expenses for our PEG-PAL, LEMS and PARP programs. The decrease in Aldurazyme gross profit in 2010 as compared to 2009 is primarily attributed to fewer shipments of Aldurazyme to Genzyme than Genzyme's shipments to third parties resulting in lower royalties payable to us. The increase in Aldurazyme gross margins in the second quarter of 2010 as compared to the second quarter of 2009 is attributed to the sell through of the previously expensed Aldurazyme lot which was written-off during the first quarter of 2010 and sold to Genzyme during the second quarter of 2010. See below for additional information related to the primary net income/loss fluctuations presented above, including details of our operating expense fluctuations.

Table of Contents

Net Product Revenues, Cost of Sales and Gross Profit

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2010	Change	2009	2010	Change
Naglazyme	\$ 42.9	\$ 47.3	\$ 4.4	\$ 82.2	\$ 95.9	\$ 13.7
Kuvan	17.0	24.7	7.7	32.5	45.9	13.4
Aldurazyme	21.6	17.5	(4.1)	38.7	31.7	(7.0)
Firdapse	0	1.1	1.1	0	1.2	1.2
Total Net Product Revenues	<u>\$ 81.5</u>	<u>\$ 90.6</u>	<u>\$ 9.1</u>	<u>\$153.4</u>	<u>\$174.7</u>	<u>\$ 21.3</u>

Net product revenues for Naglazyme in the second quarter and first six months of 2010 totaled \$47.3 million and \$95.9 million, respectively, of which \$40.8 million and \$82.0 million, respectively was earned from customers based outside the U.S. The negative impact of foreign currency exchange rates on Naglazyme sales denominated in currencies other than the U.S. dollar was approximately \$1.4 million and \$1.5 million in the second quarter and first six months of 2010. Gross profit from Naglazyme sales in the second quarter and first six months of 2010 was \$38.8 million and \$78.1 million, respectively, representing gross margins of 82% and 81%, respectively. Gross profits from Naglazyme sales in the second quarter and first six months of 2009 were \$34.1 million and \$65.5 million, respectively, representing gross margins of approximately 79% and 80%, respectively. The slight increase in gross margins during the second quarter and first six months of 2010 as compared to the second quarter and first six months of 2009 is primarily due to the impact of improved manufacturing yields.

Net product revenue for Kuvan during the second quarter and first six months of 2010 was \$24.7 million and \$45.9 million, respectively, compared to \$17.0 million and \$32.5 million during the second quarter and first six months of 2009. With the commercial launch of Kuvan in the EU during the first six months of 2009, we began receiving a royalty of approximately 4% on net sales of Kuvan from Merck Serono. During the second quarter and first six months of 2010, we earned \$0.2 million and \$0.4 million in royalties from Merck Serono on net sales of \$5.8 million and \$10.6 million, respectively. Royalties earned from Merck Serono during both the second quarter and first six months of 2009 were insignificant. Gross profit from Kuvan in the second quarter and first six months of 2010 was approximately \$20.4 million and \$38.1 million, respectively, representing gross margins of approximately 83% in both periods, compared to the second quarter and first six months of 2009 when gross profit totaled \$13.7 million and \$26.7 million, respectively, representing gross margins of approximately 81% and 82%, respectively. All periods reflect royalties paid to third parties of 11%. In accordance with our inventory accounting policy, we began capitalizing Kuvan inventory production costs after U.S. regulatory approval was obtained in December 2007. We expect U.S. gross margins for Kuvan for the foreseeable future to be in the lower 80% range as the pre-approval inventory has been mostly depleted.

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 eventually be deducted from the calculated royalty rate when the product is sold by Genzyme.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2010	Change	2009	2010	Change
Aldurazyme revenue reported by Genzyme	\$ 39.2	\$ 43.7	\$ 4.5	\$ 76.0	\$ 83.5	\$ 7.5
Royalties due from Genzyme	15.5	17.7	2.2	30.0	33.7	3.7
Incremental (previously recognized) Aldurazyme product transfer revenue	6.1	(0.2)	(6.3)	8.7	(2.0)	(10.7)
Total Aldurazyme net product revenues	<u>\$ 21.6</u>	<u>\$ 17.5</u>	<u>\$ (4.1)</u>	<u>\$ 38.7</u>	<u>\$ 31.7</u>	<u>\$ 7.0</u>
Gross profit	<u>\$ 13.9</u>	<u>\$ 16.1</u>	<u>\$ 2.2</u>	<u>\$ 27.0</u>	<u>\$ 25.7</u>	<u>\$ (1.3)</u>

