BioMarin InvestorRoom

BioMarin Announces First Quarter 2009 Financial Results

Net Product Revenue Increase of 25% Led by Naglazyme International Expansion
Conference Call and Webcast to Be Held Today at 5:00 p.m. ET (22:00 CET)

PRNewswire-FirstCall
NOVATO, Calif.

Financial Highlights ($ in millions, except per share data)

Item	Q1 2009	Q1 2008 Comparison
Total BioMarin Revenue	$74.0	23% increase
Total Net Product Revenue	$71.9	25% increase
Naglazyme Net Product Revenue	$39.4	42% increase
Aldurazyme Net Sales by Genzyme	$36.8	No change
Aldurazyme BioMarin Net Product Revenue	$17.0	29% decrease*
Kuvan Net Product Revenue	$15.5	168% increase
GAAP Net Income (Loss)	$(13.2)	$1.7
GAAP Net Income (Loss) per share	$(0.13) (basic and diluted)	$0.02 (basic and diluted)
Non-GAAP Net Income	$9.3	$4.1
Non-GAAP Net Income per share	$0.09 (basic and diluted)	$0.04 (basic and diluted)

* The decrease in Aldurazyme BioMarin net product revenue is attributable to the one-time transfer of a significant amount of Aldurazyme inventory in the first quarter of 2008 concurrent with the restructuring of the BioMarin/Genzyme LLC. Total incremental product revenue totaled $9.5 million in the first quarter of 2008, compared to $2.5 million in the first quarter of 2009. The number of patients on Aldurazyme therapy worldwide continues to increase.

BioMarin Pharmaceutical Inc. today announced financial results for the first quarter ended March 31, 2009. GAAP net loss was $13.2 million ($0.13 per fully diluted share) for the first quarter of 2009, compared to GAAP net income of $1.7 million ($0.02 per fully diluted share) for the first quarter of 2008.

Non-GAAP net income was $9.3 million ($0.09 per fully diluted share) for the first quarter of 2009, compared to non-GAAP net income of $4.1 million ($0.04 per fully diluted share) for the first quarter of 2008. Non-GAAP net income/loss excludes non-cash stock compensation expense, and to provide more clarity on BioMarin's ongoing core business, also excludes certain nonrecurring material items and the tax effect of the adjustments.

As of March 31, 2009, BioMarin had cash and short and long-term investments totaling $555.9 million.

"All three of our commercial products are independently profitable, which helps fund the advancement of several promising programs including PEG-PAL for PKU and GALNS for MPS IVA. We are strategically developing earlier stage programs and looking for attractive later stage in-licensing or acquisition opportunities to ensure continued growth," said Jean-Jacques Bienaime, Chief Executive Officer of BioMarin.

Mr. Bienaime continued, "Starting in the first quarter of 2009, we are adjusting our methodology of our non-GAAP net income to provide more clarity on our ongoing core business, Naglazyme, Kuvan and Aldurazyme, and to allow for a better basis of comparison across time periods. The 2009 non-GAAP guidance, and historical quarterly financial results presented exclude nonrecurring material items and the tax effect of those adjustments in addition to non-cash stock compensation expense. We feel confident in meeting our overall top and bottom line financial objectives for 2009. Excluding nonrecurring material items, both our R&D and SG&A expenses remained flat in the first quarter of 2009 compared to the fourth quarter of 2008. We will continue to carefully manage expenses and product development choices in our pipeline to maximize long-term value for both the company and our shareholders."

Net Product Revenue

Net product revenue from Naglazyme (galsulfase), an enzyme replacement therapy for mucopolysaccharidosis VI (MPS VI), was $39.4 million for the first quarter of 2009, an increase of 42.2 percent compared to Naglazyme net product revenue of $27.7 million for the first quarter of 2008.

Net sales of Aldurazyme (laronidase), an enzyme replacement therapy for mucopolysaccharidosis I (MPS I) recorded by Genzyme, were $36.8 million for the first quarter of 2009, which was flat compared to net sales by Genzyme for the first quarter of 2008. In the first quarter of 2009, changes in foreign exchange rates caused a negative impact of $3.6 million of Aldurazyme sales by Genzyme. However, in the first quarter of 2009, Aldurazyme unit volume increased nine percent compared to the first quarter of 2008 as the number of patients on therapy worldwide continues to grow.

