

BIOMARIN PHARMACEUTICAL INC

Form 10-Q

May 03, 2007

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2007

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 issuer as specified in its charter)

Delaware
(State of other jurisdiction
of Incorporation or organization)

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

105 Digital Drive,

94949

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Novato, California
(Address of principal executive offices)

(Zip Code)

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

(Former name, former address and former fiscal year, if changed since last report)

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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 proceeding 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: 95,801,863 shares common stock, par value \$0.001, outstanding as of April 30, 2007.

Table of Contents

BIOMARIN PHARMACEUTICAL INC.

TABLE OF C ONTENTS

	Page
PART I. <u>FINANCIAL INFORMATION</u>	
Item 1. <u>Consolidated Financial Statements (Unaudited)</u>	3
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Operations</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3. <u>Quantitative and Qualitative Disclosure about Market Risk</u>	34
Item 4. <u>Controls and Procedures</u>	34
PART II. <u>OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	35
Item 1A. <u>Risk Factors</u>	35
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	35
Item 3. <u>Defaults Upon Senior Securities</u>	35
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	35
Item 5. <u>Other Information</u>	35
Item 6. <u>Exhibits</u>	35
<u>SIGNATURE</u>	37

Table of Contents**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, 2006 (1)	March 31, 2007 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 89,162	\$ 98,331
Short-term investments	199,685	174,976
Accounts receivable, net	14,670	14,525
Advances to BioMarin/Genzyme LLC	1,596	814
Inventory	25,075	27,438
Other current assets	4,036	4,561
Total current assets	334,224	320,645
Investment in BioMarin/Genzyme LLC	31,457	31,619
Property, plant and equipment, net	55,466	56,487
Acquired intangible assets, net	11,655	10,563
Goodwill	21,262	21,262
Restricted cash	1,731	2,617
Other assets	7,641	6,571
Total assets	\$ 463,436	\$ 449,764
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 32,166	\$ 24,889
Current portion of acquisition obligation, net of discount	6,787	6,786
Current portion of deferred revenue	7,092	7,154
Total current liabilities	46,045	38,829
Convertible debt	223,940	172,500
Long-term portion of acquisition obligation, net of discount	68,548	67,945
Deferred revenue, net of current portion	5,023	3,297
Other long-term liabilities	2,078	2,479
Total liabilities	345,634	285,050
Stockholders equity:		
Common stock, \$0.001 par value: 150,000,000 shares authorized; 91,725,528 and 95,607,422 shares issued and outstanding at December 31, 2006 and March 31, 2007, respectively	92	96
Additional paid-in capital	709,359	765,540
Accumulated other comprehensive loss	(25)	(5)

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Accumulated deficit	(591,624)	(600,917)
Total stockholders' equity	117,802	164,714
Total liabilities and stockholders' equity	\$ 463,436	\$ 449,764

(1) December 31, 2006 balances were derived from the audited consolidated financial statements.
See accompanying notes to unaudited consolidated financial statements.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****For the Three Months Ended, March 31, 2006 and 2007****(In thousands, except for per share data, unaudited)**

	Three Months Ended March 31,	
	2006	2007
Net product sales	\$ 8,979	\$ 18,334
Collaborative agreement revenues	4,514	4,147
Royalty and license revenues	319	357
 Total revenues	 13,812	 22,838
Operating expenses:		
Cost of sales (excludes amortization of developed product technology)	1,722	4,117
Research and development	12,279	18,159
Selling, general and administrative	10,893	16,284
Amortization of acquired intangible assets	373	1,093
 Total operating expenses	 25,267	 39,653
 Loss from operations	 (11,455)	 (16,815)
Equity in the income of BioMarin/Genzyme LLC	3,800	6,163
Interest income	699	3,694
Interest expense	(2,824)	(2,335)
 Net loss	 \$ (9,780)	 \$ (9,293)
 Net loss per share, basic and diluted	 \$ (0.13)	 \$ (0.10)
 Weighted average common shares outstanding, basic and diluted	 74,963	 94,557

See accompanying notes to unaudited consolidated financial statements.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****Three Months Ended March 31, 2006 and 2007****(In thousands, unaudited)**

	Three Months Ended	
	March 31, 2006	2007
Cash flows from operating activities		
Net loss	\$ (9,780)	\$ (9,293)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,535	3,036
Amortization of discount on short-term investments		(2,193)
Imputed interest on acquisition obligation	1,190	1,146
Loss on disposals of property and equipment		9
Equity in the income of BioMarin/Genzyme LLC	(3,800)	(6,163)
Stock based compensation	2,104	3,815
Changes in operating assets and liabilities:		
Accounts receivable	(1,633)	145
Advances to BioMarin/Genzyme LLC	418	782
Inventory	(7,240)	(2,363)
Other current assets	(1,467)	(443)
Other assets	(536)	(524)
Accounts payable and accrued liabilities	(996)	(6,817)
Other liabilities	(58)	401
Deferred revenue	(120)	(1,664)
Net cash used in operating activities	(19,383)	(20,126)
Cash flows from investing activities		
Purchase of property and equipment	(861)	(3,235)
Sale of short-term investments	3,700	130,250
Purchase of short-term investments		(103,358)
Distributions from BioMarin/Genzyme LLC	8,000	6,000
Net settlement of foreign currency forward contracts		(53)
Net cash provided by investing activities	10,839	29,604
Cash flows from financing activities		
Proceeds from ESPP and exercise of stock options	3,647	1,440
Decrease in cash balances related to long-term debt	17,049	
Repayment of equipment and facility loans	(965)	
Repayment of acquisition obligation	(2,100)	(1,750)
Proceeds from public offering of common stock, net	127,495	
Proceeds from convertible debt offering, net	167,014	
Net cash provided by (used in) financing activities	312,140	(310)
Effect of foreign currency translation on cash	1	1

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Net increase in cash	303,597	9,169
Cash and cash equivalents:		
Beginning of period	38,092	89,162
End of period	\$ 341,689	\$ 98,331

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(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 received marketing approval for Naglazyme[®] (galsulfase) in the U.S. in May 2005, and in the E.U. in January 2006. Aldurazyme[®] (aronidase) has been approved in the U.S and E.U. and is marketed by the Company and its joint venture partner, Genzyme Corporation (Genzyme). In May 2004, BioMarin completed the transaction to acquire the Ascent Pediatrics business, for which the North American rights were sublicensed to Alliant Pharmaceuticals, Inc. (Alliant) by BioMarin in March 2006. The May 2004 transaction included the exclusive marketing and development rights to Orapred[®] (prednisolone sodium phosphate oral solution). See Note 4 for further discussion of the sublicense in 2006. The Company is incorporated in the state of Delaware.

Through March 31, 2007, the Company had accumulated losses of approximately \$600.9 million. Management believes that the Company's cash, cash equivalents and short-term investments at March 31, 2007 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 invest in new technologies or other business development activities, the Company may need additional capital. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance net future cash needs primarily through its current cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners. In April 2007, the Company raised approximately \$316.4 million in net proceeds from a public offering of senior subordinated convertible debt due in 2017. The proceeds are intended to fund future business development transactions and for general corporate purposes.

The Company is subject to a number of risks, including the financial performance of Naglazyme and the Aldurazyme joint venture; 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 such 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. 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 accounting principles generally accepted in the U.S. (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.

Operating results for the three months ended March 31, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. These consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2006, included in the Company's Annual Report on Form 10-K.

(b) Use of Estimates

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain 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.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(Unaudited)

(c) Inventory

The Company values inventories at the lower of cost or fair market 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, inventory that 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 written off and recognized as additional cost of sales.

Regulatory approval for Naglazyme was received in May 2005, and costs related to the manufacturing of Naglazyme prior to this date were 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 Naglazyme prior to regulatory approval were not capitalized as inventory. When regulatory approval was obtained in May 2005, the Company began capitalizing Naglazyme inventory at the lower of cost or fair market value. As of March 31, 2007, Naglazyme inventory includes a small amount of pre-approval manufactured finished goods, which have an insignificant cost basis. The majority of the previously expensed inventory has been sold or used in clinical trials as of March 31, 2007. Stock-based compensation of \$0.4 million was capitalized into Naglazyme inventory for each of the three months ended March 31, 2006 and 2007. See Note 7 for further information on inventory balances as of March 31, 2006 and 2007.

(d) Goodwill, Acquired Intangible Assets and Impairment of Long-Lived Assets

The Company records goodwill in a business combination when the total consideration exceeds the fair value of the net tangible and identifiable intangible assets acquired. In accordance with Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, goodwill and intangible assets with indefinite lives are not amortized. Intangible assets with definite lives are amortized over their useful lives on a straight-line basis.

The Company reviews long-lived assets for impairment annually and whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. If it is determined that the full carrying amount of an asset is not recoverable, an impairment loss is recorded in the amount by which the carrying amount of the asset exceeds its fair value. See Note 5 for further discussion of the Company's intangible asset and goodwill impairment analyses.

The Company currently operates in one business segment, the biopharmaceutical development and commercialization segment. When reviewing goodwill for impairment, SFAS No. 142 requires that the Company assess whether goodwill should be allocated to operating levels lower than its single operating segment for which discrete financial information is available and reviewed for decision-making purposes. These lower levels are referred to as reporting units. As of March 31, 2007, the Company has only one reporting unit. The Company performs an annual impairment test in the fourth quarter of each fiscal year by assessing the fair value and recoverability of its goodwill, unless facts and circumstances warrant a review of goodwill for impairment before that time. No triggering events were identified during the first quarter of 2007. The Company determines the fair value of its reporting units using a combination of discounted cash flow models, quoted market prices when available and independent appraisals.

The recoverability of the carrying value of buildings and leasehold improvements for the Company's facilities will depend on the successful execution of the Company's business plan and the Company's ability to earn sufficient returns on its approved products and product candidates. Based on management's current estimates, the Company expects to recover the carrying value of such assets.

(e) Revenue Recognition

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The Company recognizes revenue in accordance with the provisions of SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, and Emerging Issues Task Force Issue (EITF) No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*.

The Company's revenues consist of Naglazyme product sales, Orapred product sales through March 2006, revenues from its collaborative agreement with Merck Serono and revenues from its sublicense agreement with Alliant for North American Orapred rights (see Note 4). All Aldurazyme sales are reported by BioMarin/Genzyme LLC and are included in the results of the joint venture (see Note 6).

Naglazyme product sales The Company recognizes revenue from Naglazyme product sales 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. Naglazyme product sales transactions are

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(Unaudited)

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 (VAT) in foreign jurisdictions, are presented on a net basis in the Company's statements of operations, in that taxes billed to customers are not included as a component of net product sales, as per Emerging Issues Task Force Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement*.

In the U.S., Naglazyme is generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. In the E.U., Naglazyme is generally sold to the Company's authorized European distributors or directly to hospitals, which act as the end users. Additionally, the Company receives revenue from named patient sales of Naglazyme in other countries, which are generally made to local distributors. Because of the pricing of Naglazyme, the limited number of patients and the customers' limited return rights, Naglazyme customers and retailers generally carry a very limited inventory. Accordingly, the Company expects that sales related to Naglazyme will be closely tied to end-user demand.

The Company records reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product sales 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 period, and records any necessary adjustments to its reserves. The Company records fees paid to Naglazyme distributors as a reduction of revenue, in accordance with EITF Issue No. 01-09, *Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor's Products)*.

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 of Naglazyme is required, including market exclusivity of the product based on its orphan drug status, the patient population, the customers' limited return rights and the Company's joint venture's experience of returns for Aldurazyme, which is a similar product. Based on these factors, management has concluded that product returns will be minimal. 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 Naglazyme customers to make required payments. As of March 31, 2007, the Company has experienced no bad debts and had no allowance for doubtful accounts.

