BioMarin Announces Second Quarter 2009 Financial Results

Net Product Revenue Increase of 35% Drives Profitable Quarter 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	Q2 2009	Q2 2008 Comparison
Total BioMarin Revenue	$82.8	29% increase
Total Net Product Revenue	$81.5	35% increase
Naglazyme Net Product Revenue	$42.9	22% increase
Aldurazyme Net Sales by Genzyme	$39.2	1% increase
Aldurazyme BioMarin Net Product Revenue	$21.6	62% increase
Kuvan Net Product Revenue	$16.9	41% increase
GAAP Net Income	$1.3	$3.8
GAAP Net Income per share	$0.01 (basic and diluted)	$0.04 (basic and diluted)
Non-GAAP Net Income	$9.0	$9.7
Non-GAAP Net Income per share	$0.09 (basic and diluted)	$0.09 (diluted), $0.10 (basic)

BioMarin Pharmaceutical Inc. today announced financial results for the second quarter ended June 30, 2009. GAAP net income was $1.3 million ($0.01 per diluted share) for the second quarter of 2009, compared to GAAP net income of $3.8 million ($0.04 per diluted share) for the second quarter of 2008. Non-GAAP net income was $9.0 million ($0.09 per diluted share) for the second quarter of 2009, compared to non-GAAP net income of $9.7 million ($0.09 per diluted share) for the second quarter of 2008. Non-GAAP net income/loss excludes non-cash stock compensation expense, certain nonrecurring material items and the tax effect of the adjustments.

GAAP net loss for the six months ended June 30, 2009 was $11.8 million ($0.12 per diluted share), compared to GAAP net income of $5.5 million ($0.05 per diluted share) for the six months ended June 30, 2008. Non-GAAP net income was $18.4 million ($0.18 per diluted share) for the six months ended June 30, 2009, compared to non-GAAP income of $13.8 million ($0.13 per diluted share) for the six months ended June 30, 2008.

As of June 30, 2009, BioMarin had cash and short and long-term investments totaling $485.3 million. During the quarter, BioMarin made the final payment to Medicis of $70.6 million related to the Orapred transaction.

"During the quarter, we reported encouraging results from the Phase I PEG-PAL study, initiated the Phase I/II study for GALNS for MPS IVA and recently completed enrollment for this study, a noteworthy milestone for this program. On the commercial front, we announced earlier today the issuance of patents covering stable tablet formulation and the once daily dosing regimen for Kuvan, which we believe will be significant in extending patent protection an additional ten years beyond orphan drug market exclusivity. In addition, yesterday, we submitted the Kuvan NDS to Health Canada. With priority review status, we anticipate marketing approval in the first half of 2010. Also, during the quarter, we received approval for Naglazyme in Russia, which is especially significant as Russia influences many countries in Eastern Europe. In order to support the projected commercial needs for Naglazyme, Aldurazyme, GALNS and PEG-PAL through at least 2016, we are making significant investments to double our manufacturing capacity," said Jean-Jacques Bienaime, Chief Executive Officer of BioMarin. "Based on our performance to date, we feel confident in meeting our overall top and bottom line financial objectives for 2009 and have narrowed the guidance range on a few items to reflect increased visibility into the year. Our commercial products are performing well, and we continue to carefully manage expenses. We are also carefully evaluating both internal pipeline programs and external product opportunities 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 $42.9 million for the second quarter of 2009, an increase of 22.3 percent compared to Naglazyme net product revenue of $35.1 million for the second quarter of 2008. Net product revenue from

Naglazyme for the six months ended June 30, 2009 was $82.3 million, an increase of 31.0 percent from net product revenue of $62.8 million for the six months ended June 30, 2008. Changes in foreign currency rates, net of hedges caused a negative impact to Naglazyme sales of $1.7 million and $3.7 million in the three and six months ended June 30, 2009, respectively.

