BioMarin InvestorRoom

BioMarin Announces Fourth Quarter and Full Year 2009 Financial Results

Fourth Quarter Profitability Driven by Continued Growth of Naglazyme and Kuvan 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	FY 2009	FY 2008 Comparison
Total BioMarin Revenue	$324.7	9.5% increase
Total Net Product Revenue	$315.7	25.4% increase
Naglazyme Net Product Revenue	$168.7	27.1% increase
Aldurazyme BioMarin Net Product Revenue*	$70.2	$72.5
Kuvan Net Product Revenue	$76.8	64.5% increase
GAAP Net Income (Loss)	$(0.5)	$30.8**
GAAP Net Income (Loss) per share	$(0.00) (basic and diluted)	$0.31 (basic), $0.29 (diluted)
Non-GAAP Net Income	$47.1	$30.0
Non-GAAP Net Income per share	$0.47 (basic), $0.46 (diluted)	$0.30 (basic), $0.29 (diluted)

* Includes $8.4 million and $12.4 million of net incremental product transfer revenue in FY 2009 and 2008 respectively.
** Includes a $30.0 million payment from Merck Serono related to the approval of Kuvan in the EU.

BioMarin Pharmaceutical Inc. today announced financial results for the fourth quarter and year ended December 31, 2009. GAAP net income was $4.7 million ($0.05 per diluted share) for the fourth quarter of 2009, compared to GAAP net income of $24.5 million ($0.21 per diluted share) for the fourth quarter of 2008, which included a $30.0 million payment from Merck Serono related to the approval of Kuvan in the EU. Non-GAAP net income was $13.5 million ($0.13 per diluted share) for the fourth quarter of 2009, compared to non-GAAP net income of $8.0 million ($0.08 per diluted share) for the fourth 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 year ended December 31, 2009 was $0.5 million ($0.00 per diluted share), compared to GAAP net income of $30.8 million ($0.29 per diluted share) for the year ended December 31, 2008. Non-GAAP net income was $47.1 million ($0.46 per diluted share) for the year ended December 31, 2009, compared to non-GAAP net income of $30.0 million ($0.29 per diluted share) for the year ended December 31, 2008.

As of December 31, 2009, BioMarin had cash, cash equivalents and short and long-term investments totaling $470.5 million.

"Robust product sales of Naglazyme and Kuvan drove profitability in the fourth quarter and a strong finish to 2009. Commercially, we continue to aggressively pursue expansion of the Naglazyme and Kuvan markets and look forward to launching Firdapse in the EU in late March," said Jean-Jacques Bienaime, Chief Executive Officer of BioMarin. "We also have much to look forward to in terms of clinical milestones in 2010, including results from the Phase I/II trial of GALNS for MPS IVA in the second quarter, results from the Phase II PEG-PAL trial in the third quarter of 2010, results from the Phase I trial of BMN 195 for DMD in the third quarter of 2010 and the IND filing for the recently acquired PARP inhibitor from LEAD Therapeutics. Even after factoring in the Huxley and LEAD acquisitions, we expect to be slightly cash flow positive in 2010."

Net Product Revenue

Net product revenue from Naglazyme (galsulfase), an enzyme replacement therapy for mucopolysaccharidosis VI (MPS VI), was $44.4 million for the fourth quarter of 2009, an increase of 21.6 percent compared to

Naglazyme net product revenue of $36.5 million for the fourth quarter of 2008. Net product revenue from Naglazyme for the year ended December 31, 2009 was $168.7 million, an increase of 27.1 percent from net product revenue of $132.7 million for the year ended December 31, 2008. Changes in foreign currency rates, net of hedges, caused an increase to Naglazyme sales of $0.6 million in the three months ended December 31, 2009 and a decrease of $4.4 million for the year ended December 31, 2009.

Net sales of Aldurazyme (laronidase), an enzyme replacement therapy for mucopolysaccharidosis I (MPS I) recorded by Genzyme, were $38.7 million for the fourth quarter of 2009, an increase of 2.9 percent compared to net sales of Aldurazyme by Genzyme of $37.6 million for the fourth quarter of 2008. Net sales of Aldurazyme recorded by Genzyme for the year ended December 31, 2009 were $155.1 million, compared to $151.3 million for the year ended December 31, 2008. Changes in foreign currency rates caused an increase to Aldurazyme sales by Genzyme of $2.4 million in the three months ended December 31, 2009 and a decrease of $6.3 million for the year ended December 31, 2009.

