Contact:
Investors:
Traci McCarty
BioMarin Pharmaceutical Inc.
(415) 455-7558

Media:
Marni Kottle
BioMarin Pharmaceutical Inc.
(650) 374-2803

BioMarin Announces Strong Third Quarter 2023 Results, Including Continued Profitability, and 15% Total Revenue Growth Year Over Year

- Full-year 2023 Total Revenues and Earnings Per Share Financial Guidance Narrowed; VOXZOGO® and ROCTAVIAN® Net Product Revenue Guidance Adjusted for Full-year 2023
- VOXZOGO Now Approved for Children without Age Restrictions in the United States and for Children Aged 4 Months and Older in Europe
- ROCTAVIAN Reimbursement Network On-track to Support Global Patient Access and Treatment in 2024 and Beyond; Final German and Italian Prices Expected in 2023; Over 100 Treatment Eligible Companion Diagnostic Tests Completed Globally
- For Full-year 2024, BioMarin Expects Revenues to Approach $3 Billion

Financial Highlights (in millions of U.S. dollars, except per share data, unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% Change	2023	2022	% Change
Total Revenues	**$ 581.3**	**$ 505.3**	**15 %**	**$ 1,773.0**	**$ 1,558.5**	**14 %**
Total Enzyme Product Revenues [1]	**$ 401.5**	**$ 388.0**	**3 %**	**$ 1,270.4**	**$ 1,240.2**	**2 %**
VIMIZIM® Net Product Revenues	$ 158.9	$ 155.5	2 %	$ 525.6	$ 511.7	3 %
VOXZOGO Net Product Revenues	$ 123.1	$ 48.3	155 %	$ 324.2	$ 102.3	217 %
NAGLAZYME® Net Product Revenues	$ 108.9	$ 99.5	9 %	$ 322.0	$ 343.3	(6)%
PALYNZIQ® Net Product Revenues	$ 78.9	$ 66.2	19 %	$ 216.1	$ 182.7	18 %
KUVAN® Net Product Revenues	$ 42.9	$ 57.0	(25)%	$ 144.0	$ 174.0	(17)%
BRINEURA® Net Product Revenues	$ 41.0	$ 37.8	8 %	$ 118.2	$ 111.7	6 %
ALDURAZYME® Net Product Revenues	$ 13.8	$ 29.0	(52)%	$ 88.5	$ 90.8	(3)%
ROCTAVIAN Net Product Revenues	$ 0.8	$ —	nm	$ 0.8	$ —	nm
GAAP Net Income (Loss) [2]	$ 40.4	$ (6.7)		$ 147.3	$ 141.8	
Non-GAAP Income [3]	$ 89.5	$ 52.0		$ 310.5	$ 227.6	
GAAP Diluted Earnings (Loss) per Share (EPS)	$ 0.21	$ (0.04)		$ 0.77	$ 0.75	
Non-GAAP Diluted EPS [4]	$ 0.46	$ 0.27		$ 1.60	$ 1.20	

	September 30, 2023	December 31, 2022
Total cash, cash equivalents & investments	$ 1,673.8	$ 1,625.4

(1) Enzyme Products include ALDURAZYME, BRINEURA, NAGLAZYME, PALYNZIQ, and VIMIZIM.

(2) GAAP Net Income in the nine months ended September 30, 2022, included a $89.0 million gain, net of taxes, related to the sale of the Rare Pediatric Disease Priority Review Voucher (PRV) the company received from the U.S. Food and Drug Administration (FDA) in connection with U.S. approval of VOXZOGO.

(3) Non-GAAP Income is defined by the company as reported GAAP Net Income, excluding amortization expense, stock-based compensation expense, contingent consideration, and, in certain periods, certain other specified items. The company also includes a Non-GAAP adjustment for the estimated income tax impact of reconciling items. Refer to Non-GAAP Information beginning on page 10 of this press release for a complete discussion of the company's Non-GAAP financial information and reconciliations to the comparable information reported under U.S. GAAP.