Net sales of Aldurazyme (laronidase), an enzyme replacement therapy for mucopolysaccharidosis I (MPS I) recorded by Genzyme, were $39.2 million for the second quarter of 2009, an increase of 1.0 percent compared to net sales by Genzyme of $38.7 million for the second quarter of 2008. Net sales of Aldurazyme recorded by Genzyme for the six months ended June 30, 2009 were $76.0 million, compared to net sales of $75.5 million for the six months ended June 30, 2008. Changes in foreign currency rates caused a negative impact to Aldurazyme sales by Genzyme of $3.6 million and $7.2 million in the three and six months ended June 30, 2009, respectively. However, in the second quarter of 2009, Aldurazyme unit volume increased 9.8 percent compared to the second quarter of 2008 as the number of patients on therapy worldwide continues to grow.

Net product revenue to BioMarin related to Aldurazyme was $21.6 million for the second quarter of 2009, including $6.1 million of incremental product transfer revenue. This compares to net product revenue to BioMarin of $13.4 million for the second quarter of 2008. During the second quarter of 2009, BioMarin recorded net product revenue that was higher than the royalty earned on Genzyme third party sales due to the incremental product transfer revenue related to net increases in Genzyme Aldurazyme inventory levels during the period.

Net product revenue from Kuvan (sapropterin dihydrochloride) Tablets, a product for the treatment of phenylketonuria (PKU), was $16.9 million for the second quarter of 2009, compared to $12.0 million for the second quarter of 2008. In the second quarter of 2009, net product revenue from Kuvan was negatively impacted by $0.7 million due to increased and retroactive federal rebates. Net product revenue from Kuvan for the six months ended June 30, 2009 was $32.5 million, compared to net revenue of $17.8 million for the six months ended June 30, 2008. The quantity of commercial tablets dispensed to patients in the U.S., the best metric to track true patient demand, increased 14.8 percent in the second quarter of 2009 compared to the first quarter of 2009.

2009 Guidance

Revenue Guidance ($ in millions)

Item	2009 Guidance	Previous 2009 Guidance
Total BioMarin Revenues	$311 to $336	$307 to $336
Total Net Product Revenues	$304 to $329	$300 to $329
Naglazyme Net Product Revenue	$165 to $175	$160 to $175
Kuvan Net Product Revenue	Unchanged	$70 to $80
Aldurazyme Net Product Revenue to BioMarin	Unchanged	$69 to $74

Selected Income Statement Guidance ($ in millions)

Item	Guidance	Previous 2009 Guidance
Cost of Sales (% of Total Revenue)	Unchanged	19% to 21%
Selling, General and Admin. Expense	Unchanged	$120 to $130
Research and Development Expense*	Unchanged	$118 to $128
Interest Income	Unchanged	$5 to $7
Impairment Loss on La Jolla and Summit Investments**	$5.9	$7.9
GAAP Net Income (Loss)	$(12) to $(6)	$(15) to $0
Stock Compensation Expense	$34	$32 to $35
Non-GAAP Net Income***	$35.4 to $41.4	$33.7 to $51.7

* 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.

*** 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 quarter and six months ended June 30, 2009 and 2008, full year results for 2008 and financial guidance for 2009 are presented both as determined in accordance with GAAP and on a non-GAAP basis. 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 second quarter of 2009 and the second quarter of 2008 excluded (1) stock compensation expense of $9.0 million in the second quarter of 2009 and $5.9 million in the second quarter of 2008; (2) gain on the sale of equity investments of $1.6 million in the second quarter of 2009 and (3) income tax effect of $0.3 million in the second quarter of 2009. Non-GAAP net income in the six months ended June 30, 2009 and the six months ended June 30, 2008 excluded (1) stock compensation expense of $16.8 million in the six months ended June 30, 2009 and $10.4 million in the six months ended June 30, 2008; (2) upfront license fees of $8.8 million in the six months ended June 30, 2009; (3) impairment charges of $5.9 million in the six months ended June 30, 2009; (4) Aldurazyme transfer revenue of $2.3 million in the six months ended June 30, 2008; (5) gain on the sale of equity investments of $1.6 million in the six months ended June 30, 2009 and (6) income tax effect of $0.3 million and $0.2 million in the six months ended June 30, 2009 and 2008, respectively.