Net product revenue to BioMarin related to Aldurazyme was $16.8 million for the fourth quarter of 2009, compared to net product revenue to BioMarin of $14.4 million for the fourth quarter of 2008. During the fourth quarter of 2009, BioMarin transferred more inventory to Genzyme compared to units shipped to third party customers by Genzyme, which resulted in an increase in BioMarin net product revenue from the royalty payable to BioMarin by Genzyme. During the fourth quarter of 2008, 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. Net product revenue to BioMarin related to Aldurazyme was $70.2 million for the year ended December 31, 2009, compared to $72.5 million for the year ended December 31, 2008.

Net product revenue from Kuvan (sapropterin dihydrochloride) Tablets, a product for the treatment of phenylketonuria (PKU), was $22.7 million for the fourth quarter of 2009, compared to $15.1 million for the fourth quarter of 2008. Net product revenue from Kuvan for the year ended December 31, 2009 was $76.8 million, compared to net revenue of $46.7 million for the year ended December 31, 2008. The quantity of commercial tablets dispensed to patients in the U.S., the best metric to track true patient demand, increased 17.8 percent in the fourth quarter of 2009 compared to the third quarter of 2009.

2010 Guidance

Revenue Guidance ($ in millions)

Item	2010 Guidance	2009 Actual
Total BioMarin Revenues	$374 to $405	$324.7
Total Net Product Revenues	$368 to $398	$315.7
Naglazyme Net Product Revenue	$190 to $200	$168.7
Kuvan Net Product Revenue	$98 to $108	$76.8
Aldurazyme Net Product Revenue to BioMarin	$70 to $75	$70.2
Firdapse Net Product Revenue	$10 to $15	NA

Selected Income Statement Guidance ($ in millions)

Item	2010 Guidance	2009 Actual
Cost of Sales (% of Total Revenue)	19% to 21%	20%
Selling, General and Admin. Expense	$145 to $150	$124.3
Research and Development Expense	$140 to $145	$115.1
Amortization/Other Costs- Acquisitions*	$7 to $9	NA
Interest Income	$3 to $4	$5.1
GAAP Net Income (Loss)	$2 to $12	$(0.5)
Stock Compensation Expense	$37	$34.5
Non-GAAP Net Income	$39 to $49	$47.1

* Represents ongoing amortization and other charges associated with the upfront and milestone payments of the Huxley and LEAD acquisitions.

Firdapse Launch Update

BioMarin is on track to launch Firdapse for LEMS in the EU on a country by country basis beginning in late March. Firdapse pricing has been filed in Germany at 23 Euros per tablet. Since dosages can range from 15 mg to 60 mg a day, the annual cost of therapy can vary widely from patient to patient. BioMarin estimates that the annual cost will range be between 10,000 and 50,000 Euros per year.

Anticipated Upcoming Milestones
March 2010: Launch of Firdapse in the EU
March 2010: American College of Medical Genetics (ACMG) Meeting - data from multiple investigator-sponsored Kuvan trials
June 2010: Initiation of Kuvan neurocognitive outcomes study
2Q 2010: Results from Phase I/II trial for GALNS for MPS IVA
3Q 2010: Results from PEG-PAL Phase II trial
3Q 2010: Results from Phase 1 trial for BMN 195 for DMD
4Q 2010/1Q 2011: Initiation of pivotal Phase III trial for GALNS for MPS IVA
Late 2010: File IND for BMN-673 (PARP Inhibitor)
1H 2011: 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.