Orapred product sales The Company does not expect to report Orapred product sales in future periods following sublicensing the North American rights to the product to Alliant in March 2006. The Company recognized revenue from Orapred product sales when persuasive evidence of an arrangement existed, the product had been shipped, title and risk of loss passed to the customer, the price to the buyer was fixed or determinable and collection from the customer was reasonably assured. Orapred product sales transactions were evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

The Company established and maintained rebate reserves for amounts payable to managed care organizations and state Medicaid programs for the reimbursement of a portion of the retail price of prescriptions filled that are covered by the respective plans. The amounts estimated to be paid relating to products sold are recognized as revenue reductions and as additions to accrued expenses at the time of the original sale. The rebate reserves were generally based on the Company's best estimate of the expected prescription fill rate to these managed care organizations and state Medicaid patients. The estimates were developed using the product's rebate history adjusted to reflect known and forecasted changes in the factors that impact such reserves. During the first quarter of 2006, the Company reduced its Orapred rebate reserves by \$1.1 million, which increased net revenues by \$0.9 million for rebates related to product sold by the Company and decreased operating expenses by \$0.2 million for rebates related to product sold by the previous seller of Orapred. The reduction was due to the sublicense of North American Orapred rights to Alliant, which reduced the Company's liability for certain rebates. No significant adjustments were made in the first quarter of 2007.

Provisions for sales discounts and estimates for chargebacks and product returns were established as a reduction of product sales at the time such revenues were recognized. These revenue reductions were established by the Company's management as its best estimate at the time of the original sale based on the product's historical experience adjusted to reflect known and forecasted changes in the factors that impact such

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

reserves. These revenue reductions were generally reflected either as a direct reduction to gross sales and accounts receivable through an allowance or as an addition to accrued expenses. The Company generally permits product returns only if the product is damaged or if it is returned near or after expiration.

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of March 31, 2006 and 2007, the Company's allowance for doubtful accounts was insignificant.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(Unaudited)

Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue. 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. There is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono. 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 (sapropterin dihydrochloride) development costs under the agreement, which are recorded as research and development expenses. Collaborative agreement revenues during the first quarter of 2006 and 2007 include \$1.9 million and \$1.8 million, respectively, of the up-front license fee received from Merck Serono recognized as revenue and \$2.6 million and \$2.3 million of reimbursable Kuvan development costs incurred during the first quarter of 2006 and 2007, respectively.

Royalty and license revenues Royalty revenue is recognized based on sublicensee sales of Orapred liquid and Orapred ODT (Oral Disintegrating Tablets) subsequent to the execution of the sublicense of Orapred North American rights in March 2006. Royalties are recognized as earned in accordance with the contract terms, when the royalty amount is fixed or determinable based on information received from the sublicensee and when collectibility is reasonably assured.

The timing of customer purchases and the resulting product shipments have a significant impact on the amount of royalty revenue that the Company recognizes in a particular period. The majority of Orapred sales are made to wholesalers, which, in turn, resell the product to retail outlets. Inventory in the distribution channel consists of inventory held by wholesalers, who are the principal customers for Orapred, and inventory held by retailers. Royalty revenues from Orapred sales in a particular period will be impacted by increases or decreases in wholesaler inventory levels. If wholesaler inventories substantially exceed retail demand, the Company could experience reduced royalty revenue from sales in subsequent periods.

The up-front license fee of \$2.5 million received from Alliant in March 2006 was deferred and was recognized as revenue on a straight-line basis over approximately 5 months, which represented the best estimate of the time from inception of the agreement until commercial launch of Orapred ODT in August 2006, at which point the Company's performance obligations ended. Royalty and license revenue during the first quarter of 2006 includes \$0.3 million of the up-front license fee received from Alliant that was recognized as revenue. Royalty and license revenues include royalty revenues from Orapred product sold by the sublicense of \$42,000 and \$0.3 million in the first quarter of 2006 and 2007, respectively. There are no cost of sales associated with the royalty and license revenues recorded during the periods and no related costs are expected in future periods.

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.

(f) 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. Generally, 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.

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

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, at which time inventory is capitalized at the lower of cost or fair value.

(g) Net Loss Per Share

Net loss per share is calculated by dividing net loss by the weighted average shares of common stock outstanding during the

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)**

period. Diluted net loss per share is calculated by dividing net loss by the weighted average shares of common stock outstanding and potential shares of common stock during the period. Potential shares of common stock include dilutive shares issuable upon the exercise of outstanding common stock options, contingent issuances of common stock related to convertible debt, acquisition payable and purchases under the Employee Stock Purchase Plan. For all periods presented, such potential shares of common stock were excluded from the computation of diluted net loss per share, as their effect is antidilutive.

Potentially dilutive securities include (in thousands):

	March 31,	
	2006	2007
Options to purchase common stock	8,107	10,280
Common stock issuable under convertible debt	19,324	10,404
Portion of acquisition payable in common stock at the option of the Company	641	498
Potentially issuable common stock for ESPP purchases	147	146
Total	28,219	21,328

In April 2007, the Company sold approximately \$324.9 million in 1.875% convertible senior subordinated debt due 2017, which will be convertible into approximately 16.0 million shares of common stock and are excluded from the table above.

(h) Stock Based Compensation

Stock-based compensation is accounted for in accordance with SFAS No. 123R, *Share-Based Payment* and related interpretations. Under the fair value recognition provisions of this statement, share-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating future stock price volatility and employee stock option exercise behaviors. If actual results differ significantly from these estimates, stock-based compensation expense and results of operations could be materially impacted.

Expected volatility is based upon proportionate weightings of the historical volatility of the Company's stock and the implied volatility of traded options on the Company's stock. The expected life of options is based on observed historical exercise patterns, which can vary over time.

As stock-based compensation expense recognized in the consolidated statement of operations is based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience.

If factors change and different assumptions are employed in the application of SFAS No. 123R, the compensation expense recorded in future periods may differ significantly from what was recorded in the current period. See Note 3 for further discussion of the Company's accounting for stock-based compensation.

(i) Derivative Instruments

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The Company utilizes derivative financial instruments, including foreign exchange forward contracts, to manage its exposure to foreign currency exchange rate fluctuation risks. The Company does not hold or issue financial instruments for speculative or trading purposes, but rather for the intent of economic hedging.

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. Forward exchange contracts are used to hedge a portion of the net exposures. Gains or losses on net foreign currency hedges are intended to offset losses or gains on the underlying net exposures in an effort to reduce the earnings and cash flow volatility resulting from fluctuating foreign currency exchange rates. The resulting losses or gains from these instruments are included as a component of selling, general and administrative expenses on the Company's consolidated statements of operations. See Note 10 for further discussion of the Company's derivative instruments.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(Unaudited)

(j) Fair Value of Financial Instruments

SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, requires the Company to disclose the fair value of financial instruments for assets and liabilities for which it is practicable to estimate that value.

The carrying amounts of all cash equivalents and forward exchange contracts approximate fair value based upon quoted market prices. The fair value of trade accounts receivables, accounts payable and other financial instruments approximates carrying value due to their short-term nature.

(k) Comprehensive Loss and Accumulated Other Comprehensive Loss

Comprehensive loss was approximately \$9.8 million and \$9.3 million for the three months ended March 31, 2006 and 2007, respectively, and included \$1,000 and \$20,000 of other comprehensive income during the period, respectively. Other comprehensive income includes unrealized gains and losses on short-term investments designated as available for sale and foreign currency translation adjustments. There were no tax effects allocated to any components of other comprehensive income during the first quarter of 2006 and 2007.

Comprehensive loss was approximately \$187.8 million, \$73.9 million, \$28.5 million for the years ended December 31, 2004, 2005 and 2006, respectively, and included \$0.3 million of other comprehensive loss, \$0.3 million of other comprehensive income and \$9,000 of other comprehensive loss, respectively. Other comprehensive income/loss includes unrealized gains and losses on short-term investments designated as available for sale and foreign currency translation adjustments. There were no tax effects allocated to any components of other comprehensive income/loss during the years ended December 31, 2004, 2005 and 2006.

(l) Restricted Cash

Restricted cash of \$2.6 million as of March 31, 2007 includes \$1.6 million related to cash received for royalties pursuant to the Orapred sublicense agreement, which are restricted until August 2009, upon the stock purchase of Ascent Pediatrics from Medicis (see Note 4). Restricted cash also includes investments of \$1.0 million held by the Company's Nonqualified Deferred Compensation Plan (see Note 13).

(m) Other Significant Accounting Policies

For all other significant accounting policies, please refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

(n) Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. This statement provides entities the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply the hedge accounting provisions as prescribed by SFAS No. 133 *Accounting for Derivative Instruments and Hedging Activities*. This Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Management is currently evaluating the impact of adopting this Statement.

Effective January 1, 2007, the Company adopted FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes*. FIN 48 prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. As of January 1, 2007 and March 31, 2007, the Company did not have any unrecognized tax benefits. There was no effect on the Company's consolidated financial position, results of operations or cash flows as a result of adopting FIN 48. The Company's policy is to recognize accrued interest and penalties for unrecognized tax benefits as a component of tax expense. As of January 1, 2007 and March 31,

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

2007, there was no accrued interest and penalties for unrecognized tax benefits. For the first quarter of 2007, there was no interest or penalties included as a component of tax expense for unrecognized tax benefits.

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(Unaudited)

The Company or one of its subsidiaries files income tax returns in the U.S. federal jurisdiction, and various states and foreign jurisdictions. For income tax returns filed by the Company, the Company is no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for tax years before 2002, although carryforward tax attributes that were generated prior to 2002 may still be adjusted upon examination by tax authorities if they either have been or will be utilized.

(o) Reclassifications

In the first quarter, the Company's equity in the income of the BioMarin/Genzyme LLC joint venture has been presented as non-operating income in the consolidated statements of operations. During the first quarter of 2007, management determined that the significance of the joint ventures' operations with respect to the Company has decreased on a relative basis compared to the Company's other activities and that presenting the equity in the income of the joint venture as a non-operating income item was now more representative of the Company's operations as a whole. Changes to the proportionate significance of the operating nature of the joint venture to the Company's total operations include the continued world-wide commercialization of Naglazyme, the planned commercial launch of Kuvan pending FDA approval, and the increasing requirements of the Company's ongoing research and development programs. Prior periods have been reclassified to conform to the current presentation for consistency.

Certain amounts on the consolidated balance sheet as of December 31, 2006 have been revised to reflect restricted cash. Specifically, approximately \$1.7 million was reclassified from Other Assets to Restricted Cash. Certain other insignificant items in the 2006 consolidated financial statements have been reclassified to conform to the 2007 presentation.

(3) STOCK-BASED COMPENSATION

Effective January 1, 2006, BioMarin began recording compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS No. 123R, *Share Based Payment*, as interpreted by SAB No. 107. Prior to January 1, 2006, the Company accounted for stock options according to the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. BioMarin adopted the modified prospective transition method provided for under SFAS No. 123R, and consequently has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options now includes: (1) quarterly amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123; and (2) quarterly amortization related to all stock option awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. In addition, the Company records expense related to shares issued under its employee stock purchase plan over the offering period.

The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the requisite service period of the options using the straight-line method. Prior to adoption of SFAS No. 123R, benefits of tax deductions in excess of recognized compensation costs were required to be reported as operating cash flows. SFAS No. 123R requires that they be recorded as a financing cash inflow rather than as a reduction of taxes paid. For the three months ended March 31, 2007, no net excess tax benefits were generated from option exercises. The Company evaluated the need to record a cumulative effect adjustment for estimated forfeitures upon the adoption of SFAS No. 123R and determined the amount to be insignificant. Pursuant to the income tax provisions included in SFAS 123R, the Company has elected the long method of computing its hypothetical APIC pool. The Company is in the process of computing the hypothetical excess tax benefits in additional paid-in capital as of the date of adoption of SFAS No. 123R. This analysis is not expected to result in a material change to BioMarin's financial statements.