Net product revenue to BioMarin related to Aldurazyme was $17.0 million for the first quarter of 2009, including $2.5 million of incremental product transfer revenue. This compares to net product revenue to BioMarin of $24.1 million, which included $9.5 million of incremental product transfer revenue for the first quarter of 2008. During both the first quarter of 2009 and the first quarter of 2008, BioMarin recorded net product revenue that was higher than the royalty earned on Genzyme third party sales during the respective periods due to the incremental product transfer revenue related to net increases in Genzyme Aldurazyme inventory levels during each period.

Net product revenue from Kuvan (sapropterin dihydrochloride) Tablets, a product for the treatment of phenylketonuria (PKU), was $15.5 million for the first quarter of 2009, compared to $5.8 million for the first quarter of 2008. The quantity of commercial tablets dispensed to patients, the best metric to track true patient demand, increased 9.5 percent in the first quarter of 2009 compared to the fourth quarter of 2008.

Impairment Loss on La Jolla Pharmaceutical Company and Summit Corporation Investments

In the first quarter of 2009, BioMarin recorded impairment loss on investments of $5.9 million, comprised of $1.4 million related to its equity investment in Summit Corporation plc and $4.5 million related to its equity investment in La Jolla Pharmaceutical Company. The remaining investments of $0.2 million in Summit Corporation and $1.8 million in La Jolla Pharmaceutical are reflected on the balance sheet as of March 31, 2009. Since both of these companies have announced that they do not have sufficient resources to fund operations for the next twelve months, the guidance below reflects the assumption that the remaining investments in both companies will be written down to zero by the end of the year.

2009 Guidance

All revenue and selected income statement guidance remains unchanged from the press release issued February 18, 2009 with the exception of research and development expense, impairment loss on investments and non-GAAP net income.

Revenue Guidance ($ in millions)

Item	2009 Guidance	2008 Actual
Total BioMarin Revenues	$307 to $336	$296.5
Total Net Product Revenues	$300 to $329	$251.9
Naglazyme Net Product Revenue	$160 to $175	$132.7
Kuvan Net Product Revenue	$70 to $80	$46.7
Aldurazyme Net Product Revenue to BioMarin	$69 to $74	$72.5

Selected Income Statement Guidance ($ in millions)

Item	Guidance	2008 Actual
Cost of Sales (% of Total Revenue)*	19% to 21%	17.7%
Selling, General and Admin. Expense	$120 to $130	$106.6
Research and Development Expense**	$118 to $128	$93.3
Interest Income	$5 to $7	$16.4
Impairment Loss on La Jolla and Summit Investments***	$7.9	$4.1
GAAP Net Income (Loss)	$(15) to $0	$30.8
Stock Compensation Expense	$32 to $35	$25.3
Non-GAAP Net Income****	$33.7 to $51.7	$30.0

* Cost of sales as a percent of total revenue was lower in 2008 due to the impact of higher collaborative revenue, including the $30 million milestone payment from Merck Serono.

** Includes upfront research and development expenses of $8.8 million

associated with the La Jolla Pharmaceutical Company transaction.

*** Represents impairment losses on investments in La Jolla Pharmaceutical Company of $4.5 million and Summit plc of $1.4 million during the first quarter of 2009 and additionally, BioMarin expects to record up to an additional $2.0 million of impairment losses totaling $7.9 million during 2009.

**** Non-GAAP net income excludes non-cash stock compensation expense, nonrecurring material items and the tax effect of the adjustments. Please see the table provided at the end of this press release for a full reconciliation between GAAP and non-GAAP expected net income.

Non-GAAP Financial Information and Reconciliation

The above results for the first quarter of 2009, first quarter of 2008, full year results for 2008 and financial guidance for 2009 are determined in accordance with GAAP. As used in this release, non-GAAP income is calculated in accordance with GAAP, but excludes non-cash stock compensation expense, certain nonrecurring material items and the tax effect of the adjustments.

Non-GAAP net income in the first quarter of 2009 and the first quarter of 2008 excluded (1) stock compensation expense of $7.8 million in the first quarter of 2009 and $4.5 million for the first quarter of 2008; (2) upfront license fees of $8.8 million associated with the Riquent transaction classified as research and development expense in the first quarter of 2009; (3) impairment charges of $5.9 million in the first quarter of 2009; (4) the gross margin associated with the initial Aldurazyme product transfer to Genzyme of $2.3 million associated with the restructuring BioMarin/Genzyme LLC in the first quarter of 2008 and (5) income tax effect of $0.2 million in the first quarter of 2008.