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 $34 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 $5.9 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; (6) gain on the sale of equity investments of $1.6 million in 2009 and (7) income tax effect of $0.3 million and $2.2 million in 2009 and 2008, respectively. 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 making significant investments in manufacturing and laboratory facilities to support the advancement of these programs.

- PEG-PAL for PKU: BioMarin reported results from the Phase I trial in early June. The FDA has accepted the design of the Phase II protocol, and the company expects to initiate the study in the third quarter of 2009, pending IRB approval from the clinical trial sites. 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 and completed enrollment in mid-July. 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 Pulmonary Arterial Hypertension (PAH): 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. BioMarin expects to communicate a decision on the future of the 6R-BH4 PAH program in the second half of 2009.
- BMN-195 - Utrophin upregulator for Duchenne Muscular Dystrophy:

BioMarin is completing formulation 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: 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. BioMarin continues to explore partnering options for this program.

-- BMN-185 - IgA protease for IgA nephropathy: BioMarin is completing early preclinical work and expects to make a decision on the 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.

-- Kuvan lifecycle development: Several programs are underway to expand and protect the market, and improve the ability of healthcare providers and patients to better manage their disease. These programs include a ProDrug form of BH4, as well as a state-of-the-art handheld device to measure blood Phe levels in PKU patients. Human studies for each of these are planned for 2010. Regulatory approval and commercial availability of the handheld blood Phe monitor is expected in the first half of 2011.

-- Additional early development candidates: BioMarin is working on multiple early development opportunities and expects that at least one new program will be announced by the first quarter of 2010.

Anticipated Upcoming Milestones

3Q09: Initiation of PEG-PAL Phase II trial

3Q09: International Congress of Inborn Errors of Metabolism (ICIEM) meeting - Data on first cohort of patients from trial evaluating the impact of Kuvan on executive function

2H09: Decision on 6R-BH4 PAH program

1Q10: Initiation of Phase I trial for BMN-195 for DMD

1Q10: American College of Medical Genetics (ACMG) Meeting - Possible data from study of Kuvan in institutionalized PKU patients

1H10: Results from Phase I/II trial for GALNS for MPS IVA

Mid-2010: Results from PEG-PAL Phase II trial

Mid-2010: IND filing for existing preclinical candidate

2H10: Initiation of pivotal Phase III trial for GALNS for MPS IVA

1H11: Availability of blood Phe monitor

Conference Call Details

BioMarin will host a conference call and webcast to discuss second quarter 2009 financial results today, Thursday, July 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: July 30, 2009
Time: 5:00 p.m. ET (22:00 CET)
U.S. / Canada Dial-in Number: 866.272.9941
International Dial-in Number: 617.213.8895
Participant Code: 45596036
Replay Dial-in Number: 888.286.8010
Replay International Dial-in Number: 617.801.6888
Replay Code: 74141589

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 (galsulfase) for mucopolysaccharidosis VI (MPS VI), a product wholly developed and commercialized by BioMarin; Aldurazyme (laronidase) for mucopolysaccharidosis I (MPS I), a product which BioMarin developed through a 50/50 joint venture with Genzyme Corporation; and Kuvan (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 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.