Stock-based compensation costs for the three months ended March 31, 2007 totaled \$4.0 million, of which \$0.4 million was capitalized into inventory, \$2.1 million was included in selling, general and administrative expense, \$1.3 million was included in research and development expense and \$0.2 million of stock-based compensation was included in cost of goods sold. Stock-based compensation costs for the three months

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

ended March 31, 2006 totaled \$2.1 million, of which \$0.4 million was capitalized into inventory, \$0.8 million was included in selling, general and administrative expense, \$0.9 million was included in research and development expense and \$0 was included in cost of goods sold.

Stock Options

BioMarin's 2006 Share Incentive Plan, which was approved on June 21, 2006 and replaces the Company's previous stock option plans, provides for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date,

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)**

as well as other forms of equity compensation. As of March 31, 2007, the only awards issued under the 2006 Share Incentive Plan were stock options. The options generally vest over a four-year period on a cliff basis six months after the grant date and then monthly thereafter. The term of the outstanding options is generally ten years. Options assumed under past business acquisitions generally vest over periods ranging from immediately upon grant to five years from the original grant date and have terms ranging from two to ten years.

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 table 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 March 31, 2007. The expected volatility of stock options is based upon proportionate weightings of the historical volatility of BioMarin stock and the implied volatility of traded options on the Company's stock for fiscal periods in which there is sufficient trading volume in options on the Company's 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 BioMarin has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

Stock Option Valuation Assumptions	Three Months Ended March 31,	
	2006	2007
Expected volatility	57.87%	48.28%
Dividend yield	zero	zero
Expected life	4.9 years	5.2 years
Risk-free interest rate	4.35%	4.68%

The Company recorded \$1.6 million and \$3.9 million of compensation costs related to stock options for the three months ended March 31, 2006 and 2007, respectively, recognized in accordance with SFAS No. 123R. As of March 31, 2007, there was \$34.1 million of total unrecognized compensation cost related to unvested stock options. These costs are expected to be recognized over a weighted average period of 3.2 years.

A summary of stock option activity under the plans for the three months ended March 31, 2007 is presented as follows:

	Shares	Exercise Price	Weighted	Weighted	Aggregate
			Average Fair	Average	
			Value of	Remaining	
			Options	Contractual	Intrinsic
			Granted	Term (Years)	Value
					(in thousands)
Balance as of December 31, 2006	10,374,194	\$ 11.75			
Granted	176,800	\$ 16.95	\$ 8.26		
Exercised	(211,295)	\$ 6.83			\$ 2,278
Expired and Forfeited	(59,358)	\$ 13.35			

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Balance as of March 31, 2007	10,280,341	\$	11.93	7.76	\$	56,588
Options expected to vest as of March 31, 2007	4,497,585	\$	13.32	9.00	\$	18,145
Exercisable as of March 31, 2007	4,465,350	\$	9.96	6.11	\$	33,757

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of our common stock as of the end of the period. There were 7.9 million options that were in-the-money at March 31, 2007. The aggregate intrinsic value of options exercised was determined as of the date of option exercise.

At March 31, 2007, an aggregate of 14.4 million unissued shares were authorized for future issuance under the Company's stock plans, which include shares issuable under the Company's 2006 Share Incentive Plan and the Company's Employee Stock Purchase Plan. Awards under the 2006 Share Incentive Plan that expire or are cancelled without delivery of shares generally become available for issuance under the plans. Awards that expire or are cancelled under the Company's suspended 1997 Stock Plan or 1998 Director Option Plan may not be reissued.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)**

An initial option is granted to each new outside member of BioMarin's Board of Directors to purchase 30,000 shares of common stock at the fair value on the date of the grant. Until January 2007, on each anniversary date of becoming a director, each outside member was granted options to purchase 30,000 shares of common stock at the fair market value on such date. The Board of Directors is currently evaluating the appropriate annual equity compensation for outside directors. These options vest over one year and have a term of ten years.

As of March 31, 2007, the options outstanding consisted of the following:

	Options Outstanding Weighted			Options Exercisable	
	Average	Weighted		Weighted	
	Remaining	Average	Number of	Average	
	Number of Options	Contractual	Exercise	Options	Exercise
Range of exercise prices	Outstanding	Life	Price	Exercisable	Price
\$ 3.50 to 7.00	1,979,668	6.72	\$ 5.95	1,216,876	\$ 5.80
7.01 to 10.50	2,090,022	6.61	8.68	1,579,524	8.67
10.51 to 14.00	2,986,755	7.98	12.22	1,174,620	12.24
14.01 to 17.50	956,303	8.87	16.01	216,537	15.68
17.51 to 21.00	2,057,593	9.39	17.63	67,793	19.90
21.01 to 24.50	210,000	3.11	22.00	210,000	22.00
	10,280,341			4,465,350	

Employee Stock Purchase Plan

Under BioMarin's Employee Stock Purchase Plan, which was approved on June 21, 2006 and replaces the Company's previous plan, employees meeting specific employment qualifications are eligible to participate and can purchase shares on established dates semi-annually through payroll deductions at the lower of 85% of the fair market value of the stock at the commencement or each purchase date of the offering period. Each offering period will span up to two (2) years. The Employee Stock Purchase Plan permits eligible employees to purchase common stock through payroll deductions for up to 10% of qualified compensation. The Employee Stock Purchase Plan has been treated as a compensatory plan. The Company recorded compensation costs of \$0.1 million related to the Employee Stock Purchase Plan in both of the three month periods ended March 31, 2006 and 2007.

The fair value of each award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the table below. The expected volatility of Employee Stock Purchase Plan shares is based on the implied volatility of traded options on the Company's stock for periods in which there is sufficient trading volume in those options. Otherwise, historical volatility is utilized. 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 BioMarin has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

Employee Stock Purchase Plan	Three Months Ended March 31,	
	2006	2007
Expected volatility	44% to 52%	44% to 54%
Dividend yield	zero	zero
Expected life	6-24 months	6-24 months
Risk-free interest rate	4.4%	3.9% to 5.2%

(4) SUBLICENSE OF NORTH AMERICAN ORAPRED RIGHTS

In March 2006, the Company entered into a license agreement with Alliant for the continued sale and commercialization of Orapred and other Orapred formulations then under development, including Orapred ODT. Through the agreement, Alliant acquired exclusive rights to market these products in North America, and BioMarin retained exclusive rights to market these products outside of North America. BioMarin and Alliant are individually responsible for the costs of commercializing the products within their respective territories. The third party will also pay BioMarin royalties on its net sales of these products. BioMarin will also transfer the North American intellectual property to Alliant in August 2009, following the purchase of the stock of Ascent Pediatrics from Medicis.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)**

Pursuant to the agreement, Alliant paid BioMarin \$2.5 million as consideration for executing the agreement, and agreed to make additional milestone payments of \$15.5 million based on the approval and successful commercial launch of Orapred ODT, of which \$11.5 million were received during 2006. During the three months ended March 31, 2006 and 2007, the Company recognized \$42,000 and \$0.3 million, respectively, in royalty revenues from Orapred products sold by the sublicensee.

(5) ACQUIRED INTANGIBLE ASSETS AND GOODWILL*(a) Acquired Intangible Assets*

Acquired intangible assets relate to the Ascent Pediatrics transaction completed during May 2004 and consist of the Orapred product technology as of March 31, 2007. The gross and net carrying value of the Orapred product technology as of March 31, 2007 were as follows (in thousands):

Gross value	\$ 20,437
Accumulated amortization	(9,874)
Net carrying value	\$ 10,563

Upon execution of the sublicense of the North American rights of Orapred in March 2006, which was determined to be a triggering event according to SFAS No. 144, the Company performed an impairment test and determined that no impairment of intangible assets existed as of March 31, 2006. No triggering events were identified during the first quarter of 2007.

The Orapred product technology is being amortized on a straight-line basis over its revised estimated useful life of 3.5 years. The estimated useful life was revised from 15 years following the execution of the sublicense for the North American rights to Orapred, which includes an asset transfer of the underlying intangible assets in August 2009, representing the revised useful life of the asset. The estimated amortization expense associated with the revised estimated useful life of the Orapred product technology for each of the succeeding three years is as follows (in thousands):

	As of
	March 31, 2007
Remainder of 2007	\$ 3,278
2008	4,371
2009	2,914
Total	\$ 10,563

Amortization expense for the three months ended March 31, 2006 and 2007 was \$0.4 million and \$1.1 million, respectively.

(b) Goodwill

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Goodwill as of March 31, 2007 relates to the Ascent Pediatrics transaction completed during May 2004. The aggregate amount of goodwill acquired in the transaction was approximately \$21.3 million. Using the reporting unit basis required by SFAS No. 142, *Goodwill and Other Intangible Assets*, the Company completed an impairment test during March 2006, upon execution of the sublicense of North American rights, which was determined to be a triggering event according to SFAS No. 142. The Company determined that no impairment of goodwill existed as of March 2006. Following the sublicense of North American rights of Orapred in March 2006, the Company has concluded it only has one reporting unit. Whether or not goodwill will be impaired in the future is dependent upon the future estimated fair value of the Company. No triggering events were identified during the first quarter of 2007.

(6) JOINT VENTURE

(a) Joint Venture Financial Data

The results of the joint venture's operations for the three months ended March 31, 2006 and 2007, are presented in the table below (in thousands). Equity in the Income of BioMarin/Genzyme LLC represents the Company's 50% share of the joint venture's

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)**

income. The joint venture's results and summarized assets and liabilities as presented below give effect to the difference in inventory cost basis between the Company and the joint venture. The difference in basis primarily represents the difference in inventory capitalization policies between the joint venture and the Company. The Company began capitalizing Aldurazyme inventory costs in May 2003 after regulatory approval was obtained. The joint venture began capitalizing Aldurazyme inventory costs in January 2002 when inventory production for commercial sale began. The difference in inventory capitalization policies resulted in greater operating expense recognized by the Company prior to regulatory approval compared to the joint venture. Correspondingly, this results in less cost of goods sold recognized by the Company when the previously expensed product is sold by the joint venture and less operating expenses when this previously expensed product is used in clinical trials. The difference will be eliminated when all of the product produced prior to obtaining regulatory approval has been sold or used in clinical trials. The majority of the difference has been eliminated as of March 31, 2007.

	Three Months Ended March 31,	
	2006	2007
Net product sales	\$ 21,332	\$ 26,822
Cost of goods sold	5,623	6,302
Gross profit	15,709	20,520
Operating expenses	8,267	8,366
Income from operations	7,442	12,154
Other income	158	171
Net income	\$ 7,600	\$ 12,325
Equity in the income of BioMarin/Genzyme LLC	\$ 3,800	\$ 6,163

At March 31, 2007, the summarized assets and liabilities of the joint venture and the components of the Company's investment in the joint venture are as follows (in thousands):

	December 31,	March 31,
	2006	2007
Assets	\$ 71,192	\$ 69,103
Liabilities	(8,278)	(5,865)
Net equity	\$ 62,914	\$ 63,238
Investment in BioMarin/Genzyme LLC (50% share of net equity)	\$ 31,457	\$ 31,619

(b) Joint Venture Critical Accounting Policies

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Revenue recognition BioMarin/Genzyme LLC recognizes revenue from product sales 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. Revenue transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

The timing of product shipment and receipts can have a significant impact on the amount of revenue that BioMarin/Genzyme LLC recognizes in a particular period. Also, Aldurazyme is sold in part through distributors. Inventory in the distribution channel consists of inventory held by distributors, who are BioMarin/Genzyme LLC's customers, and inventory held by retailers, such as pharmacies and hospitals.