Anticipated non-GAAP net income for the year ended December 31, 2009 and actual results for the year ended December 31, 2008 exclude (1) stock compensation expense in the range of $32 million to $35 million for 2009 and $25.3 million for 2008; (2) upfront license fees of $8.8 million associated with the Riquent transaction million in 2009 and $1.4 million associated with the Summit transaction in 2008; (3) impairment charges of $7.9 million in 2009 and $4.1 million in 2008; (4) Kuvan approval milestones of $31.5 million in 2008; (5) the gross margin of the initial Aldurazyme product transfer to Genzyme of $2.3 million associated with the restructuring of BioMarin/Genzyme LLC in the first quarter of 2008 and (6) income tax effect of $2.2 million in 2008. The reconciliation of these measures to the estimated GAAP net income is detailed in the table provided at the end of the press release.

BioMarin believes that this non-GAAP information is useful to investors, taken in conjunction with BioMarin's GAAP information because it provides additional information regarding the performance of BioMarin's core ongoing business, Naglazyme, Kuvan and Aldurazyme and development of its pipeline. By providing information about both the overall GAAP financial performance and the non-GAAP measures that focus on continuing operations, the company believes that the additional information enhances investors' overall understanding of the company's business and prospects for the future. Further, the company uses both the GAAP and the non-GAAP results and expectations internally for its operating, budgeting and financial planning purposes.

Research and Development Programs

BioMarin continues to make significant investments in research and development to ensure continued growth of the company. The current pipeline includes programs which are in various stages of development and are focused on treating a range of unmet medical needs. BioMarin is also making investments in manufacturing and laboratory facilities to support the advancement of these programs.

- PEG-PAL for PKU: BioMarin has completed dosing the fifth cohort of patients in the Phase I trial. The company is in communication with the FDA regarding the Phase II trial design and expects to initiate the study in the second quarter of 2009. Results from the Phase II PEG-PAL trial are expected in mid-2010.
- GALNS for MPS IVA: BioMarin initiated the Phase I/II trial in mid-April 2009. The Phase I/II study is an open-label, within-patient dose escalation trial followed by a treatment continuation phase. The company expects to report initial results in the first half of 2010. Assuming positive results from the Phase I/II study, BioMarin expects to initiate a pivotal Phase III study in the second half of 2010.
- 6R-BH4 for cardiovascular indications: The investigator-sponsored Phase Ib multi-center, open-label dose-escalation study in PAH showed that the drug was well-tolerated and improved six-minute walk distance in patients compared to their pre-treatment baseline levels. The

single-center, investigator-sponsored trial of chronic kidney disease showed that 6R-BH4 was safe and well-tolerated in patients but showed no improvements in either the primary endpoint of albuminuria or secondary endpoints. BioMarin expects to communicate a decision on the future of the 6R-BH4 cardiovascular program by the third quarter of 2009.

-- BMN-195 - Utrophin upregulator for Duchenne Muscular Dystrophy: BioMarin is completing reformulation work and toxicology studies and expects to initiate a Phase I trial by the first quarter of 2010. BMN-195 is an orally available small molecule which may upregulate utrophin, a potential replacement for the missing dystrophin protein in DMD patients.

-- BMN-103 - alpha-glucosidase (GAA) for Pompe Disease: BioMarin expects to make a decision on the strategic direction for BMN-103 by the third quarter of 2009. BMN-103 is a highly phosphorylated GAA enzyme, which the company believes could result in more efficient uptake in cells and potentially lead to improved glycogen reduction in key affected muscle groups not addressed with current therapy.

-- BMN-168 - 6R-BH4 Prodrug: BioMarin is proceeding with important preclinical studies and plans to initiate IND-enabling toxicology studies by the third quarter of 2009. A small-scale GMP process is in place, and BioMarin expects to proceed with large-scale process development by the end of 2009.

-- BMN-185 - IgA protease for IgA nephropathy: BioMarin is completing lead optimization and preclinical work and expects to make a decision on continuation of the program by the end of 2009. IgA proteases have been shown to cleave IgA complexes, the deposition of which causes IgA nephropathy, an orphan kidney disorder with few treatment alternatives.

-- Handheld blood Phe monitor: BioMarin has successfully completed early proof-of-concept studies and is proceeding with prototype development. Near term plans include user studies as well as engineering scale-up and finalization of commercial product design, with expected availability in late 2010.