Advanced Programs
-- Firdpase: BioMarin is on track to launch Firdapse for LEMS in the EU on a country by country basis beginning in late March. The company also expects to meet with the FDA regarding the development strategy in the U.S. in the first half of 2010 and to explore additional possible indications.
-- GALNS for MPS IVA: The Phase I/II study is a 36-week, open-label, within-patient dose escalation trial followed by a treatment continuation phase. Encouraging preliminary results include: (1) decrease in keratan sulfate (KS) levels within a few weeks after the start of therapy; (2) improvements in 6-minute walk distance, 3-minute stair climb and pulmonary function at 24 weeks are consistent with those observed with clinical studies for MPS I, MPS II, and MPS VI; and (3) the frequency and severity of infusion reactions appear comparable to those observed with Naglazyme and Aldurazyme. The company expects to report full top-line results in the second quarter of 2010. Assuming positive results from the Phase I/II study, BioMarin expects to initiate a pivotal Phase III study by the fourth quarter of 2010 or first quarter of 2011.
-- Kuvan outcomes study/ Lifecycle development: BioMarin expects to initiate a randomized, placebo-controlled, 13-week Kuvan outcomes study in June 2010. Endpoints include clinically validated measures of neuropsychiatric symptoms. Several other 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.

Mid-Stage Programs
-- 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 approximately 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 3Q 2010.
-- BMN-195 - Utrophin upregulator for Duchenne Muscular Dystrophy: BioMarin initiated the Phase I trial in the first quarter of 2010 and expects to report results in the third 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. Assuming a successful Phase I trial, BioMarin expects to initiate a Phase II trial in Q1 2011.

Preclinical Programs
-- 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.

-- BMN-673 (PARP Inhibitor) and additional early development candidates: BioMarin is working on multiple early development opportunities, including the recently acquired BMN-673 from LEAD. The company expects to file an IND for BMN-673 by the end of 2010.

-- Undisclosed programs: Two additional undisclosed biologics are advancing toward IND-enabling decisions.

Non-GAAP Financial Information and Reconciliation

The above results for the quarter and year ended December 31, 2009 and 2008 and financial guidance for 2010 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. The following tables detail the reconciliation of non-GAAP to GAAP financial metrics:

Reconciliation of GAAP Net Income (Loss) to Non-GAAP Net Income
(In millions)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,		Year Ending December 31,
Notes:	2008	2009	2008	2009	2010
					(forecast)
GAAP Net Income (Loss)	$24.5	4.7	$30.8	$(0.5)	$2.0 to 12.0
Stock-based compensation expense	7.4	8.8	25.3	34.5	37.0
Upfront license fees (1)	-	-	1.4	8.8	-
Impairment charges (2)	4.1	-	4.1	5.9	-
Kuvan Approval Milestones (3)	(30.0)	-	(31.5)	-	-
Initial Aldurazyme transfer revenue (4)	-	-	(2.3)	-	-
Net gain on the sale of equity investments	-	-	-	(1.6)	-
Income tax effect of Non-GAAP adjustments (5)	2.0	-	2.2	-	-
Non-GAAP net income	$8.0	$13.5	$30.0	$47.1	$39.0 to 49.0

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 profit 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.

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 the fourth quarter of 2008 and non-GAAP diluted earnings per share for the fourth quarter of 2009 includes 26.3 million shares related to the outstanding convertible debt. The calculation of non-GAAP diluted earnings per share for full year 2009 includes 16.0 million shares associated with the 2017 notes but excludes the 10.3 million shares associated with the 2013 notes as their impact is considered anti-dilutive. These calculations reflect the exclusion of the interest expense from net earnings that would no longer be incurred if the Company's convertible notes were converted into shares.

Conference Call Details

BioMarin will host a conference call and webcast to discuss fourth quarter and full year 2009 financial results today, Tuesday, February 23, at 5:00 p.m. ET. This event can be accessed on the investor section of the BioMarin website at www.BMRN.com.

Date: February 23, 2010
Time: 5:00 p.m. ET
U.S. / Canada Dial-in Number: 800.299.0433
International Dial-in Number: 617.801.9712
Participant Code: 98862458
Replay Dial-in Number: 888-286-8010
Replay International Dial-in Number: 617-801-6888
Replay Code: 46860097