BioMarin/Genzyme LLC's revenue in a particular period can be impacted by increases or decreases in distributor inventories. If distributor inventories increased to excessive levels, BioMarin/Genzyme LLC could experience reduced purchases in subsequent periods. To determine the amount of Aldurazyme inventory in the joint venture's U.S. distribution channel, BioMarin/Genzyme LLC receives data on sales and inventory levels directly from its primary distributors for the product.

BioMarin/Genzyme LLC records reserves for rebates payable under Medicaid and third-party payer contracts, such as managed care organizations, as a reduction of revenue at the time product sales are recorded.

Certain components of the BioMarin/Genzyme LLC rebate reserves are calculated based on the amount of inventory in the distribution channel, and are impacted by BioMarin/Genzyme LLC's assessment of distribution channel inventory. BioMarin/Genzyme LLC's calculation also requires other estimates, including estimates of sales mix, to determine which sales will be subject to rebates and the amount of such rebates. BioMarin/Genzyme LLC updates its estimates and assumptions each period, and records any necessary adjustments to its reserves.

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)**

BioMarin/Genzyme LLC 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 the nature of Aldurazyme and its patient population, the customers' limited return rights, Genzyme's experience of returns for similar products and BioMarin/Genzyme LLC's estimate of distribution channel inventory, based on sales and inventory level information provided by the primary distributors for Aldurazyme, as described above. Based on these factors, BioMarin/Genzyme LLC has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

Inventory BioMarin/Genzyme LLC values inventories at the lower of cost or fair value. BioMarin/Genzyme LLC determines the cost of raw materials using the average cost method and the cost of work in process and finished goods using the specific identification method. BioMarin/Genzyme LLC analyzes its inventory levels quarterly and writes down to its net realizable value inventory that has expired, become obsolete, has a cost basis in excess of its expected net realizable value, or is in excess of expected requirements. If actual market conditions are less favorable than those projected by the joint venture, additional inventory write-offs may be required.

BioMarin/Genzyme LLC capitalizes inventory produced for commercial sale. Refer to Note 6(a) above for discussion of the difference in inventory cost basis between the Company and BioMarin/Genzyme LLC.

(7) SUPPLEMENTAL BALANCE SHEET INFORMATION

As of December 31, 2006 and March 31, 2007, accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31,	March 31,
	2006	2007
Accounts payable	\$ 2,285	\$ 748
Accrued accounts payable	13,901	11,795
Accrued vacation	2,109	2,488
Accrued compensation	6,302	3,703
Accrued interest and taxes	1,305	202
Accrued Naglazyme royalties	819	921
Other accrued expenses	996	255
Accrued rebates	819	1,077
Acquired rebates and returns reserve	906	666
Returns reserves	2,633	2,930
Current portion of deferred rent	91	104
	\$ 32,166	\$ 24,889

As of December 31, 2006 and March 31, 2007, other long-term liabilities consisted of the following (in thousands):

December 31, March 31,

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

	2006	2007
Long-term portion of deferred rent	\$ 1,234	\$ 1,477
Deferred compensation liability	844	1,002
Total other long-term liabilities	\$ 2,078	\$ 2,479

As of December 31, 2006 and March 31, 2007, inventory consisted of the following (in thousands):

	December 31,	March 31,
	2006	2007
Naglazyme raw materials	\$ 2,747	\$ 3,488
Naglazyme work in process	13,305	9,743
Naglazyme finished goods	9,023	14,207
Total inventory	\$ 25,075	\$ 27,438

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)****(8) PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment at December 31, 2006 and March 31, 2007, consisted of (in thousands):

Category	December 31, 2006	March 31, 2007	Estimated Useful Lives
Leasehold improvements	\$ 24,733	\$ 25,021	Shorter of life of asset or lease term
Building and improvements	22,604	26,742	20 years
Manufacturing and laboratory equipment	16,045	16,523	5 years
Computer hardware and software	6,484	7,373	3 years
Office furniture and equipment	3,617	3,856	5 years
Land	4,259	4,259	
Construction-in-progress	4,777	1,492	
	\$ 82,519	\$ 85,265	
Less: Accumulated depreciation	(27,053)	(28,778)	
Total property, plant and equipment, net	\$ 55,466	\$ 56,487	

Depreciation for the three months ended March 31, 2006 and 2007 was, \$1.9 million and \$1.7 million, respectively, of which \$0.7 and \$0.4 million was capitalized into inventory, respectively.

(9) CONVERTIBLE DEBT

In March 2006, the Company sold \$172.5 million of senior subordinated convertible debt due on March 29, 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 no call provision included and the Company is unable to unilaterally redeem the debt prior to maturity in 2013. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

In connection with the placement of the 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 \$0.2 million of amortization expense during the three months ended March 31, 2007. Amortization expense was insignificant for the three months ended March 31, 2006.

In June 2003, the Company sold \$125 million of convertible debt due on June 15, 2008. As of December 31, 2006, the Company had an outstanding balance of \$51.4 million of the Company's 3.5% Senior Subordinated Convertible Notes due 2008, which was converted into approximately 3.7 million shares of common stock in January 2007. As a result of this conversion, approximately \$0.5 million in previously capitalized debt offering costs were reclassified to additional paid in capital.

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Interest expense for the three months ended March 31, 2006 and 2007 was, \$2.8 million and \$2.3 million, respectively, and included \$1.2 million and \$1.1 million in imputed interest expense, respectively. Interest paid for the three months ended March 31, 2006 and 2007 was \$0.3 million and \$2.2 million, respectively. Capitalized interest related to the Company's fixed asset purchases during the first quarter of 2007 was insignificant.

Subsequent Event

In April 2007, the Company sold approximately \$324.9 million of senior subordinated convertible notes due on April 23, 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

Table of Contents**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****March 31, 2007****(Unaudited)**

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 no 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.

(10) DERIVATIVE FINANCIAL INSTRUMENTS

The Company periodically enters into foreign currency forward contracts, which have a maturity of less than one year. These contracts have not been designated as hedges and, accordingly, unrealized gains or losses on these contracts are reported in current earnings.

At March 31, 2007, the Company had net outstanding foreign exchange forward contracts to sell \$11.9 million of foreign currencies, comprised of sell contracts of \$7.0 million of equivalent Euros and \$4.9 million of equivalent British Pounds, both of which have a term of less than 3 months.

None of the Company's forward exchange contracts are designated as hedges under SFAS No. 133. As a result, the fair value changes of all contracts are reported in earnings as foreign exchange gain or loss. For the three months ended March 31, 2007, foreign exchange loss of approximately \$48,000 has been included in the Company's consolidated statement of operations with respect to the Company's forward exchange contracts.

(11) SUPPLEMENTAL CASH FLOW INFORMATION

The following significant non-cash transactions took place in the periods presented (in thousands):

	Three Months Ended	
	March 31, 2006	March 31, 2007
Conversion of 3.5% convertible debt due 2008	\$	\$ 51,440
Deferred offering costs reclassified to additional paid in capital as a result of the conversion of the remaining debt due 2008		512
Change in accrued payables related to fixed asset additions	8	(460)
Stock-based compensation capitalized into inventory	383	416

(12) FINANCIAL INSTRUMENTS CONCENTRATIONS OF CREDIT RISK

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. All cash, cash equivalents, and short-term investments are placed in financial institutions with strong credit ratings, which minimizes the risk of loss due to nonpayment. Accounts receivable as of March 31, 2007 related to net product sales of Naglazyme. A significant portion of net product sales are made to a limited number of financially viable specialty pharmacies and distributors. The Company's largest customer is its authorized European distributor and accounted for 61% of the Company's total net product sales of Naglazyme for the three months ended March 31, 2007. For the three months ended March 31, 2007, net product sales of Naglazyme were \$4.2 million from customers based in the U.S. and \$14.2 million from customers based outside of the U.S.

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

The Company does not require collateral from its customers, but performs periodic credit evaluations of its customers' financial condition and requires immediate payment in certain circumstances. The Company has not experienced any significant losses related to its financial instruments and management does not believe a significant credit risk existed at March 31, 2007.

(13) DEFERRED COMPENSATION PLAN

In December 2005, the Company adopted the BioMarin Pharmaceutical Inc. Nonqualified Deferred Compensation Plan (the "Deferred Compensation Plan"). The 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 Board the opportunity to make voluntary deferrals of compensation to specified future dates, retirement or death. Participants are permitted to defer portions of

Table of Contents

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2007

(Unaudited)

their salary and annual cash bonus. The Company may not make additional direct contributions to the Deferred Compensation Plan on behalf of the participants, without further action by the Board. Deferred compensation is held in trust and generally invested to match the investment benchmarks selected by participants. The recorded cost of any investments will approximate fair value. Investments of \$0.8 million and \$1.0 million and the related deferred compensation liability of \$0.8 million and \$1.0 million were recorded as of December 31, 2006 and March 31, 2007, respectively. The change in market value was insignificant for each of the three months ended March 31, 2006 and 2007.

Table of Contents

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
Forward-Looking Statements**

This 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 risk. These forward-looking statements may be found in *Overview*, and other sections of this 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 Form 10-K for the year ended December 31, 2006 as well as those discussed elsewhere in this 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 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 Form 10-Q to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the notes thereto appearing elsewhere in this annual report. In addition to the other information in this Form 10-Q, investors should carefully consider the following discussion and the information under *Risk Factors* when evaluating us and our business.

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. Our product portfolio is comprised of two approved products and multiple investigational product candidates. Approved products include Naglazyme® (galsulfase) and Aldurazyme® (laronidase). Additionally, we have rights to receive payments and royalties related to Orapred® (prednisolone sodium phosphate) and Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets) subsequent to the sublicense of North American right in March 2006.

Naglazyme is a recombinant form of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) indicated for patients with mucopolysaccharidosis VI (MPS VI). MPS VI is a debilitating life-threatening genetic disease for which no other drug treatment currently exists and is caused by the deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B), an enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). Patients with MPS VI typically become progressively worse and experience multiple severe and debilitating symptoms resulting from the build-up of carbohydrate residues in all tissues in the body.

Naglazyme was granted marketing approval in the U.S. in May 2005 and in the E.U. in January 2006. We market Naglazyme in the U.S. and E.U. using our own sales force and commercial organization. We have launched the product in the major markets of the E.U. and are continuing launch efforts on a country-by-country basis in the other E.U. countries. Additionally, we are receiving revenue from named patient sales of Naglazyme in other countries. We initiated commercial operations in Brazil during 2006 and are currently evaluating commercialization options in other countries, including the use of local distributors of Naglazyme. Naglazyme net product sales for the first quarter of 2006 totaled \$7.0 million and increased to \$18.4 million for the first quarter of 2007.

Aldurazyme has been approved for marketing in the U.S., E.U., Japan and other countries for patients with mucopolysaccharidosis I (MPS I), for which no other drug treatment currently exists. MPS I is a progressive and debilitating life-threatening genetic disease that is caused by the deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of GAGs. Patients with MPS I typically become progressively worse and experience multiple severe and debilitating symptoms resulting from the build-up of carbohydrate residues in all tissues in the body.

We have developed Aldurazyme through a 50/50 joint venture with Genzyme Corporation. We are responsible for product development, manufacturing and U.S. regulatory submissions. Genzyme is responsible for sales, marketing, distribution, obtaining reimbursement for Aldurazyme worldwide and international regulatory submissions. See *Management's Discussion and Analysis of Financial Condition and Results of Operations BioMarin/Genzyme LLC* for discussion of the financial results of Aldurazyme. Aldurazyme net revenue recorded by our joint venture for the first quarter of 2007 totaled \$26.8 million, compared to \$21.3 million for the first quarter of 2006.

