BioMarin Announces Third Quarter 2009 Financial Results

Third Quarter Results Drive Improved 2009 Net Income Guidance Conference Call and Webcast to Be Held Today at 5:00 p.m. ET

PRNewswire-FirstCall
NOVATO, Calif.

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

Item	Q3 2009	Q3 2008 Comparison
Total BioMarin Revenue	$80.8	11% increase
Total Net Product Revenue	$78.4	16% increase
Naglazyme Net Product Revenue	$42.1	26% increase
Aldurazyme BioMarin Net Product Revenue	$14.6	$20.7 ($5.6 net inventory transfer)
Kuvan Net Product Revenue	$21.7	57% increase
GAAP Net Income	$6.6	$0.8
GAAP Net Income per share	$0.07 (basic), $0.06 (diluted)	$0.01 (basic and diluted)
Non-GAAP Net Income	$15.5	$8.2
Non-GAAP Net Income per share	$0.16 (basic), $0.13 (diluted)	$0.08 (basic and diluted)

BioMarin Pharmaceutical Inc. today announced financial results for the third quarter ended September 30, 2009. GAAP net income was $6.6 million ($0.06 per diluted share) for the third quarter of 2009, compared to GAAP net income of $0.8 million ($0.01 per diluted share) for the third quarter of 2008. Non-GAAP net income was $15.5 million ($0.13 per diluted share) for the third quarter of 2009, compared to non-GAAP net income of $8.2 million ($0.08 per diluted share) for the third quarter of 2008. Non-GAAP net income excludes non-cash stock compensation expense, certain nonrecurring material items and the tax effect of the adjustments. The reconciliation of the non-GAAP measures to the estimated GAAP net income is detailed in the table provided at the end of the press release.

GAAP net loss for the nine months ended September 30, 2009 was $5.2 million ($0.05 per diluted share), compared to GAAP net income of $6.3 million ($0.06 per diluted share) for the nine months ended September 30, 2008. Non-GAAP net income was $33.9 million ($0.33 per diluted share) for the nine months ended September 30, 2009, compared to non-GAAP net income of $21.9 million ($0.21 per diluted share) for the nine months ended September 30, 2008.

As of September 30, 2009, BioMarin had cash, cash equivalents and short and long-term investments totaling $491.8 million.

"During the quarter, we continued to advance our clinical pipeline as we completed enrollment for the Phase I/II study of GALNS for MPS IVA and initiated the Phase II trial of PEG-PAL for PKU. On the commercial front, we were issued patents covering stable tablet formulation and the once daily dosing regimen for Kuvan, and received claims covering the approved administration of Kuvan with food. We believe that these patents are significant in extending protection beyond orphan drug market exclusivity," said Jean-Jacques Bienaime, Chief Executive Officer of BioMarin. "Based on our performance to date, we have narrowed the guidance range on a few items to reflect increased visibility into the year, including improved expectations for the bottom line. 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. Also, as announced earlier this week, we acquired Huxley Pharmaceuticals, which is developing a proprietary form of 3,4-DAP for the rare autoimmune disease Lambert Eaton Myasthenic Syndrome. A positive opinion was issued by the EMEA last week, and we expect to launch this product in the EU in the first quarter of 2010. This low-risk deal leverages our EU commercial infrastructure, fits our orphan drug

strategy with a specialist oriented and potentially high priced therapeutic and has the potential for near-term value creation."

Net Product Revenue

Net product revenue from Naglazyme (galsulfase), an enzyme replacement therapy for mucopolysaccharidosis VI (MPS VI), was $42.1 million for the third quarter of 2009, an increase of 26.0 percent compared to Naglazyme net product revenue of $33.3 million for the third quarter of 2008. Net product revenue from Naglazyme for the nine months ended September 30, 2009 was $124.3 million, an increase of 29.2 percent from net product revenue of $96.2 million for the nine months ended September 30, 2008. Changes in foreign currency rates, net of hedges caused a negative impact to Naglazyme sales of $1.3 million and $5.0 million in the three and nine months ended September 30, 2009, respectively.