Table of Contents

In the second quarter and first six months of 2010, Aldurazyme gross margins were 92% and 81%, respectively, compared to 64% and 70% in the second quarter and first six 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 first quarter of 2010 we recognized a \$2.1 million write-off of an outdated registration lot of Aldurazyme as a result of delays in the qualification of a new third-party fill-finish provider. During the second quarter of 2010, we recognized product transfer revenue related to this Aldurazyme lot, which had no corresponding cost of goods sold due to the write-off of the lot in the first quarter of 2010. In the second quarter of 2010, Aldurazyme net product revenues were primarily comprised of royalty revenues, compared to the same period in 2009, when the revenue mix was 72% royalty revenues and 28% 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 second quarter and first six months of 2010 was \$14.4 million and \$31.8 million, respectively, compared to \$19.8 million and \$34.2 million in the second quarter and first six months of 2009, respectively. The decrease in cost of sales in the second quarter of 2010 compared to the second quarter of 2009 is attributed to improved manufacturing yields for Naglazyme and the \$2.1 million Aldurazyme write-off during the first quarter of 2010 discussed above. The increase in cost of sales in the first half of 2010 compared to the same periods in 2009 is primarily attributed to the increase in Naglazyme, Kuvan product sales and Aldurazyme product transfer revenues.

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 second quarter and first six months of 2010 were \$0.2 million and \$0.4 million, respectively, compared to \$0.9 million and \$1.4 million, 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 six months ended June 30, 2009 and 2010 (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2010	Change	2009	2010	Change
Orapred product royalties	\$ 0.2	\$ 0.9	\$ 0.7	\$ 1.6	\$ 1.4	\$ (0.2)
6R-BH4 royalty revenues	0.2	0.3	0.1	0.4	0.5	0.1
Total	<u>\$ 0.4</u>	<u>\$ 1.2</u>	<u>\$ 0.8</u>	<u>\$ 2.0</u>	<u>\$ 1.9</u>	<u>\$ (0.1)</u>

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.

Table of Contents

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 \$9.3 million and \$5.0 million, to \$35.6 million and \$65.7 million during the second quarter and first six months of 2010, respectively, from \$26.3 million and \$60.7 million in the second quarter and first six months of 2009, respectively. The change in research and development expense for the three and six months ended June 30, 2010 was primarily a result of the following (in millions):

	Three Months Ended	Six Months Ended
	June 30,	June 30,
Research and development expense for period ended June 30, 2009	\$ 26.3	\$ 60.7
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	(1.5)	(3.4)
Increased PEG-PAL development expenses	1.3	3.4
Increased PARP & non-PARP development expenses	3.1	3.9
Decreased Prodrug development expenses	(0.9)	(1.8)
Increased GALNS for Morquio Syndrome Type A development expense	2.8	2.6
Increased stock-based compensation expense	0.8	1.6
Increased development expenses related to commercial products	1.5	2.1
Increased (Decreased) Duchenne muscular dystrophy program development expense	(0.3)	1.1
Increased research and development expenses on early development stage programs	0.8	1.4
Increase in non-allocated research and development expenses and other net changes	1.7	2.9
Research and development expense for the period ended June 30, 2010	<u>\$ 35.6</u>	<u>\$ 65.7</u>

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 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 PEG-PAL development expense is attributed to increased clinical trial activities related to the product candidate. The increase in Duchenne muscular dystrophy program development expense for the first six months of 2010 is primarily attributed to increased pre-clinical and Phase 1 clinical trial activities related to the product candidate. 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 half of 2010 compared to the same period in 2009. 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 research and development expenses related to commercial products is primarily attributed to long-term Kuvan clinical activities related to post-approval regulatory commitments. 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.

Table of Contents

Selling, general and administrative expenses increased by \$6.8 million and \$12.2 million to \$37.3 million and \$71.3 million for the second quarter and first six months of 2010, respectively, from \$30.5 million and \$59.1 million for the second quarter and first six months of 2009, respectively. The components of the change for the three and six months ended June 30, 2010 primarily include the following (in millions):

	Three Months Ended	Six Months Ended
	June 30,	June 30,
Selling, general and administrative expense for the period ended June 30, 2009	\$ 30.5	\$ 59.1
Increased Naglazyme sales and marketing expenses	2.3	3.3
Increased Firdapse commercial preparation expenses	1.2	2.3
Increased (Decreased) Kuvan commercialization expenses	0.6	(0.4)
Decreased stock-based compensation expense	(0.1)	(0.5)
Increased depreciation expense	0.3	0.7
Increased foreign exchange losses on un-hedged transactions	0.2	0.5
Net increase in corporate overhead and other administrative expenses	2.3	6.3
Selling, general and administrative expense for the period ended June 30, 2010	<u>\$ 37.3</u>	<u>\$ 71.3</u>

The increase in Naglazyme sales and marketing expenses in the second quarter and first six 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. The increase in corporate overhead and other administrative costs during the second quarter and first six months of 2010 is primarily comprised of increased employee related costs, legal costs and facility costs. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme, the European commercialization activities for Firdapse and the U.S. commercialization activities for Kuvan.