Table of Contents

In May 2004, we completed the transaction to acquire the Orapred product line from Ascent Pediatrics, a wholly owned subsidiary of Medicis. In March 2006, we entered into an agreement with Alliant Pharmaceuticals, Inc. (Alliant) for the continued sale and commercialization of the Orapred product line. Through the sublicense agreement, Alliant acquired exclusive rights to market these products in North America. Alliant is responsible for the costs of commercializing the products in North America. In June 2006, the FDA granted marketing approval for Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets), the first orally disintegrating tablet form of prednisolone available in the United States.

In May 2005, we entered into an agreement with Merck Serono, for the further development and commercialization of Kuvan and Phenylase for PKU and 6R-BH4, the active ingredient in Kuvan, for other diseases such as cardiovascular indications including those associated with endothelial dysfunction. Through the agreement, Merck Serono acquired exclusive rights to market these products in all territories outside the U.S. and Japan, and we retained exclusive rights to market these products in the U.S. Merck Serono and we will generally share equally all development costs following successful completion of Phase 2 clinical trials for each product candidate in each indication. Merck Serono and we are individually responsible for the costs of commercializing the products within our respective territories. Merck Serono will also pay us royalties on its net sales of these products and milestone payments for the successful completion of certain development and approval milestones.

PKU is an inherited metabolic disease that we estimate affects at least 50,000 diagnosed patients under the age of 40 in the developed world. We believe that 30% to 50% of those with PKU could benefit from treatment with Kuvan, if approved. PKU is caused by a deficiency of activity of an enzyme, phenylalanine hydroxylase (PAH), which is required for the metabolism of Phe. Phe is an essential amino acid found in all protein-containing foods. Without sufficient quantity or activity of PAH, Phe accumulates to abnormally high levels in the blood resulting in a variety of serious neurological complications, including severe mental retardation and brain damage, mental illness, seizures and other cognitive problems. Kuvan, our lead product candidate for the treatment of PKU, is a proprietary synthetic oral form of 6R-BH4, a naturally occurring enzyme co-factor for PAH. If approved, Kuvan could become the first drug for the treatment of PKU.

On March 15, 2006, we announced positive results from the Phase 3 clinical trial, which was a six-week, multi-center international, double-blind placebo-controlled study of Kuvan. On December 18, 2006, we announced positive results from the Phase 3 extension study, and on January 16, 2007, we announced positive results from the Phase 3 diet study. We have received orphan drug designation for Kuvan for the treatment of PKU in both the U.S. and E.U. If Kuvan is the first approved drug for PKU, it will have seven years of market exclusivity in the U.S. and 10 years of market exclusivity in the E.U. In January 2006, the FDA designated Kuvan as a fast track product for the treatment of PKU. We expect to file the New Drug Application (NDA) for Kuvan with the FDA in the second quarter of 2007.

We are also developing BH4 for the treatment of other indications, including indications associated with endothelial dysfunction. Endothelial dysfunction has been associated with many cardiovascular diseases, such as peripheral arterial disease. Endothelial dysfunction is a condition characterized by the inability of the endothelium (the single cell layer lining of the blood vessels) to respond to physiological changes correctly. In preclinical and investigator-sponsored studies, administration of BH4 has improved vascular endothelial function in animal models and in patients with diabetes and other cardiovascular diseases. BH4 is a naturally occurring enzyme cofactor required for the production of nitric oxide, a molecule that is key to the regulation of dilation and constriction of blood vessels. Data from preclinical and clinical trials suggest that treatment with BH4 is generally safe and well tolerated.

We initiated our Phase 2 clinical trial of 6R-BH4 for poorly controlled hypertension in July 2006, which was an 8-week, multi-center, double-blind, placebo-controlled study. On February 20, 2007, we announced results from the Phase 2 clinical study of 6R-BH4 in poorly controlled hypertension. Results demonstrated that there was no statistically significant or clinically meaningful effect of 6R-BH4 on any efficacy or safety parameter measured, relative to placebo.

In January 2007, we announced the initiation of a Phase 2 clinical trial of 6R-BH4 for peripheral arterial disease, which is a 24-week, multi-center, double-blind, placebo-controlled study. We expect results from the Phase 2 clinical trial in the second half of 2008, depending on trial enrollment rates. We plan to initiate several additional preclinical and clinical studies of BH4 for other indications, including those related to endothelial dysfunction in 2007.

Phenylase is an investigational enzyme substitution therapy currently in preclinical development. It is being developed as a subcutaneous injection and is intended for those who suffer from classic PKU and for those who do not respond to Kuvan. In preclinical models, Phenylase produced a rapid, dose-dependent reduction in blood Phe levels. We plan to conduct additional preclinical studies of Phenylase in 2007.

Key components of our results of operations for the three months ended March 31, 2006 and 2007, include the following:

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Three Months Ended

	March 31,	
	2006	2007
Total net product sales	\$ 8,979	\$ 18,334
Research and development expense	12,279	18,159
Selling, general and administrative expense	10,893	16,284
Net loss	(9,780)	(9,293)
Stock-based compensation expense	1,720	3,564

Table of Contents

Our research and development expense during the three months ended March 31, 2007, primarily related to the ongoing support of Naglazyme and development of Kuvan, BH4 for cardiovascular indications and Phenylase. Our cash, cash equivalents and short-term investments totaled \$273.3 million as of March 31, 2007 compared to \$288.8 million as of December 31, 2006.

Critical Accounting Policies and Estimates

In preparing our consolidated financial statements, we make assumptions, judgments and estimates that can have a significant impact on our net loss, as well as on the value of certain assets and liabilities on our consolidated balance sheets. 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 and make changes accordingly. Unless otherwise noted below, there have not been any recent changes to our assumptions, judgments or estimates included in our critical accounting policies. We believe that the assumptions, judgments and estimates involved in the accounting for the impairment of long-lived assets, revenue recognition and related reserves, income taxes, inventory, research and development, clinical trial accruals and stock option plans have the greatest potential 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. For further information on our critical and other accounting policies, see Note 2 to the accompanying consolidated financial statements.

Impairment of Long-Lived Assets

Our long-lived assets include our investment in BioMarin/Genzyme LLC, property, plant and equipment, and the acquired Orapred intangible assets and goodwill. We regularly review long-lived assets for impairment. The recoverability of long-lived assets, other than goodwill and our investment in BioMarin/Genzyme LLC, is measured by comparing the asset's carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. If the carrying amount of the asset is not recoverable, an impairment loss is recorded for the amount that the carrying value of the asset exceeds its fair value. No significant impairments were recognized for the three months ended March 31, 2006 and 2007.

We currently operate in one business segment, the biopharmaceutical development and commercialization segment. When reviewing goodwill for impairment, we assess whether goodwill should be allocated to operating levels lower than our single operating segment for which discrete financial information is available and reviewed for decision-making purposes. These lower levels are referred to as reporting units. Currently, we have identified only one reporting unit as per SFAS No. 142, *Goodwill and Other Intangible Assets*. The amount of our goodwill originated from the acquisition of the Orapred business in 2004. No triggering events occurred during the first quarter of 2007 that required an impairment test. We also perform an annual impairment test in the fourth quarter of each fiscal year by assessing the fair value and recoverability of our goodwill by comparing the carrying value of the reporting unit to its fair value as determined by available market value, a discounted cash flow model or appraisals, unless facts and circumstances warrant a review of goodwill for impairment before that time.

Determining whether an impairment has occurred typically requires various estimates and assumptions, including determining which cash flows are directly related to the potentially impaired asset, the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. In turn, measurement of an impairment loss requires a determination of fair value, which is based on the best information available. We use internal cash flow estimates, quoted market prices when available and independent appraisals as appropriate to determine fair value. We derive the required cash flow estimates from our historical experience and our internal business plans and apply an appropriate discount rate.

We believe that our investment in the joint venture will be recovered because we project that the joint venture will maintain sustained positive earnings and cash flows in the future. The joint venture recorded net income of \$7.6 million and \$12.3 million during the first quarter of 2006 and 2007, respectively. We and our joint venture partner maintain the ability and intent to fund the joint venture's operations, if necessary.

The recoverability of the carrying value of buildings and leasehold improvements for our facilities will depend on the successful execution of our business initiatives and our ability to earn sufficient returns on our approved products and product candidates. Based on management's current estimates, we expect to recover the carrying value of such assets.

Table of Contents**Revenue Recognition**

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104: *Revenue Recognition*, and Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Our revenues consist of Naglazyme product sales during 2006 and 2007, Orapred product sales through March 2006, revenues from our collaborative agreement with Merck Serono and revenues from our Orapred sublicense agreement.

Naglazyme product sales We recognize revenue from Naglazyme product sales 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. Naglazyme 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 (VAT) in foreign jurisdictions, are presented on a net basis in our income statement, in that taxes billed to customers are not included as a component of net product sales, as per Emerging Issues Task Force (EITF) Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement*.

In the U.S., Naglazyme is generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. In the E.U., Naglazyme is generally sold to our authorized European distributor and also to hospitals, which act as end-users. Additionally, we also receive revenue from named patient sales of Naglazyme in other countries, which are generally made to local distributors. Because of the pricing of Naglazyme, the limited number of patients and the customers' limited return rights, Naglazyme customers and retailers generally carry a very limited inventory. We also sell Naglazyme to certain larger pharmaceutical wholesalers, which, with respect to Naglazyme, act as intermediaries between us and end-users and generally do not stock quantities of Naglazyme. Accordingly, we expect that sales related to Naglazyme will be closely tied to end-user demand.

We record reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product sales are recorded. Our reserve calculations require estimates, including estimates of sales mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period, and record any necessary adjustments to our reserves. To the extent actual rebates differ from our estimates, additional reserves may be required or reserves may need to be reversed.

We record 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 product based on its orphan drug status, the patient population, the customers' limited return rights and our joint venture's experience of returns for Aldurazyme, which is a similar product. Based on these factors, management has concluded that Naglazyme product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

As Naglazyme was approved for commercial sale in the U.S. during the second quarter of 2005, we have only approximately 21 months of historical experience with rebates and returns specific to Naglazyme. Until additional historical experience is obtained to serve as a reasonable basis for our estimates of rebates and returns, management will use, to the extent available, current estimated sales mix of which sales will be eligible for rebates, estimated rebate rates for state Medicaid programs and other government programs, as well as experience obtained through the commercialization of Aldurazyme by our joint venture with Genzyme, which is a similar product. Certain of our customers receive distributor fees based on sales volume. In accordance with EITF Issue No. 01-09, *Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor's Products)*, these fees are presumed to be a reduction of the selling price of Naglazyme and, therefore, are presented as a reduction of revenue on our consolidated statements of operations. The nature and amount of our current estimates of the applicable revenue dilution item that are currently applied to aggregate world-wide gross sales of Naglazyme to derive net sales are described in the table below.

Revenue Dilution Item	Percentage	
	Sales	Description
Rebates	2-3%	Rebates payable to state Medicaid, other government programs and certain managed care providers
Distributor fees	2-3%	Fees paid to authorized distributors
Cash discounts	0-2%	

Discounts offered to customers for prompt payment of accounts receivable

Total 4-8%

We maintain a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of Naglazyme

Table of Contents

customers to make required payments. As of March 31, 2007, we had not experienced any bad debts and had no allowance for doubtful accounts. However, since we cannot predict changes in the financial stability of our customers, we cannot guarantee that allowances will not be required in the future. If we begin to experience credit losses, our operating expenses would increase.