About BioMarin

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company's product portfolio comprises four 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; Kuvan® (sapropterin dihydrochloride) Tablets, for phenylketonuria (PKU), developed in partnership with Merck Serono, a division of Merck KGaA of Darmstadt, Germany; and Firdapse(TM) (amifampridine phosphate), which has been approved by the European Commission for the treatment of Lambert Eaton Myasthenic Syndrome (LEMS). Other product candidates include PEG-PAL (PEGylated recombinant phenylalanine ammonia lyase), which is currently in Phase II clinical development for the treatment of PKU; GALNS (N-acetylgalactosamine 6-sulfatase), which is currently in Phase I/II clinical development for the treatment of MPS IVA and BMN 195, which is currently in Phase I clinical development for the treatment of Duchenne Muscular Dystrophy. 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, Firdapse, and Aldurazyme; the financial performance of the BioMarin as a whole; the timing of BioMarin's clinical trials of PEG-PAL, GALNS, BMN-195 and other product candidates; the continued clinical development and commercialization of Aldurazyme, Naglazyme, Kuvan, Firdapse, and its product candidates; and actions by regulatory authorities, particularly with respect to the recently acquired Firdapse. 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, Kuvan, and Firdapse; 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, Kuvan and Firdapse; actual sales of Aldurazyme, Naglazyme

Kuvan and Firdapse; 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)	December 31, 2009
		(unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$222,900	$167,171
Short-term investments	336,892	133,506
Accounts receivable, net	54,298	73,540
Inventory	73,162	78,662
Other current assets	50,444	14,848
Total current assets	737,696	467,727
Investment in BioMarin/Genzyme LLC	915	441
Long-term investments	1,633	169,849
Property, plant and equipment, net	124,979	199,141
Intangible assets, net	7,626	40,977
Goodwill	21,262	23,722
Other assets	12,584	15,306
Total assets	$906,695	$917,163
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable, accrued liabilities and other current liabilities	$59,033	$78,068
Acquisition obligation, net of discount	70,741	-
Deferred revenue	307	86
Total current liabilities	130,081	78,154
Convertible debt	497,083	497,083
Other long-term liabilities	2,856	19,741
Total liabilities	630,020	594,978
Stockholders' equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2008 and 2009; 99,868,145 and 100,961,922 shares issued and outstanding at December 31, 2008 and 2009, respectively	100	101
Additional paid-in capital	852,947	899,950
Company common stock held by deferred compensation plan	(882)	(1,715)
Accumulated other comprehensive income	1,106	933
Accumulated deficit	(576,596)	(577,084)

Total stockholders' equity	276,675	322,185
Total liabilities and stockholders' equity	$906,695	$917,163

(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 Twelve Months Ended December 31, 2008 and 2009
(In thousands, except for per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2009	2008 (1)	2009
	(unaudited)	(unaudited)		(unaudited)
Revenues:				
Net product revenues	$65,956	$83,951	$251,851	$315,721
Collaborative agreement revenues	31,518	355	38,907	2,379
Royalty and license revenues	1,803	2,775	5,735	6,556
Total revenues	99,277	87,081	296,493	324,656
Operating expenses:				
Cost of sales	11,665	16,729	52,509	65,909
Research and development	25,733	27,443	93,291	115,116
Selling, general and administrative	28,730	36,528	106,566	124,290
Amortization of acquired intangible assets	1,093	-	4,371	2,914
Total operating expenses	67,221	80,700	256,737	308,229
Income (loss) from operations	32,056	6,381	39,756	16,427
Equity in the loss of BioMarin/ Genzyme LLC	(579)	(821)	(2,270)	(2,594)
Interest income	3,231	1,035	16,388	5,086
Interest expense	(4,096)	(2,715)	(16,394)	(14,090)
Impairment loss on equity investments	(4,056)	-	(4,056)	(5,848)
Net gain from sale of investments	-	-	-	1,585
Income before income taxes	26,556	3,880	33,424	566
Provision for income taxes	2,050	(831)	2,593	1,054
Net income (loss)	$24,506	$4,711	$30,831	$(488)
Net income (loss) per share, basic	$0.25	$0.05	$0.31	$(0.00)
Net income (loss) per share, diluted	$0.21	$0.05	$0.29	$(0.00)
Weighted average common shares outstanding, basic	99,777	100,768	98,975	100,271

Weighted average common shares outstanding, diluted	128,296	102,454	103,572	100,271

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2009	2008 (1)	2009
	(unaudited)	(unaudited)		(unaudited)
Cost of sales	$503	$769	$1,521	$3,948
Research and development expense	2,466	3,432	8,584	11,919
Selling, general and administrative expense	4,471	4,617	15,145	18,681
Total stock-based compensation expense	$7,440	$8,818	$25,250	$34,548

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

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