Intangible Asset Amortization and Contingent Consideration Expense

Intangible asset amortization and contingent consideration expense for the second quarter and first six months of 2010 was \$1.6 million and \$2.2 million, respectively, compared to \$1.8 million and \$2.9 million in the second quarter and first six months of 2009, respectively. The following table details the components of intangible asset amortization and contingent consideration expense for the second quarters and first six months of 2009 and 2010 (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2010	2009	2010
Amortization of Orapred intangible assets	\$ 1.8	\$ 0	\$ 2.9	\$ 0
Amortization of Firdapse European marketing rights	0	0.8	0	0.8
Change in the fair value of the contingent consideration payable to the former stockholders of Huxley Pharmaceuticals	0	0.6	0	1.2
Change in the fair value of the contingent consideration payable to the former stockholders of LEAD	0	0.2	0	0.2
Total	<u>\$ 1.8</u>	<u>\$ 1.6</u>	<u>\$ 2.9</u>	<u>\$ 2.2</u>

Intangible asset amortization and contingent consideration expense during the second quarter of 2010 was comprised of the change in fair value of the contingent consideration payable to the former stockholders of Huxley Pharmaceuticals, Inc. and LEAD Therapeutics (See Note 15 of the accompanying unaudited consolidated financial statements for additional discussion) and the amortization of the European marketing rights for Firdapse. Amortization of intangible assets for the first quarter of 2009 included three months of amortization expense related to the intangible assets acquired in the Ascent Pediatrics transaction in May 2004, including the Orapred developed and core technology. In June 2009, we completed the purchase of all of the outstanding shares of capital stock of BioMarin Pediatrics II (formerly known as Ascent Pediatrics, Inc. and Medicis Pediatrics, Inc.), a wholly-owned subsidiary of Medicis Pharmaceutical Corporation (Medicis) as required by the original transaction agreement of 2004 for \$70.6 million. Medicis' sole substantive asset was the intellectual property related to the Orapred franchise. Subsequently, we transferred the exclusive intellectual property rights to our sublicense in July 2009.

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.

Table of Contents

Equity in the loss of the joint venture totaled \$0.9 million and \$1.6 million, respectively, for the second quarter and first six months of 2010, compared to \$0.5 million and \$1.1 million for the second quarter and first six 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 \$2.2 million in the second quarter and first six months of 2010, respectively, compared to \$0.9 million and \$3.0 million in the second quarter and first six months of 2009, respectively. The reduced interest yield during the second quarter and first six 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 second quarter and first six months of 2010 was \$2.6 million and \$5.1 million, respectively, compared to \$4.4 million and \$8.5 million in the second quarter and first six months of 2009, respectively. Interest expense in the second quarter and first six months of 2009 included imputed interest of \$1.5 million and \$2.6 million, respectively. Imputed interest will not be incurred in periods subsequent to June 2009 as the Medicis obligation was paid in full in June 2009.

Changes in Financial Position

June 30, 2010 Compared to December 31, 2009

From December 31, 2009 to June 30, 2010, our cash, cash equivalents and short-term and long-term investments decreased by \$15.1 million, primarily as a result the acquisition of LEAD Therapeutics, Inc., milestone payments 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 \$4.1 million due to increased sales of Naglazyme and Kuvan and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. Our net property, plant and equipment increased by approximately \$13.5 million from December 31, 2009 to June 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 \$37.0 million, \$16.6 million and \$21.8 million, respectively, primarily as a result of the LEAD acquisition. Due to several ongoing facility improvement projects substantially completed in 2009, we expect depreciation expense to increase as the assets are placed into service.