Net sales of Aldurazyme (laronidase), an enzyme replacement therapy for mucopolysaccharidosis I (MPS I) recorded by Genzyme, were $40.3 million for the third quarter of 2009, an increase of 5.5 percent compared to net sales of Aldurazyme by Genzyme of $38.2 million for the third quarter of 2008. Net sales of Aldurazyme recorded by Genzyme for the nine months ended September 30, 2009 were $116.4 million, compared to $113.7 million for the nine months ended September 30, 2008. Changes in foreign currency rates caused a negative impact to Aldurazyme sales by Genzyme of $1.5 million and $8.7 million in the three and nine months ended September 30, 2009, respectively. In the third quarter of 2009, Aldurazyme unit volume increased 11.6 percent compared to the third quarter of 2008 as the number of patients on therapy worldwide continues to grow.

Net product revenue to BioMarin related to Aldurazyme was $14.6 million for the third quarter of 2009, compared to net product revenue to BioMarin of $20.7 million for the third quarter of 2008. The timing of inventory transfers to Genzyme reduced net product revenue reported by BioMarin in the third quarter of 2009. During the third quarter of 2009, BioMarin transferred less inventory to Genzyme compared to units shipped to third party customers by Genzyme, which resulted in a reduction in BioMarin net product revenue from the royalty payable to BioMarin by Genzyme. During the third quarter of 2008, Genzyme's Aldurazyme inventory levels increased, which resulted in BioMarin recorded net product revenue that was higher than the royalty earned on Genzyme third party sales. Net product revenue to BioMarin related to Aldurazyme was $53.4 million for the nine months ended September 30, 2009, compared to $58.1 million for the nine months ended September 30, 2008.

Net product revenue from Kuvan (sapropterin dihydrochloride) Tablets, a product for the treatment of phenylketonuria (PKU), was $21.7 million for the third quarter of 2009, compared to $13.8 million for the third quarter of 2008. Net product revenue from Kuvan for the nine months ended September 30, 2009 was $54.1 million, compared to net revenue of $31.6 million for the nine months ended September 30, 2008. The quantity of commercial tablets dispensed to patients in the U.S., the best metric to track true patient demand, increased 8.5 percent in the third quarter of 2009 compared to the second quarter of 2009.

2009 Guidance

Revenue Guidance ($ in millions)

Item	2009 Guidance	Previous 2009 Guidance
Total BioMarin Revenues	$313 to $327	$311 to $336
Total Net Product Revenues	$306 to $320	$304 to $329
Naglazyme Net Product Revenue	$165 to $170	$165 to $175
Kuvan Net Product Revenue	$72 to $76	$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)	19% to 20%	19% to 21%
Selling, General and Administrative Expense	$120 to $125	$120 to $130
Research and Development Expense*	$117 to $121	$118 to $128
Interest Income	$5	$5 to $7
Impairment Loss on La Jolla and Summit Investments**	Unchanged	$5.9
GAAP Net Income (Loss)	$(8) to $(4)	$(12) to $(6)

Stock Compensation Expense	$35	$34
Non-GAAP Net Income***	$39.8 to $43.8	$35.4 to $41.4

* 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.

Anticipated Upcoming Milestones
1Q10: Launch of amifampridine phosphate in the EU
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

2Q10: Initiation of Kuvan neurocognitive outcome study
1H10: Announcement of next IND candidate
1H10: Results from Phase I/II trial for GALNS for MPS IVA
Mid-2010: Results from PEG-PAL Phase II trial

Late 2010/ Early 2011: Initiation of pivotal Phase III trial for GALNS for MPS IVA

1H11: Availability of blood Phe monitor

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.

-- 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 a 36-week, 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 late 2010 or early 2011.
-- PEG-PAL for PKU: BioMarin initiated the Phase II trial in September 2009. The Phase II clinical trial is an open-label, multi-center study to be conducted in up to 35 patients in a series of dose-escalating cohorts. The primary treatment period of eight once weekly injections at a fixed dose will be followed by eight weeks of dose and frequency optimization and an extension period. Results from the Phase II PEG-PAL trial are expected in mid-2010.
-- BMN-195 - Utrophin upregulator for Duchenne Muscular Dystrophy: BioMarin is in the final stages of preparing the regulatory filing 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 substitution for the missing dystrophin protein in DMD patients.
-- Kuvan lifecycle development: Several programs are underway to expand and protect the market and to improve the ability of healthcare providers and patients to better manage PKU. These programs include a state-of-the-art handheld device to measure blood Phe levels in PKU patients. Human studies are planned for 2010. Regulatory approval and commercial availability of the handheld blood Phe monitor is expected in the first half of 2011.
-- BMN-185 - IgA protease for IgA nephropathy: BioMarin is completing early preclinical work and expects to move to the next phase of research in the first half of 2010. IgA proteases have been shown to cleave IgA complexes, the deposition of which causes IgA nephropathy, an orphan kidney disorder with few treatment alternatives.
-- Additional early development candidates: BioMarin is working on

multiple early development opportunities and expects to announce the next IND candidate in the first half of 2010.