(4) Non-GAAP Diluted EPS is defined by the company as Non-GAAP Income divided by Non-GAAP diluted shares outstanding.

nm Not meaningful

SAN RAFAEL, Calif., November 1, 2023 – BioMarin Pharmaceutical Inc. (NASDAQ: BMRN) today announced financial results for the nine months and third quarter ended September 30, 2023.

"Results in the quarter drove double-digit revenue growth year-over-year and supports BioMarin's full-year 2023 revenue and profitability objectives, set at the beginning of the year," said Jean-Jacques Bienaimé, Chairman and Chief Executive Officer of BioMarin.

"We were very pleased to have recently received FDA approval for VOXZOGO for children under 5 years of age with achondroplasia, making it available in the U.S. for children of all ages with open growth plates. We also recently received approval in Europe to expand VOXZOGO treatment to children aged 4 months and older. These important age expansions will ensure that the youngest children treated with VOXZOGO have the opportunity to experience greater clinical benefit due to a longer potential treatment window. In parallel with exceptional commercial and regulatory execution of VOXZOGO during the quarter, we concluded key reimbursement steps to facilitate ROCTAVIAN treatment in Europe and the U.S. All together, these developments drive our expectation that total BioMarin revenues will approach $3 billion in 2024," said Mr. Bienaimé.

"In Germany, we have tentative agreement with the German Health Insurance Fund on the final ROCTAVIAN price, which we expect to be formalized in the coming weeks. With the final German price expected to be published by year-end, and 60 people in Germany eligible for next steps based on CDx testing results for AAV5 antibodies, we are encouraged by progress made in the quarter. We are also pleased to share that price negotiations with the Italian Medicines Agency are going well and that we expect a final price by year-end," Mr. Bienaimé added, "In the U.S. since gaining FDA approval of ROCTAVIAN on June 29, 2023, the commercial team has been building the reimbursement network to facilitate patient access, setting the stage for meaningful uptake of ROCTAVIAN in 2024."

Third Quarter Financial Highlights:

- **Total Revenues** for the third quarter of 2023 were $581.3 million, an increase of 15% compared to the same period in 2022. The increase in Total Revenues was primarily attributed to the following:
    - higher VOXZOGO sales volume due to new patients initiating therapy across all regions;
    - higher PALYNZIQ product revenues primarily due to new patients initiating therapy, particularly in U.S.; partially offset by
    - lower ALDURAZYME product revenues primarily driven by the timing of order fulfillment to Sanofi; and
    - lower KUVAN product revenues attributed to increasing generic competition as a result of the loss of exclusivity in the U.S.
- **GAAP and Non-GAAP Net Income** of $40.4 million and $89.5 million resulted in increases of $47.1 million and $37.5 million for the third quarter of 2023 compared to the same period in 2022, respectively. The increased net income was primarily due to higher gross profit driven by increased revenues, as well as lower income tax expense, partially offset by higher spend in research and development programs to support both

early-stage research and clinical activities and higher sales and marketing expenses to support the commercial launch of ROCTAVIAN.

Global Commercial Launches of ROCTAVIAN and VOXZOGO

- In the U.S., following the June 29, 2023, FDA approval of ROCTAVIAN, a one-time, gene therapy for the treatment of adults with severe hemophilia A, the company executed a number of critical steps to drive awareness among patients, physicians and patient advocates, as well as prepare Hemophilia Treatment Center (HTC) sites for patient uptake. At the end of the quarter, payers representing more than 205 million U.S. lives had published ROCTAVIAN coverage policies. Warranty policies had been secured by payers representing more than 95 million lives. As reimbursement and HTC readiness become more connected, U.S. patient testing and treatment will be more readily accessible.