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

	December 31, 2008 (1)	June 30, 2009
		(unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$222,900	$200,050
Short-term investments	336,892	146,341
Accounts receivable, net	54,298	72,576
Inventory	73,162	72,836
Other current assets	50,444	15,178
Total current assets	737,696	506,981
Investment in BioMarin/Genzyme LLC	915	462

Long-term investments	1,633	138,863
Property, plant and equipment, net	124,979	159,789
Intangible assets, net	7,626	4,391
Goodwill	21,262	21,262
Other assets	12,584	12,689
Total assets	$906,695	$844,437

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued liabilities	$59,033	$59,104
Acquisition obligation, net of discount	70,741	-
Deferred revenue	307	929
Total current liabilities	130,081	60,033
Convertible debt	497,083	497,083
Other long-term liabilities	2,856	3,887
Total liabilities	630,020	561,003
Stockholders' equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2008 and June 30, 2009; 99,868,145 and 100,235,218 shares issued and outstanding at December 31, 2008 and June 30, 2009, respectively	100	100
Additional paid-in capital	852,947	873,378
Company common stock held by deferred compensation plan	(882)	(1,708)
Accumulated other comprehensive income	1,106	101
Accumulated deficit	(576,596)	(588,437)
Total stockholders' equity	276,675	283,434
Total liabilities and stockholders' equity	$906,695	$844,437

(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 and Six Months Ended June 30, 2008 and 2009
(In thousands, except for per share data, unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Revenues:				
Net product revenues	$60,458	$81,472	$118,083	$153,386
Collaborative agreement revenues	2,509	868	4,975	1,377
Royalty and license revenues	1,207	447	1,513	2,004
Total revenues	64,174	82,787	124,571	156,767
Operating expenses:				
Cost of sales	9,593	19,848	26,781	34,210
Research and development	23,755	26,324	41,383	60,682
Selling, general and administrative	25,203	30,527	48,872	59,095

Amortization of acquired intangible assets	1,093	1,775	2,185	2,868
Total operating expenses	59,644	78,474	119,221	156,855
Income from operations	4,530	4,313	5,350	(88)
Equity in the loss of BioMarin/Genzyme LLC	(587)	(546)	(1,120)	(1,093)
Interest income	4,101	886	9,750	3,039
Interest expense	(4,081)	(4,404)	(8,193)	(8,496)
Impairment loss on equity investments	-	-	-	(5,848)
Net gain from sale of investments	-	1,585	-	1,585
Income (Loss) before income taxes	3,963	1,834	5,787	(10,901)
Provision for income taxes	153	522	291	939
Net income (loss)	$3,810	$1,312	$5,496	$(11,840)
Net income (loss) per share, basic	$0.04	$0.01	$0.06	$(0.12)
Net income (loss) per share, diluted	$0.04	$0.01	$0.05	$(0.12)
Weighted average common shares outstanding, basic	98,923	100,065	98,285	99,984
Weighted average common shares outstanding, diluted	104,120	101,217	103,948	100,075

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Cost of sales	$392	$1,423	$589	$1,987
Research and development expense	2,059	2,605	3,617	5,080
Selling, general and administrative expense	3,497	4,986	6,206	9,743
Total stock-based compensation expense	$5,948	$9,014	$10,412	$16,810

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

	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,	
Notes:	2008	2009	2008	2009	2008	2009
						(forecast)
GAAP Net Income (Loss)	$3.8	$1.3	$5.5	$(11.8)	$30.8	$(12.0) to (6.0)

Stock-based compensation expense	5.9	9.0	10.4	16.8	25.3	34.0	
Upfront license fees	(1)	-	-	-	8.8	1.4	8.8
Impairment charges	(2)	-	-	-	5.9	4.1	5.9
Kuvan Approval Milestones	(3)	-	-	-	-	(31.5)	-
Aldurazyme Transfer revenue	(4)	-	-	(2.3)	-	(2.3)	-
Net gain on the sale of equity investments		-	(1.6)	-	(1.6)	-	(1.6)
Income tax effect	(5)	-	0.3	0.2	0.3	2.2	0.3
Non-GAAP net income		$9.7	$9.0	$13.8	$18.4	$30.0	$35.4 to 41.4

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 impairment losses on investments in Summit plc. during the fourth quarter of 2008 and the first quarter of 2009, and La Jolla Pharmaceutical Company during the first quarter of 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 of BioMarin/Genzyme LLC in the first quarter of 2008.

(5) Represents the tax effect of the adjustments.

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