Liquidity and Capital Resources

Cash and Cash Flow

As of June 30, 2010, our combined cash, cash equivalents, short-term and long-term investments totaled \$455.4 million, a decrease of \$15.1 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 six months of 2010 was \$15.1 million, which was \$61.0 million less than the net decrease in the first six months of 2009 of \$76.1 million. The primary items contributing to the decrease in net cash outflow in the first six 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)
Acquisition of LEAD Therapeutics, Inc.	(14.1)
Milestone payments to the former stockholders of Huxley Pharmaceuticals, Inc.	(6.5)
Increased proceeds from ESPP and stock option exercises	10.4
Absence of investment in La Jolla Pharmaceuticals, Inc.	6.3
Decreased capital asset purchases	11.3
Increased investments in BioMarin/Genzyme LLC	(0.8)
Net increase in cash provided by operating activities, including net payments for working capital, and other	10.8
Total increase in net cash outflow	<u>\$ 61.0</u>

Table of Contents

The net decrease in operating spend includes increases in cash receipts from net revenues, partially offset by increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, 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 six months of 2010 primarily includes increased inventory build of \$5.4 million, increased accounts receivable build of \$14.1 million and decreased other current assets build of \$30.6 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 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, 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.

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.

Table of Contents

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 second quarter and first six 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 June 30,		Six Months Ended June 30,		Since Program
	2009	2010	2009	2010	Inception
Naglazyme	\$ 2.8	\$ 1.9	\$ 5.1	\$ 4.1	\$ 136.5
Kuvan	3.2	3.5	5.8	6.5	107.8
GALNS for Morquio Syndrome Type A	3.8	6.6	7.9	10.5	44.6
6R-BH4 for indications other than PKU	1.4	0	3.6	0.2	46.7
PEG-PAL	2.4	3.7	4.7	8.1	50.5
Not allocated to specific major current projects	12.7	19.9	33.6	36.3	288.0
	<u>\$ 26.3</u>	<u>\$ 35.6</u>	<u>\$ 60.7</u>	<u>\$ 65.7</u>	<u>\$ 674.1</u>

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;

Table of Contents

- 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 debt 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. There is a no call provision included 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 June 30, 2010 is presented in the table below (in thousands).

	Payments Due by Period					Total
	2010	2011	2012 -2013	2014-2015	2016 and Thereafter	
Convertible debt and related interest	\$ 5,200	\$10,401	\$190,853	\$12,183	\$334,012	\$552,649
Operating leases	2,172	4,037	6,495	2,238	4,548	19,490
Research and development and purchase commitments	33,993	8,872	6,504	3,766	4,369	57,504
Total	<u>\$41,365</u>	<u>\$23,310</u>	<u>\$203,852</u>	<u>\$18,187</u>	<u>\$342,929</u>	<u>\$629,643</u>

We are also subject to contingent payments related to various development activities totaling approximately \$250.1 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 June 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.

Table of Contents

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 June 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 quarter ended March 31, 2010, which was filed with the SEC on May 3, 2010.

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#	First Amendment to Stock Purchase Agreement executed on April 1, 2010, that amends that certain Stock Purchase Agreement, dated as of October 20, 2009 by and among BioMarin Pharmaceutical Inc. and Huxley Pharmaceuticals, Inc. and the stockholders of Huxley.
10.2*	Amended and Restated BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan (1)
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

Table of Contents

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

Confidential treatment registered for a portion of this document. Omitted parts have been filed separately with the SEC.

* Indicates management contract or compensatory plan.

(1) Incorporated by reference to Appendix A of the Company's Definitive Proxy Statement on Schedule 14A, as filed with the Securities and Exchange Commission on March 26, 2010.

** Furnished herewith and not "filed" for purposes of Section 18 of the SEC 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.

CONFIDENTIAL TREATMENT REQUESTED

Redacted portions are indicated by [**].**

**Redacted portions filed separately with
Confidential Treatment Application.**

**FIRST AMENDMENT TO
STOCK PURCHASE AGREEMENT**

THIS FIRST AMENDMENT TO STOCK PURCHASE AGREEMENT (this “Amendment”) is effective as of March 26, 2010 and amends that certain Stock Purchase Agreement, dated as of October 20, 2009 (the “Agreement”), by and among BioMarin Pharmaceutical Inc., a Delaware corporation (the “Purchaser”), Huxley Pharmaceuticals, Inc., a Delaware corporation (the “Company”), and the stockholders of the Company party thereto (collectively, the “Stockholders”).