-- BMN-103 - a-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.

-- 6R-BH4 Cardiovascular: BioMarin has decided to put the PAH opportunity for 6R-BH4 on hold, pending discussions with potential partners. Although the early data suggest a potential for 6R-BH4 to be a safe and efficacious therapy for PAH, BioMarin decided that the additional investment in time and resources required to demonstrate this effect is better allocated to other early pipeline candidates.

Non-GAAP Financial Information and Reconciliation

The above results for the quarter and nine months ended September 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 third quarter of 2009 and the third quarter of 2008 excluded (1) stock compensation expense of $8.9 million in the third quarter of 2009 and $7.4 million in the third quarter of 2008; (2) upfront license fees paid of $1.4 million in the third quarter of 2008; (3) Kuvan approval milestones received of $1.5 million in the third quarter of 2008 and (4) income tax effect of $0.1 million in the third quarter of 2008. Non-GAAP net income in the nine months ended September 30, 2009 and the nine months ended September 30, 2008 excluded (1) stock compensation expense of $25.7 million in the nine months ended September 30, 2009 and $17.8 million in the nine months ended September 30, 2008; (2) upfront license fees paid of $8.8 million in the nine months ended September 30, 2009 and $1.4 million in the nine months ended September 30, 2008; (3) impairment charges of $5.9 million in the nine months ended September 30, 2009; (4) Kuvan approval milestones received of $1.5 million in the nine months ended September 30, 2008; (5) initial Aldurazyme transfer revenue of $2.3 million in the nine months ended September 30, 2008; (6) net gain on the sale of equity investments of $1.6 million in the nine months ended September 30, 2009 and (7) income tax effect of $0.3 million and $0.2 million in the nine months ended September 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 of $35.0 million anticipated for 2009 and $25.3 million for 2008; (2) upfront license fees of $8.8 million associated with the La Jolla Pharmaceutical Corporation transaction 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 received of $31.5 million earned 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.

Diluted Earnings Per Share Calculation

The calculation of GAAP diluted earnings per share for all of the 2009 periods presented and non-GAAP diluted earnings per share for the third quarter and first nine months of 2008 reflect the theoretical exclusion of the interest expense from net earnings that would no longer be incurred if the Company's convertible notes were converted into shares as their impact is considered anti-dilutive. Non-GAAP diluted earnings per share for the third quarter and first nine months of 2009 include 16.0 million shares related to the Company's convertible notes due in April 2017. The March 2013 notes reflecting 10.4 million shares are excluded from the non-GAAP diluted earnings per share for the 2009 periods presented as their impact is considered anti-dilutive.

Conference Call Details

BioMarin will host a conference call and webcast to discuss third quarter 2009 financial results today, Wednesday, October 28, at 5:00 p.m. ET. This event can be accessed on the investor section of the BioMarin website at www.BMRN.com.

Date: October 28, 2009
Time: 5:00 p.m. ET
U.S. / Canada Dial-in Number: 800.299.6183
International Dial-in Number: 617.801.9713
Participant Code: 51404008
Replay Dial-in Number: 888.286.8010
Replay International Dial-in Number: 617.801.6888
Replay Code: 51416825

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 Phase II 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, particularly with respect to the recently acquired 3,4-DAP product. 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.