- Today in Germany, the second commercial patient was treated with ROCTAVIAN. Over the last several weeks, the company and the German National Association of Statuary Health Insurance Funds (GKV) tentatively agreed on a final ROCTAVIAN price and expect to complete all formalities by year-end. In Germany, 60 people are eligible for next steps ahead of treatment with ROCTAVIAN based on CDx testing to determine seronegativity to AAV5. In Italy, final price negotiations with the Italian Medicines Agency are going well and are expected to be formalized by year-end 2023.

- As a result of global delays securing pricing and reimbursement, and other market preparations for ROCTAVIAN treatment, and proximity to the holiday season, full-year 2023 guidance has been lowered to less than $10 million.

- At the end of September 2023, approximately 2,320 children with achondroplasia were being treated with VOXZOGO across 38 active markets. In the third quarter, patient growth remained strong worldwide. Based on these trends, and the expectation that approximately 2,600 children will be receiving VOXZOGO treatment by year-end, today the company updated full-year 2023 VOXZOGO guidance to between $435 million and $455 million. Additionally, based on increased fill-finish manufacturing commitments, VOXZOGO supply is planned to increase from 2023 levels through the first and second quarters of 2024 and is expected to be fully unconstrained by mid-year 2024.

- On October 24, 2023, the European Commission adopted the decision to expand the indication for VOXZOGO to treat children with achondroplasia aged 4 months and older with open growth plates. VOXZOGO is approved for the treatment of children with achondroplasia of all ages with open growth plates in Japan and the U.S.

VOXZOGO and ROCTAVIAN Market Expansion Opportunities

- In the coming weeks, the company plans to begin the pivotal program with VOXZOGO for the treatment of children with hypochondroplasia, a condition characterized by impaired bone growth. Hypochondroplasia is a genetic statural condition caused by a mutation (gene change) in the fibroblast growth factor receptor-3 (FGFR3) gene. The 6-month observation arm of the study will be followed by the 52-week randomized, double-blind, placebo-controlled phase of the 80-participant clinical trial. If successful, this study is expected to support regulatory approval in this large indication.

- The company is also preparing to initiate two additional clinical programs in 2024 with VOXZOGO, one in idiopathic short stature and one in genetic short stature conditions.

- Additional product expansion opportunities with ROCTAVIAN continue, including a clinical study investigating ROCTAVIAN treatment in those with active or prior inhibitors and continued exploration of methods of administering ROCTAVIAN in people with pre-existing antibodies against AAV5.

Earlier-stage Development Portfolio On-track; Seven Product Candidates Advancing

- **BMN 255** for hyperoxaluria in chronic liver disease. The company believes the availability of a potent, orally bioavailable, small molecule like BMN 255 may be able to significantly reduce disease and treatment burden in a patient population with significant unmet need. The company expects to have a determination of clinical proof of concept in 2024.

- **BMN 331** gene therapy for Hereditary Angioedema (HAE) is in the Phase 1/2 HAERMONY study to evaluate this investigational AAV5-mediated gene therapy for people living with HAE. The company expects to dose additional patients with an optimized corticosteroid regimen with an anticipated clinical proof of concept determination by 2025.

- **BMN 351** for Duchenne Muscular Dystrophy (DMD), is an antisense oligonucleotide therapy for individuals with exon 51-skip-amenable DMD. The company is currently enabling a global clinical development plan and expects to have a determination of clinical proof of concept in 2025.

- **BMN 349** for alpha-1 antitrypsin deficiency, an orally bioavailable, small molecule that preferentially sequesters mutant protein, preventing polymerization in liver cells that drive the progressive liver disease form of the illness. The company plans to initiate a global clinical program with BMN 349 in 2024 and expects to have a determination of clinical proof of concept in 2025.

- **BMN 293** for MYBPC3 hypertrophic cardiomyopathy (HCM). IND enabling studies are underway and have incorporated pre-IND feedback from the FDA. The company plans to initiate a global clinical program with BMN 293 in 2024 and expects to have a determination of clinical proof of concept in 2026.