Orapred product sales As a result of our sublicense of North American rights to Alliant in March 2006, we do not expect to record future net product sales related to the Orapred product line. Future revenue streams related to the Orapred product will be realized through recognition of revenue for the up-front and milestone payments as well as royalty revenue for future sales of Orapred products by Alliant. Prior to the sublicense, we recognized revenue from Orapred product sales when persuasive evidence of an arrangement existed, the product had been shipped, title and risk of loss had passed to the customer, the price to the buyer was fixed or determinable and collection from the customer was reasonably assured. Orapred product sales transactions were evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

We established and maintained reserves for amounts payable to managed care organizations and state Medicaid programs for the reimbursement of a portion of the retail price of prescriptions filled that are covered by the respective plans. The amounts estimated to be paid relating to products sold were recognized as revenue reductions and as additions to accrued expenses at the time of the original sale. The rebate reserves were based on our best estimate of the expected prescription fill rate to these managed care organizations and state Medicaid patients, as well as the rebate rates associated with eligible prescriptions. The estimates were developed using the product's rebate history adjusted to reflect known and forecasted changes in the factors that impact such reserves. These factors included changes in the mix of prescriptions that were eligible for rebates, changes in the contract rebate rates and the lag time related to the processing of rebate claims by our customers and managed care organizations. The length of time between the period of prescriptions and the processing of the related rebates was consistent historically at between three and nine months, depending on the nature of the rebate. The length of time between the period of original sale by us and the processing of the related rebate is dependent upon both the length of time that the product is in the distribution channel and the lag time related to rebate processing by third parties. Additionally, we experienced longer than usual rebate processing lag times as a result of the transition of the product from Medicis after the acquisition and high levels of Orapred inventory held by wholesalers. In the first quarter of 2006, our liability for certain rebates was reduced due to the sublicense of North American rights for Orapred to Alliant. The decrease in estimated future rebates resulted in reserve reversals and an increase in net revenue of approximately \$0.9 million, which was recorded in the first quarter of 2006. No significant adjustments were made to these reserves in the first quarter of 2007. To the extent actual rebates differ from our estimates, additional reserves may be required or reserves may need to be reversed.

Provisions for sales discounts and estimates for chargebacks and product returns were established as a reduction of product sales at the time such revenues were recognized. These revenue reductions were established by our management as its best estimate at the time of the original sale based on the product's historical experience adjusted to reflect known changes in the factors that impact such reserves. These revenue reductions were generally reflected either as a direct reduction to gross sales and accounts receivable through an allowance or as an addition to accrued expenses. We generally permit product returns only if the product is damaged or if it is returned near or after expiration.

Our estimates for future product returns are primarily based on the actual return history for the product and estimates of future demand related to estimated wholesaler inventory levels. Although we are unable to quantify wholesaler inventory levels of Orapred with any certainty, to the extent necessary based on the expiration date and our estimates of quantity of product in the distribution channel, we adjust our estimate for future returns as appropriate. We estimate wholesaler inventory levels, to the extent possible, based on limited information obtained from certain of our wholesale customers and through other internal analyses. Our internal analyses utilize information such as historical sales to wholesalers, product shelf-life based on expiration dating, estimates of the length of time product is in the distribution channel and historical prescription data, which are provided by a third-party vendor. We also evaluate the current and future commercial market for Orapred and consider factors such as Orapred's performance compared to its existing competitors.

As discussed above and prior to the sublicense of the North American rights to Orapred to Alliant in March 2006, our estimates of revenue dilution items were based primarily on the historical experience for the product, as adjusted to reflect known and forecasted changes in the factors that could impact the revenue dilutions. The nature and amount of our estimates of the applicable effective rates for revenue dilution items that were applied to gross sales of Orapred to derive net sales are described in the table below. There were no additional material revenue dilution items other than those disclosed below.

	Estimated	
Revenue Dilution Item	Rate	Description
Sales Returns	3-4%	Provision for returns of product sales, mostly due to product expiration

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Rebates	8-9%	Rebates offered to managed care organizations and state Medicaid programs
Cash Discounts	2%	Discounts offered to customers for prompt payment of accounts receivable
Total	13-15%	

25

Table of Contents

We periodically evaluated the need to maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. When making this evaluation, we made judgments about the creditworthiness of customers based on ongoing credit evaluations and the aging profile of customer accounts receivable and assess current economic trends that might impact the level of credit losses in the future. The Orapred product had not experienced significant credit losses. We had no allowance for doubtful accounts as of March 31, 2007.

Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue. Nonrefundable up-front license fees where we have continuing involvement through research and development collaboration are initially deferred and recognized as license revenue over the estimated period for which we continue to have a performance obligation. License revenue includes the portion of the \$25.0 million up-front license fee received from Merck Serono recognized as revenue during the development period.

Our estimates of the period over which we have an ongoing performance obligation are based on the contractual terms of the underlying arrangement, the level of effort required for us to fulfill our obligation and the anticipated timing of the fulfillment of our obligation. Accordingly, we have deferred the up-front license fee received from Merck Serono and are recognizing it as revenue on a straight-line basis over approximately 3.4 years, which represents our estimate of the time from inception of the agreement until European regulatory approval of Kuvan, for the treatment of PKU, at which point our performance obligations for developing Kuvan for the treatment of PKU will end. Our estimate of the Kuvan commercialization period is based on several underlying assumptions about uncertain events, including actions by European regulatory authorities, results of our ongoing clinical trials and successful commercial scale manufacturing of Kuvan. As Kuvan advances through the clinical development and regulatory process, our estimates of our performance obligation period may change. Changes in our estimates of our performance obligation period will be recognized prospectively over the remaining estimated performance obligation period. We regularly review our estimates of the period over which we have an ongoing performance obligation. There is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono.

Nonrefundable reimbursements 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 represented Merck Serono's share of Kuvan development costs under the agreement, which are recorded as research and development expenses.

Royalty and license revenues We recognize royalty revenue and royalty receivables in the periods these royalties are earned, in advance of collection. Royalty revenue and receivables are based upon data provided by the sublicensee.

The timing of customer purchases and the resulting product shipments have a significant impact on the amount of royalty revenue that we recognize in a particular period. The majority of Orapred sales are made to wholesalers, which, in turn, resell the product to retail outlets. Inventory in the distribution channel consists of inventory held by wholesalers, who are the principal customers for Orapred, and inventory held by retailers. Royalty revenues from Orapred sales in a particular period will be impacted by increases or decreases in wholesaler inventory levels. If wholesaler inventories continue to substantially exceed the retail demand, we could experience reduced royalty revenue in subsequent periods.

We deferred the up-front license fee of \$2.5 million received from Alliant for the North American Orapred rights, and recognized it as revenue on a straight-line basis over a period of approximately 5 months, which represented the estimated time from inception of the agreement until commercial launch of Orapred ODT, at which point our performance obligations ended. There are no cost of sales associated with the royalties and license revenues recorded during the period and we do not expect to incur related cost of sales in future periods. The commercial launch of Orapred ODT by our sublicensee occurred in August 2006.

As a result of the FDA approval for the marketing application for Orapred ODT in June 2006 and the commercial launch of Orapred ODT in August 2006, we received milestone payments of \$7.5 million and \$4.0 million, respectively. Milestone payments are recognized in full when the related milestone performance goal is achieved and we have no future performance obligations related to that payment.

Inventory

We value inventories at the lower of cost or fair value. We determine the cost of inventory using the average cost method. We analyze our inventory levels quarterly and write down inventory that has become obsolete, inventory that 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

Table of Contents

related costs are written off. The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical estimate in this determination is the estimate of the future expected inventory requirements, whereby we compare our internal sales forecasts to inventory on hand. Actual results may differ from those estimates and additional inventory write-offs may be required.

Regulatory approval for Naglazyme was received in May 2005, and costs related to the manufacturing of Naglazyme prior to this date were expensed as research and development expenses. We consider 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 related manufacturing costs for Naglazyme, prior to regulatory approval, were not capitalized as inventory. When regulatory approval was obtained in May 2005, we began capitalizing inventory at the lower of cost or fair value. As of March 31, 2007, Naglazyme inventory includes a small amount of pre-approval manufactured finished goods, which have an insignificant cost basis. The majority of the previously expensed inventory has been sold or used in clinical trials as of March 31, 2007. Stock-based compensation of \$0.4 million was capitalized into Naglazyme inventory for each of the three months ended March 31, 2006 and 2007.

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. Generally, in instances where we enter 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.

A critical accounting assumption by our management is that we believe that regulatory approval of our product candidates is uncertain, and do not assume that product manufactured prior to regulatory approval will be sold commercially. As a result, inventory costs for product candidates are expensed as research and development expenses until regulatory approval is obtained, at which time inventory is capitalized at the lower of cost or fair value. Historically, there have been no changes to this assumption.

Clinical Trial Accruals

We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CROs), clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in research and development expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed. No adjustments for material changes in estimates have been recognized in any period presented.

Stock Option Plans

We account for stock-based compensation in accordance with SFAS No. 123R, *Share-Based Payment*. Under the fair value recognition provisions of this statement, share-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating our stock price volatility and employee stock option exercise behaviors. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Our expected volatility is based upon proportionate weightings of the historical volatility of our stock and the implied volatility of traded options on our stock. The expected life of options is based on contractual life and observed historical exercise patterns, which can vary over time.

As stock-based compensation expense recognized in the consolidated statement of operations is based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical

experience.

Table of Contents

If factors change and we employ different assumptions in the application of SFAS No. 123R, the stock-based compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

Recent Accounting Pronouncements

See Note 2(n) of our accompanying consolidated financial statements for a full description of recent accounting pronouncements and our expectation of their impact on our results of operations and financial condition.

Results of Operations

All of the activities related to the manufacture, distribution and sale of Aldurazyme are reported in the results of the joint venture. Because of this presentation and the significance of the joint venture's results of operations, we have divided our discussion of the results of operations into two sections, BioMarin in total and BioMarin/Genzyme LLC. The discussion of the joint venture's operations includes the total amounts for the joint venture, not just our 50% interest in the operations.

BioMarin Results of Operations**Net Loss**

Our net loss in the first quarter of 2007 decreased by \$0.5 million, to \$9.3 million, from \$9.8 million for the first quarter of 2006. Net loss for the first quarter of 2007 decreased primarily as a result of the following (in millions):

Net loss for the first quarter of 2006	\$ (9.8)
Increased Naglazyme gross profit	8.2
Increased 6R-BH4 development costs for other indications, including endothelial dysfunction	(3.1)
Increased Naglazyme sales and marketing expenses	(2.6)
Increased profits from BioMarin/Genzyme LLC	2.4
Increased Phenylase development costs	(1.8)
Increased Kuvan commercial preparation costs	(0.8)
Decreased Naglazyme development expenses	0.5
Decreased collaborative agreement revenues	(0.4)
Decreased Orapred operating income	(0.4)
Increased Kuvan manufacturing and clinical trial costs	(0.3)
Increased stock-based compensation expense	(1.8)
Increased amortization of acquired intangible assets	(0.7)
Decreased interest expense	0.5
Increased interest income	3.0
Increase in corporate overhead and other	(2.2)
Net loss for the first quarter of 2007	\$ (9.3)

The increase in Naglazyme gross profit during the first quarter of 2007 as compared to the first quarter of 2006 is primarily the result of increased Naglazyme sales, primarily in the U.S. and E.U. and is the result of additional patients initiating therapy. See below for additional information related to the primary net loss fluctuations presented above. The increase in corporate overhead and other includes increases in facilities costs and salaries and benefits due to corporate expansion and increased research and development expense related to various other preclinical programs.

Net Product Sales and Gross Profit

Net product sales increased \$9.3 million to \$18.3 million in the first quarter of 2007 from \$9.0 million in the first quarter of 2006. Net product sales in the first quarter of 2007 were primarily related to net product sales of Naglazyme of \$18.4 million, which was partially offset by \$0.1 million of Orapred net product returns. Net product sales in the first quarter of 2006 of \$9.0 million included \$7.0 million of net product sales of Naglazyme and \$2.0 million of net product sales of Orapred, prior to the sublicense. We expect net product sales of Naglazyme to increase in

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

future periods, primarily due to additional patients initiating therapy.