RECITALS

A. WHEREAS, pursuant to the Agreement, the Stockholders sold, assigned, transferred and delivered to the Purchaser, and the Purchaser purchased and acquired from the Stockholders, all right, title and interest in and to all of the issued and outstanding shares of capital stock of the Company (the “Acquisition”);

B. WHEREAS, pursuant to Section 12.3 of the Agreement, the Agreement may not be amended, modified or supplemented except by written agreement between the Purchaser and the Stockholder Representative (as defined below); and

C. WHEREAS, the Purchaser and Aceras BioMedical, LLC, in its capacity as the Stockholder Representative (the “Stockholder Representative”), desire to modify the Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the foregoing, the parties hereto hereby agree as follows:

1. The following paragraph shall be added at end of Section 1.4(g) of the Agreement:

[****]

2. Section 1.4(h) of the Agreement shall be deleted in its entirety and replaced with the following new Section 1.4(h):

[****]

3. The paragraph at the end of Section 1.4 of the Agreement shall be deleted in its entirety and replaced with the following new paragraph:

[****]

[****] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

4. The following paragraph shall be added as new subsection (e) at the end of Section 10.5 of the Agreement:

“Notwithstanding anything to the contrary set forth herein, the Stockholders shall have no liability for, and the Purchaser Indemnified Parties shall have no right to indemnification with respect to, any claims, debts, liabilities, demands, obligations, guarantees, costs, expenses, fees, damages or causes of action arising out of, relating to or resulting from any claims that were or are asserted by EUSA and released by EUSA pursuant to Section 6 of that certain Settlement Agreement and General Release dated March 26, 2010, by and between Purchaser, the Company, the Stockholders Representative and EUSA, including, without limitation, any payments or obligations owed to EUSA or L’Assistance Publique – Hôpitaux de Paris’ pursuant to the License Agreement, as amended, including by that certain Second Amendment to Exclusive License and Sublicense Agreement between EUSA and the Company dated March 26, 2010.”

5. Exhibit 1.3 of the Agreement shall be deleted in its entirety and replaced with the exhibit attached hereto as Attachment 1.

6. Capitalized terms used in this Amendment but not otherwise defined herein shall have the meanings set forth in the Agreement.

7. Except as expressly set forth in this Amendment, all other terms of the Agreement shall remain in full force and effect and once this Amendment is executed by the parties hereto, all references in the Agreement to “the Agreement” or “this Agreement,” as applicable, shall refer to the Agreement, as modified by this Amendment.

8. This Amendment and the relationship of the parties hereto shall be construed in accordance with, and governed in all respects by, the internal laws of the State of New York (without giving effect to principles of conflicts of laws).

9. This Amendment will apply to, be binding in all respects upon and inure to the benefit of the successors and permitted assigns of the parties.

10. This Amendment may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument, and shall become effective when counterparts have been signed by each of the parties and delivered to the other parties; it being understood that all parties need not sign the same counterparts. The exchange of copies of this Amendment and of signature pages by facsimile transmission (whether directly from one facsimile device to another by means of a dial-up connection or whether mediated by the worldwide web), by electronic mail in “portable document format” (“.pdf”) form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, or by combination of such means, shall constitute effective execution and delivery of this Amendment as to the parties and may be used in lieu of the original Amendment for all purposes. Signatures of the parties transmitted by facsimile or other electronic means shall be deemed to be their original signatures for all purposes.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Amendment as of the date first above written.

PURCHASER:

BIOMARIN PHARMACEUTICAL INC.

By: /s/ G. Eric Davis

Name: G. Eric Davis

Title: SVP, General Counsel

STOCKHOLDER REPRESENTATIVE:

ACERAS BIOMEDICAL, LLC

On Behalf of Itself and for All Stockholders

By: /s/ John Liatos

Name: John Liatos

Title: Managing Member

Attachment 1

Exhibit 1.3

<u>Stockholder Name</u>	<u>Outstanding Shares</u>	<u>Closing Date</u>		<u>Earnout Percentage</u>	<u>Account Information</u>
		<u>Amount</u>	<u>Escrow</u>		
Aceras BioMedical, LLC	12,854,670	[****]	94.98%	92.5%	[****]
Richard Stewart	480,000 ¹	[****]	3.54%	5.25%	[****]
Anthony Clarke	200,000 ¹	[****]	1.48%	2.25%	[****]
TOTAL :	<u>13,534,670</u>	[****]	<u>100.00%</u>	<u>100.00%</u>	

¹ Assuming exercise of outstanding options prior to Closing.

[****] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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: August 4, 2010

/s/ JEAN-JACQUES BIENAIMÉ

Jean-Jacques Bienaimé
Chief Executive Officer

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: August 4, 2010

/s/ JEFFREY H. COOPER

Jeffrey H. Cooper

Senior Vice President, Chief Financial Officer

**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 June 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

August 4, 2010

/s/ JEFFREY H. COOPER

Jeffrey H. Cooper
Senior Vice President, Chief Financial Officer

August 4, 2010