Anticipated Upcoming Milestones

-- 2Q09: Results from PEG-PAL Phase I trial
-- 2Q09: Initiation of PEG-PAL Phase II trial
-- 3Q09: Decision on strategy for BMN-103 for Pompe Disease
-- 3Q09: Decision on 6R-BH4 cardiovascular program
-- 1Q10: Initiation of Phase I trial for BMN-195 for DMD
-- 1H10: Results from Phase I/II trial for GALNS for MPS IVA
-- Mid-2010: Results from PEG-PAL Phase II trial
-- 2H10: Initiation of pivotal Phase III trial for GALNS for MPS IVA

-- 2H10: Availability of blood Phe monitor

Conference Call Details

BioMarin will host a conference call and webcast to discuss first quarter 2009 financial results today, Thursday, April 30, at 5:00 p.m. ET (22:00 CET). This event can be accessed on the investor section of the BioMarin website at www.BMRN.com.

Date: April 30, 2009
Time: 5:00 p.m. ET (22:00 CET)
U.S. / Canada Dial-in Number: 866.383.7998
International Dial-in Number: 617.597.5329
Participant Code: 63957862
Replay Dial-in Number: 888.286.8010
Replay International Dial-in Number: 617.801.6888
Replay Code: 48152268

About BioMarin

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company's product portfolio comprises three approved products and multiple clinical and pre-

clinical product candidates. Approved products include Naglazyme(R) (galsulfase) for mucopolysaccharidosis VI (MPS VI), a product wholly developed and commercialized by BioMarin; Aldurazyme(R) (laronidase) for mucopolysaccharidosis I (MPS I), a product which BioMarin developed through a 50/50 joint venture with Genzyme Corporation; and Kuvan(R) (sapropterin dihydrochloride) Tablets, for phenylketonuria (PKU), developed in partnership with Merck Serono, a division of Merck KGaA of Darmstadt, Germany. Other product candidates include PEG-PAL (PEGylated recombinant phenylalanine ammonia lyase), which is currently in Phase I clinical development for the treatment of PKU and GALNS (N-acetylgalactosamine 6-sulfatase), which is currently in Phase I/II clinical development for the treatment of MPS IVA. For additional information, please visit www.BMRN.com. Information on BioMarin's website is not incorporated by reference into this press release.

Forward-Looking Statement

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the expectations of revenue and sales related to Naglazyme, Kuvan, and Aldurazyme; the financial performance of the BioMarin as a whole; the timing of BioMarin's clinical trials of PEG-PAL, GALNS and other product candidates; the continued clinical development and commercialization of Aldurazyme, Naglazyme, Kuvan, and its product candidates; and actions by regulatory authorities. These forward-looking statements are predictions and involve risks and uncertainties such that actual results may differ materially from these statements. These risks and uncertainties include, among others: our success in the continued commercialization of Naglazyme and Kuvan; Genzyme Corporation's success in continuing the commercialization of Aldurazyme; results and timing of current and planned preclinical studies and clinical trials; our ability to successfully manufacture our products and product candidates; the content and timing of decisions by the U.S. Food and Drug Administration, the European Commission and other regulatory authorities concerning each of the described products and product candidates; the market for each of these products and particularly Aldurazyme, Naglazyme and Kuvan; actual sales of Aldurazyme, Naglazyme and Kuvan; Merck Serono's activities related to Kuvan; and those factors detailed in BioMarin's filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption "Risk Factors" in BioMarin's 2008 Annual Report on Form 10-K, and the factors contained in BioMarin's reports on Form 10-Q. Stockholders are urged not to place undue reliance on forward-looking statements, which speak only as of the date hereof. BioMarin is under no obligation, and expressly disclaims any obligation to update or alter any forward-looking statement, whether as a result of new information, future events or otherwise.

Contact:

Investors
Eugenia Shen
BioMarin Pharmaceutical Inc.
(415) 506-6570

Media
Susan Berg
BioMarin Pharmaceutical Inc.
(415) 506-6594

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except for share and per share data)

	December 31, 2008 (1)	March 31, 2009 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$222,900	$214,579
Short-term investments	336,892	337,290
Accounts receivable, net	54,298	61,355
Inventory	73,162	76,423
Other current assets	50,444	23,928
Total current assets	737,696	713,575
Investment in BioMarin/Genzyme LLC	915	367
Long-term investments	1,633	4,011
Property, plant and equipment, net	124,979	142,252
Intangible assets, net	7,626	6,316
Goodwill	21,262	21,262
Other assets	12,584	12,500