We received marketing approval for Naglazyme in the U.S. in May 2005 and began shipping product in June 2005. In January 2006, we received marketing approval for Naglazyme in the E.U. Net product sales for Naglazyme in the first quarter of 2007 were \$18.4 million, of which \$14.2 million was from customers based outside of the U.S. The impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. in the first quarter of 2007 was a decrease to net product sales of approximately \$0.1 million. Gross profit was approximately \$14.2 million, representing gross margins of approximately 78%. In

Table of Contents

accordance with our inventory accounting policy, we began capitalizing Naglazyme inventory production costs after U.S. regulatory approval was obtained in May 2005. As a result, some of the product sold in the first quarter of 2007 had an insignificant cost basis and therefore lower cost of goods sold was reported. The majority of inventory with an insignificant cost basis has been sold or used in clinical trials as of March 31, 2007. Net product sales of Naglazyme during the first quarter of 2006 were \$7.0 million, of which \$3.9 million was from customers based outside of the U.S. A large portion of the product sold in the first quarter of 2006 also had an insignificant cost basis and gross profit in the first quarter of 2006 was \$6.1 million, representing gross margins of approximately 87%, as much of the product sold was manufactured prior to regulatory approval. Additionally, cost of sales in the first quarter of 2006 included \$0.5 million related to inventory write-offs. Excluding the inventory write-offs, gross margin would have been approximately 94%.

Commencing with our acquisition of the Ascent Pediatrics business in May 2004 and continuing through the sublicense in March 2006, our net product sales include sales of Orapred. During the first quarter of 2006, we recognized net product sales of \$2.0 million related to the Orapred product line, and approximately \$1.2 million of gross profit, representing a gross margin of approximately 60%. Net product sales in the first quarter of 2006 include a \$0.9 million benefit related to the reversal of certain rebate reserves. Excluding the rebate reserve reversal, gross margin would have been approximately 27%, reflecting approximately \$0.8 million of net product sales for the transfer of Orapred inventory to the sublicensee which was near our recorded cost. Cost of sales excluded the amortization of the developed product technology resulting from the acquisition of the Ascent Pediatrics business.

In March 2006, we sublicensed rights to sell and distribute Orapred in North America for up-front and milestone payments of \$18.0 million and royalties on future sales of all Orapred products, including Orapred ODT. As a result of the sublicense, we do not expect to record future net product sales related to the Orapred product line. Current and future revenue streams related to the Orapred product will include license and royalty revenues for future sales of Orapred product by the sublicensee, which are discussed below.

Collaborative Agreement Revenues

Collaborative agreement revenues include both license revenue and contract research revenue under our agreement with Merck Serono, which was executed in May 2005. License revenues are related to amortization of the \$25.0 million up-front license payment received from Merck Serono and contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. As development spending of the Kuvan and 6R-BH4 for other indications program increases or decreases, contract research revenues will also change proportionately following the completion of Phase 2 clinical trials for each indication. The related costs are included in research and development expenses.

Collaborative agreement revenues in the first quarter of 2006 and 2007 were \$4.5 million and \$4.1 million, respectively, and includes the amortization of \$1.9 million and \$1.8 million, respectively, of the up-front license fee received from Merck Serono and recognized as revenue during the period, and \$2.6 million and \$2.3 million, respectively, of reimbursable Kuvan development costs incurred during the period.

Royalty and License Revenues

Royalty and license revenues include royalty revenues from Orapred product sold by the sublicense of \$42,000 and \$0.3 million in the first quarter of 2006 and 2007, respectively. Royalty and license revenue for the first quarter of 2006 includes \$0.3 million related to the amortization of the \$2.5 million up-front license fee received from Alliant.

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 expenses increased by \$5.9 million to \$18.2 million for the first quarter of 2007, from \$12.3 million for the first quarter of 2006. Research and development expenses changed for the first quarter of 2007 primarily as a result of the following (in millions):

Research and development expenses for the first quarter of 2006	\$ 12.3
Increased 6R-BH4 development costs for other indications, including endothelial dysfunction	3.1
Increased Phenylase development costs	1.8

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

Decreased Naglazyme development expenses	(0.5)
Increased Kuvan clinical trial and manufacturing costs	0.3
Increased stock-based compensation expense	0.4
Increased research and development on other programs	0.8
Research and development expenses for the first quarter of 2007	\$ 18.2

Table of Contents

The increase in 6R-BH4 development costs is related to increases for pre-clinical studies of 6R-BH4 in other indications including endothelial dysfunction and costs related to planning and conducting Phase 2 clinical trials in peripheral arterial disease and sickle cell disease. The increase in Phenylase development costs is related to increases for pre-clinical studies and manufacturing costs. The decrease in Naglazyme development costs is primarily due to decreased clinical trial and manufacturing expenses, after marketing approval was received in May 2005. However, we expect to continue incurring significant Naglazyme research and development costs for the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments. The increase in research and development on other programs primarily includes increases in facilities costs and salaries and benefits. We expect research and development expense to increase in future periods, primarily as a result of spending on our 6R-BH4 program for other indications and on our Phenylase program.

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 in support of Naglazyme and our product candidates; human resources; finance, legal and support personnel expenses; and other corporate costs such as insurance, audit and legal expenses.

Selling, general and administrative expenses increased by \$5.4 million, to \$16.3 million for the first quarter of 2007, from \$10.9 million for the first quarter of 2006. The components of the increase for the first quarter of 2007 primarily include the following (in millions):

Selling, general and administrative expenses for the first quarter of 2006	\$ 10.9
Increased Naglazyme sales and marketing expenses	2.6
Increased stock-based compensation expense	1.3
Increased Kuvan commercial preparation costs	0.8
Decreased Orapred sales and marketing expenses	(0.3)
Net increase in corporate overhead and other administrative costs	1.0
Selling, general and administrative expenses for the first quarter of 2007	\$ 16.3

We initiated commercial operations in the E.U and Brazil during 2006 and incurred related costs during the first quarter of 2007 primarily related to the commercialization of Naglazyme. We expect additional costs to be incurred in future periods as a result. The increase in stock-based compensation expense is the result of an increased number of options outstanding and a higher average stock price on the related grant date. The increase in corporate overhead and other administrative costs is primarily related to increases in salaries and benefits for commercial and administrative support personnel and various other related support costs. We expect selling, general and administrative expenses to increase in future periods as a result of the increasing sales for Naglazyme and preparation for the potential commercial launch of Kuvan.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets includes the current amortization expense of the intangible assets acquired in the Ascent Pediatrics transaction in May 2004, including the Orapred developed and core technology. The acquired intangible assets are being amortized over approximately 3.5 years and the amortization expense for the first quarter of 2007 was \$1.1 million, compared to \$0.4 million for the first quarter of 2006. The increase in amortization expense is due to the change in expected useful life as the amortization period was revised from 15 years to 3.5 years following the sublicense of North American rights to Orapred in March 2006. Following our expected purchase of the common stock of Ascent Pediatrics from Medicis in August 2009, the underlying intellectual property will be transferred to Alliant. We expect that the recurring annual amortization expense associated with the intangible assets will be approximately \$4.4 million through the end of the expected useful life in August 2009.

Equity in the Income of BioMarin/Genzyme LLC

Equity in the income of BioMarin/Genzyme LLC includes our 50% share of the joint venture's income for the period. Equity in the income of BioMarin/Genzyme LLC was \$6.2 million for the first quarter of 2007, compared to \$3.8 million for the first quarter of 2006. The increase in profit from BioMarin/Genzyme LLC in the first quarter of 2007 was principally due to increases in Aldurazyme net revenue, which totaled \$26.8 million for the first quarter of 2007, compared to \$21.3 million for the first quarter of 2006. We expect our equity in the income of BioMarin/Genzyme LLC to increase in future periods, as net revenues for Aldurazyme continue to increase.

Table of Contents

Our equity in the income of the BioMarin/Genzyme LLC is now being presented as non-operating income in the consolidated statements of operations. During the first quarter of 2007, we determined that the significance of the joint ventures' operations had decreased on a relative basis compared to our other activities and that presenting the equity in the income of the joint venture as a non-operating income item was now more representative of the Company's operations as a whole. Changes to the proportionate significance of the operating nature of the joint venture to our total operations include the continued world-wide commercialization of Naglazyme, the planned commercial launch of Kuvan pending FDA approval, and the increasing requirements of our ongoing research and development programs. Prior periods have also been reclassified to conform to the current presentation.

See the *BioMarin/Genzyme LLC Results of Operations* section below for further discussion of the joint venture's results of operations.

Interest Income

We invest our cash and short-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income increased to \$3.7 million for the first quarter of 2007, from \$0.7 million for the first quarter of 2006, primarily due to higher interest rates and increased levels of cash and short-term investments during the first quarter of 2007.

Interest Expense

We incur interest expense on our convertible debt and on our equipment and facility loans. Interest expense also includes imputed interest expense on the discounted acquisition obligation for the Ascent Pediatrics transaction. Interest expense was \$2.3 million for the first quarter of 2007, as compared to \$2.8 million for the first quarter of 2006, representing a decrease of \$0.5 million. The decrease in the first quarter of 2007 is primarily due to the absence of the equipment and facility loans, which were repaid in April 2006, and for which \$0.3 million in interest expense was incurred during the first quarter of 2006. The decrease is also attributable to the conversion of the remaining \$51.4 million of 3.5% Senior Subordinated Convertible Notes due 2008 that were converted into approximately 3.7 million shares of common stock in the first quarter of 2007. Imputed interest expense totaled \$1.1 million for the first quarter of 2007, as compared to \$1.2 million for the first quarter of 2006.

In September 2006, certain holders of our 3.5% Senior Subordinated Convertible Notes due 2008 agreed to convert \$73.6 million in aggregate principal amount of the debt to approximately 5.25 million shares of our common stock. As a result of the conversion, we agreed to pay an inducement to the holders of approximately \$3.3 million. In January 2007, the remaining outstanding balance of \$51.4 million for our 3.5% Senior Subordinated Convertible Notes due 2008 were converted into approximately 3.7 million shares of common stock. In April 2007, we sold approximately \$324.9 million of 1.875% Senior Subordinated Convertible Notes due 2017. As a result, we expect interest expense to increase in future periods.

BioMarin/Genzyme LLC Results of Operations

The discussion below gives effect to the inventory capitalization policy that we use for inventory held by the joint venture, which is different from the joint venture's inventory capitalization policy. We began capitalizing Aldurazyme inventory production costs in May 2003, after U.S. regulatory approval was obtained. The joint venture began capitalizing Aldurazyme inventory production costs in January 2002, when inventory production for commercial sale began. The difference in inventory capitalization policies results in a greater operating expense realized by us prior to regulatory approval, and lower cost of goods sold with higher gross profit realized by us post-regulatory approval as the previously expensed product is sold by the joint venture, as well as lower research and development expense when Aldurazyme is used in on-going clinical trials. These differences will be eliminated when all of the product manufactured prior to regulatory approval has been sold or has been used in clinical trials. The majority of the differences have been eliminated as of March 31, 2007. See Note 6(a) to the accompanying consolidated financial statements for further discussion of the difference in inventory cost basis between the joint venture and us.