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

	December 31, 2008 (1)	September 30, 2009
		(unaudited)

ASSETS		
Current assets:		
Cash and cash equivalents	$222,900	$191,778
Short-term investments	336,892	171,566
Accounts receivable, net	54,298	68,378
Inventory	73,162	75,441
Other current assets	50,444	13,104
Total current assets	737,696	520,267
Investment in BioMarin/Genzyme LLC	915	522
Long-term investments	1,633	128,435
Property, plant and equipment, net	124,979	182,099
Intangible assets, net	7,626	4,194
Goodwill	21,262	21,262
Other assets	12,584	12,578
Total assets	$906,695	$869,357
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$59,033	$63,921
Acquisition obligation, net of discount	70,741	-
Deferred revenue	307	149
Total current liabilities	130,081	64,070
Convertible debt	497,083	497,083
Other long-term liabilities	2,856	4,351
Total liabilities	630,020	565,504
Stockholders' equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2008 and September 30, 2009; 99,868,145 and 100,723,649 shares issued and outstanding at December 31, 2008 and September 30, 2009, respectively	100	101
Additional paid-in capital	852,947	887,966
Company common stock held by deferred compensation plan	(882)	(1,715)
Accumulated other comprehensive income	1,106	(704)
Accumulated deficit	(576,596)	(581,795)
Total stockholders' equity	276,675	303,853
Total liabilities and stockholders' equity	$906,695	$869,357

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

	Three Months Ended September 30,	Nine Months Ended September 30,

	2008	2009	2008	2009
Revenues:				
Net product revenues	$67,812	$78,383	$185,895	$231,769
Collaborative agreement revenues	2,414	648	7,389	2,025
Royalty and license revenues	2,420	1,776	3,933	3,780
Total revenues	72,646	80,807	197,217	237,574
Operating expenses:				
Cost of sales	14,063	14,970	40,844	49,180
Research and development	26,175	26,991	67,559	87,673
Selling, general and administrative	28,964	28,667	77,836	87,762
Amortization of acquired intangible assets	1,093	46	3,278	2,914
Total operating expenses	70,295	70,674	189,517	227,529
Income (loss) from operations	2,351	10,133	7,700	10,045
Equity in the loss of BioMarin/Genzyme LLC	(572)	(680)	(1,692)	(1,773)
Interest income	3,407	1,012	13,157	4,051
Interest expense	(4,105)	(2,880)	(12,297)	(11,375)
Impairment loss on equity investments	-	-	-	(5,848)
Net gain from sale of investments	-	-	-	1,585
Income (loss) before income taxes	1,081	7,585	6,868	(3,315)
Provision for income taxes	252	945	543	1,884
Net income (loss)	$829	$6,640	$6,325	$(5,199)
Net income (loss) per share, basic	$0.01	$0.07	$0.06	$(0.05)
Net income (loss) per share, diluted	$0.01	$0.06	$0.06	$(0.05)
Weighted average common shares outstanding, basic	99,537	100,331	98,705	100,098
Weighted average common shares outstanding, diluted	103,403	101,906	103,916	100,189

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2009	2008	2009
Cost of sales	$430	$1,192	$1,019	$3,179
Research and development expense	2,501	3,408	6,118	8,488

Selling, general and administrative expense	4,468	4,321	10,674	14,064	
Total stock-based compensation expense	$7,399	$8,921	$17,811	$25,731	

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

	Notes:	Three Months Ended September 30, 2008	2009	Nine Months Ended September 30, 2008	2009	Year Ended December 31, 2008	2009
							(forecast)
GAAP Net Income (Loss)		$0.8	$6.6	$6.3	$(5.2)	$30.8	$(4.0) to
Stock-based compensation expense		7.4	8.9	17.8	25.7	25.3	35.0
Upfront license fees	(1)	1.4	-	1.4	8.8	1.4	8.8
Impairment charges	(2)	-	-	-	5.9	4.1	5.9
Kuvan Approval Milestones	(3)	(1.5)	-	(1.5)	-	(31.5)	-
Initial Aldurazyme transfer revenue	(4)	-	-	(2.3)	-	(2.3)	-
Net gain on the sale of equity investments		-	-	-	(1.6)	-	(1.6)
Income tax effect of Non-GAAP adjustments	(5)	0.1	-	0.2	0.3	2.2	0.3
Non-GAAP net income		$8.2	$15.5	$21.9	$33.9	$30.0	$39.8 to 43.8

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.

Contact:

Investors	Media
Eugenia Shen	Susan Berg
BioMarin Pharmaceutical Inc.	BioMarin Pharmaceutical Inc.
(415) 506-6570	(415) 506-6594

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/