Total assets	$906,695	$900,283
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$59,033	$55,877
Acquisition obligation, net of discount	70,741	70,317
Deferred revenue	307	120
Total current liabilities	130,081	126,314
Convertible debt	497,083	497,083
Other long-term liabilities	2,856	2,946
Total liabilities	630,020	626,343
Stockholders' equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2008 and March 31, 2009; 99,868,145 and 99,977,953 shares issued and outstanding at December 31, 2008 and March 31, 2009, respectively	100	100
Additional paid-in capital	852,947	862,373
Company common stock held by deferred compensation plan	(882)	(854)
Accumulated other comprehensive income	1,106	2,069
Accumulated deficit	(576,596)	(589,748)
Total stockholders' equity	276,675	273,940
Total liabilities and stockholders' equity	$906,695	$900,283

(1) December 31, 2008 balances were derived from the audited consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three Months Ended March 31, 2008 and 2009
(In thousands, except for per share data, unaudited)

	Three Months Ended March 31,	
	2008	2009
Revenues:		
Net product revenues	$57,625	$71,914
Collaborative agreement revenues	2,465	509
Royalty and license revenues	306	1,557
Total revenues	60,396	73,980
Operating expenses:		
Cost of sales	17,188	14,362
Research and development	17,628	34,358
Selling, general and administrative	23,669	28,568
Amortization of acquired intangible assets	1,093	1,093
Total operating expenses	59,578	78,381
Income (Loss) from operations	818	(4,401)
Equity in the loss of BioMarin/Genzyme LLC	(533)	(547)
Interest income	5,649	2,153
Interest expense	(4,110)	(4,087)
Impairment loss on equity investments	-	(5,853)
Income (Loss) before income taxes	1,824	(12,735)
Provision for income taxes	138	417

Net income (loss)	$1,686	$(13,152)
Net income (loss) per share, basic and diluted	$0.02	$(0.13)
Weighted average common shares outstanding, basic	97,647	99,902
Weighted average common shares outstanding, diluted	103,869	99,933

	Three Months Ended March 31,	
	2008	2009
Cost of sales	$197	$564
Research and development expense	1,557	2,475
Selling, general and administrative expense	2,710	4,757
Total stock-based compensation expense	$4,464	$7,796

Reconciliation of GAAP Net Income (Loss) to Non-GAAP Net Income
(In millions, except per share data)
(Unaudited)

		Three Months Ended March 31,		Year Ended December 31,	
Notes:		2008	2009	2008	2009
		(actuals)		(actuals)	(forecast)
GAAP Net Income (Loss)		$1.7	$(13.2)	$30.8	$(15.0) to 0.0
Stock-based compensation expense		4.5	7.8	25.3	32.0 to 35.0
Upfront license fees	(1)	-	8.8	1.4	8.8
Impairment loss on La Jolla and Summit investments	(2)	-	5.9	4.1	7.9
Kuvan Approval Milestones	(3)	-	-	(31.5)	-
Aldurazyme transfer revenue	(4)	(2.3)	-	(2.3)	-
Income tax effect	(5)	0.2	-	2.2	(0.0)
Non-GAAP net income		$4.1	$9.3	$30.0	$33.7 to $51.7

Notes:

(1) Represents upfront license payments related to our collaboration agreements with Summit Corporation plc and La Jolla Pharmaceutical Company in 2008 and 2009, respectively.

(2) Includes $5.9 million of impairment losses on investments in La Jolla Pharmaceutical Company and Summit plc. during the first quarter of 2009. If their respective stock prices decrease further during 2009, BioMarin expects to record up to an additional $2.0 million of impairment losses totaling $7.9 million during 2009.

(3) Represents approval milestones earned in July 2008 of $1.5 million for the Japanese approval of Kuvan and in December 2008 of $30.0 million for the EMEA approval of Kuvan.

(4) Represents gross margin associated with the initial Aldurazyme product transfer to Genzyme of $2.3 million associated with the restructuring BioMarin/Genzyme LLC in the first quarter of 2008.

(5) Represents the tax effect of the adjustments.

First Call Analyst:

FCMN Contact: eshen@bmrn.com

SOURCE: BioMarin Pharmaceutical Inc.

CONTACT: Investors, Eugenia Shen, +1-415-506-6570, or Media, Susan Berg,
+1-415-506-6594, both of BioMarin Pharmaceutical Inc.

Web Site: http://www.bmrn.com/