Revenue and Gross Profit

The joint venture received marketing approval for Aldurazyme in the U.S. in April 2003 and in the E.U. in June 2003. We have subsequently received marketing approval in other countries. Aldurazyme was launched commercially in May 2003 in the U.S. and in June 2003 in the E.U. The joint venture recognized \$26.8 million of net revenue for the first quarter of 2007, compared to \$21.3 million for the first quarter of 2006. The increase in net revenue of \$5.5 million is primarily attributable to an increase in the number of patients receiving therapy. We expect net revenue of Aldurazyme to increase in future periods, primarily due to additional patients initiating therapy.

Table of Contents

Gross profit was \$20.5 million for the first quarter of 2007, as compared to \$15.7 million for the first quarter of 2006, representing an increase of \$4.8 million. Gross margins for the first quarter of 2007 were approximately 77%, as compared to gross margins for the first quarter of 2006 of 74%. The increase in gross margin during the first quarter of 2007 as compared to the first quarter of 2006 is attributable to improvements in manufacturing yields for Aldurazyme.

Operating Expenses

Operating expenses of the joint venture include the costs associated with the development and commercial support of Aldurazyme and totaled \$8.4 million for the first quarter of 2007, as compared to \$8.3 million for the first quarter of 2006. Operating expenses in the first quarter of 2007 included \$5.8 million of selling, general and administrative expenses associated with the commercial support of Aldurazyme, and \$2.6 million of research and development costs, primarily long-term clinical trial and regulatory costs. Operating expenses in the first quarter of 2006 included \$4.8 million of selling, general and administrative expenses associated with the commercial support of Aldurazyme, and \$3.5 million of research and development expenses, primarily long-term clinical trial and regulatory costs.

Liquidity and Capital Resources**Cash and Cash Flow**

As of March 31, 2007, our combined cash, cash equivalents and short-term investments totaled \$273.3 million, a decrease of \$15.5 million from \$288.8 million at December 31, 2006. During the first quarter of 2007, we financed our operations primarily through available cash, cash equivalents and short-term investments, the related interest income earned thereon and net product sales. During the first quarter of 2006, we received \$127.5 million of net proceeds from a public offering of common stock, \$167.0 million of net proceeds from a public offering of convertible senior subordinated debt and \$2.5 million as consideration for execution of our sublicense of North American rights for Orapred.

The decrease in cash, cash equivalents, short-term investments and cash balances related to long-term debt during the first quarter of 2007 was \$15.5 million, which was \$3.9 million more than the net decrease in cash, cash equivalents, short-term investments and cash balances related to long-term debt during the first quarter of 2006 of \$11.6 million, excluding net offering proceeds of \$294.5 million. The primary items contributing to the increase in net cash outflow, excluding net offering proceeds, in the first quarter of 2007 were as follows (in millions):

Increased capital asset purchases	\$ (2.4)
Decreased proceeds from stock option exercises	(2.2)
Absence of license proceeds related to sublicense of North American Orapred rights	(2.5)
Decreased cash flows from BioMarin/Genzyme LLC	(1.6)
Decreased operating spend, net, partially offset by working capital increases	3.6
Other	1.2
Total increase in net cash outflow excluding net offering proceeds	\$ (3.9)

The net decreased 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 the Results of Operations section above. Increases in net payments for working capital primarily include accounts payable and accrued liabilities of \$5.8 million. Our accounts payable and accrued liabilities decreased by \$6.8 million during the first quarter of 2007 as compared to a decrease of \$1.0 million during the first quarter of 2006.

Pursuant to our settlement of a dispute with Medicis in January 2005, Medicis made available to us a convertible note of up to \$25.0 million beginning July 1, 2005 based on certain terms and conditions and provided that the Company does not experience a change of control. Money advanced under the convertible note is convertible into our common stock, at Medicis' option, according to the terms of the convertible note. As of March 31, 2007, we have not made any draws on the note. We anticipate that we will only draw funds from this note to the extent necessary to fund operations.

In April 2007, we received approximately \$316.4 million of net proceeds from a public offering of convertible senior subordinated debt.

Funding Commitments

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

We expect to fund our operations with our net product sales, cash, cash equivalents and short-term investments supplemented by

Table of Contents

proceeds from equity or debt financings, loans or collaborative agreements with corporate partners, to the extent necessary. We expect our current cash, cash equivalents and short-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 the amounts that we elect to spend on our development programs, including potentially multiple indications for 6R-BH4.

Our investment in our product development programs has a major impact on our operating performance. Our research and development expenses for the first quarter of 2006 and 2007 and for the period since inception (March 1997) represent the following (in millions):

	Three Months Ended		Since
	March 31, 2006	March 31, 2007	Program Inception
Naglazyme	\$ 2.9	\$ 2.4	\$ 106.6
Kuvan	5.1	5.4	64.5
6R-BH4 for other indications, including endothelial dysfunction	0.6	3.4	15.8
Phenylase	1.0	2.8	9.8
Orapred	0.6	0.2	10.7
Not allocated to specific major current projects	2.1	4.0	128.4
	\$ 12.3	\$ 18.2	\$ 335.8

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, 2006, for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in our 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 and 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 time frames 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 and Kuvan; preclinical studies and clinical trials for our other product candidates; potential licenses and other acquisitions of complementary technologies, products and companies; general corporate purposes; payment of the amounts due with respect to the Ascent Pediatrics transaction; 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;

our joint venture partner's ability to successfully commercialize Aldurazyme;

the progress, timing, scope and results of our preclinical studies and clinical trials;

the amount of royalties we receive from our license of Orapred;

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;

Table of Contents

the time and cost necessary to respond to technological and market developments;

any changes made to or new developments in our existing collaborative, licensing and other commercial relationships or any new collaborative, licensing and other commercial relationships that we may establish; and

whether our convertible debt is converted to common stock in the future.

Borrowings and Contractual Obligations

Our \$172.5 million of 2.5% Senior Subordinated Convertible Notes due 2013 will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayment of the debt in 2013. There is no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2013. 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.

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, which will also impact our liquidity. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of our common stock at a conversion price of approximately \$20.36 per share, subject to adjustment in certain circumstances. There is no call provision included and the Company is 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 its common stock.

As a result of the Ascent Pediatrics transaction, we expect to pay Medicis \$85.4 million through 2009, of which \$5.3 million is payable during the remainder of 2007. At our option, we may elect to pay Medicis \$8.6 million of the amounts due in 2009 through the issuance of our common stock.

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 March 31, 2007 is presented below (in thousands).

	Payments Due by Period					2013 and
	Total	Remainder of 2007	2008	2009-2010	2011-2012	Thereafter
Medicis obligations	\$ 85,350	\$ 5,250	\$ 6,500	\$ 73,600	\$	\$
Convertible debt and related interest (1)	198,375	2,156	4,313	8,625	8,625	174,656
Operating leases	24,933	2,725	3,815	7,872	7,350	3,171
Research and development and purchase commitments	21,913	14,622	6,277	115	115	784
Total	\$ 330,571	\$ 24,753	\$ 20,905	\$ 90,212	\$ 16,090	\$ 178,611

(1) Amounts exclude payments related to the \$324.9 million of 1.875% Senior Subordinated Convertible Notes due 2017, which were sold in April 2007.

We are also subject to contingent payments related to various development activities totaling approximately \$30.0 million, which are due upon achievement of certain regulatory and licensing milestones, and if they occur before certain dates in the future.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Our market risks at March 31, 2007 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2006, on file with the Securities and Exchange Commission (SEC).

Item 4. 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, of 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) 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 are sufficiently effective to ensure that the information required to be disclosed by us in this Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and instructions for Form 10-Q. There was no change in our internal control over financial reporting that occurred during the period covered by this Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

The Company is not party to any legal proceedings not arising in the ordinary course of its business.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the trading price of our securities to decline, and you may lose all or part of your investment. The risk factors previously disclosed in Item 1A. of our Form 10-K for fiscal year ended December 31, 2006 have remained substantially unchanged.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds. None.

Item 3. Defaults upon Senior Securities. None.

Item 4. Submission of Matters to a Vote of Security Holders. None.

Item 5. Other Information.

On April 9, 2007, we entered into updated employment agreements with each of our executive officers, except for our Chief Executive Officer. The following executive officers signed employment agreements, with base annual salaries as indicated: Jeffrey H. Cooper, Senior Vice President, Chief Financial Officer, \$280,500; Emil D. Kakkis, M.D., Ph.D., Chief Medical Officer, \$315,000; Stephen Aselage, Senior Vice President, Global Commercial Operations, \$296,000; Robert A. Baffi, Ph.D., Senior Vice President, Technical Operations, \$285,000; Stuart J. Swiedler, M.D., Ph.D., Senior Vice President, Clinical Affairs, \$285,500; and G. Eric Davis, Vice President, General Counsel, \$276,900. These agreements superseded any prior agreement that we had with the respective executive officer. Copies of these agreements are attached as exhibits hereto.

Item 6. Exhibits.

- 1.1 Purchase Agreement dated April 17, 2007, by and between BioMarin Pharmaceutical Inc. and Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, previously filed with the Commission on April 23, 2007 as Exhibit 1.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 4.1 Second Supplemental Indenture dated April 23, 2007, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on April 23, 2007 as Exhibit 4.1 to the Company's Form 8-K, which is incorporated herein by

Edgar Filing: BIOMARIN PHARMACEUTICAL INC - Form 10-Q

reference.

- 4.3 Form of 1.875% Senior Subordinated Convertible Notes due 2017, previously filed with the Commission on April 23, 2007 as Exhibit 4.2 to the Company's Form 8-K, which is incorporated herein by reference.
- 10.1* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Jeffrey H. Cooper dated April 9, 2007.
- 10.2* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Emil D. Kakkis, M.D., Ph.D., dated April 9, 2007.

Table of Contents

- 10.3* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Robert A. Baffi, Ph.D., dated April 9, 2007.
- 10.4* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Stephen Aselage, dated April 9, 2007.
- 10.5* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Stuart J. Swiedler, M.D., Ph.D., dated April 9, 2007.
- 10.6* Employment Agreement by and between BioMarin Pharmaceutical Inc. and G. Eric Davis dated April 9, 2007.
- 10.7* License Agreement between BioMarin Pharmaceutical Inc. and Women s and Children s Hospital dated February 7, 2007. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 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. 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.

* - Filed herewith

Table of Contents

SIGNATURE

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

BIOMARIN PHARMACEUTICAL INC.

Dated: May 3, 2007

By: /s/ JEFFREY H. COOPER
Jeffrey H. Cooper, Chief Financial Officer
(On behalf of the registrant and as principal financial officer)

37

Table of Contents

Exhibit Index

- 1.1 Purchase Agreement dated April 17, 2007, by and between BioMarin Pharmaceutical Inc. and Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, previously filed with the Commission on April 23, 2007 as Exhibit 1.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 4.1 Second Supplemental Indenture dated April 23, 2007, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on April 23, 2007 as Exhibit 4.1 to the Company's Form 8-K, which is incorporated herein by reference.
- 4.3 Form of 1.875% Senior Subordinated Convertible Notes due 2017, previously filed with the Commission on April 23, 2007 as Exhibit 4.2 to the Company's Form 8-K, which is incorporated herein by reference.
- 10.1* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Jeffrey H. Cooper dated April 9, 2007.
- 10.2* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Emil D. Kakkis, M.D., Ph.D., dated April 9, 2007.
- 10.3* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Robert A. Baffi, Ph.D., dated April 9, 2007.
- 10.4* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Stephen Aselage, dated April 9, 2007.
- 10.5* Employment Agreement by and between BioMarin Pharmaceutical Inc. and Stuart J. Swiedler, M.D., Ph.D., dated April 9, 2007.
- 10.6* Employment Agreement by and between BioMarin Pharmaceutical Inc. and G. Eric Davis dated April 9, 2007.
- 10.7* License Agreement between BioMarin Pharmaceutical Inc. and Women's and Children's Hospital dated February 7, 2007. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 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. 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.

* - Filed herewith