- **BMN 365** for AAV gene therapy for PKP2 arrhythmogenic cardiomyopathy. The company is currently conducting IND-enabling studies and expects to initiate global clinical programs in 2025 with an anticipated clinical proof of concept determination by 2027.

- **BMN 355** monoclonal antibody for long-QT syndrome. The company is currently conducting IND-enabling studies and expects to initiate global clinical programs in 2025 with an anticipated clinical proof of concept determination by 2026.

2023 Full-Year Financial Guidance (in millions, except % and EPS amounts)

Item	Provided July 31, 2023			Updated November 1, 2023		
Total Revenues	$2,375	to	$2,500	$2,390	to	$2,470
Enzyme Product Revenues[1]	$1,700	to	$1,850	$1,700	to	$1,775
ROCTAVIAN Revenues	$50	to	$150	less than $10M		
VOXZOGO Revenues	$400	to	$440	$435	to	$455
Gross Profit %	77.5%	to	79%	77.8%	to	79%
R&D % of Revenue	30%	to	32%	Unchanged		
SG&A % of Revenue	35.5%	to	37.5%	36%	to	38%
GAAP Net Income	$165	to	$215	$170	to	$210
GAAP Diluted EPS	$0.83	to	$1.08	$0.85	to	$1.05
Non-GAAP Income	$370	to	$420	$380	to	$410
Non-GAAP Diluted EPS	$1.85	to	$2.10	$1.90	to	$2.05

(1) Enzyme Products include ALDURAZYME, BRINEURA, NAGLAZYME, PALYNZIQ and VIMIZIM.

BioMarin will host a conference call and webcast to discuss third quarter 2023 financial results and full-year financial guidance today, Wednesday, November 1, 2023, at 4:30 p.m. ET. This event can be accessed through this link or on the investor section of the BioMarin website at www.biomarin.com.

U.S./Canada Dial-in Number: 888-330-3073	Replay Dial-in Number: 800-770-2030
International Dial-in Number: 646-960-0683	Replay International Dial-in Number: 647-362-9199
No Conference ID: 1816377	Conference ID: 1816377

About BioMarin

Founded in 1997, BioMarin is a global biotechnology company dedicated to transforming lives through genetic discovery. The company develops and commercializes targeted therapies that address the root cause of genetic conditions. BioMarin's robust research and development capabilities have resulted in multiple innovative commercial therapies for patients with rare genetic disorders. The company's distinctive approach to drug discovery has produced a diverse pipeline of commercial, clinical, and pre-clinical candidates that address a significant unmet medical need, have well-understood biology, and provide an opportunity to be first-to-market or offer a substantial benefit over existing treatment options. For additional information, please visit www.biomarin.com.

Forward-Looking Statements

This press release and the associated conference call and webcast contain forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc. (BioMarin), including, without limitation, statements about: the expectations of Total Revenues, Net Product Revenues, Enzyme Product Revenues, Gross Profit, Research and Development Expense (R&D), Selling, General and Administrative Expense (SG&A), GAAP Net Income (Loss), Non-GAAP Income, GAAP Diluted EPS and Non-GAAP Diluted EPS for the full-year 2023; cash flows from operating activities; the timing of orders for commercial products; the timing of BioMarin's clinical development and commercial prospects, including announcements of data from clinical studies and trials; the clinical development and commercialization of BioMarin's product candidates and commercial products, including (i) the potential to leverage VOXZOGO in conditions beyond achondroplasia, such as hypochondroplasia, and to expand the indication of VOXZOGO for children with achondroplasia aged 4 months and older in Europe, (ii) the results from clinical studies regarding product expansion opportunities for ROCTAVIAN, (iii) BioMarin's plans to observe the highest dose of BMN 255 in a patient population and, if the response is positive, engage to move to a pivotal Phase 2/3 study in 2024, (iv) with respect to BMN 331, BioMarin's plan to dose additional patients with an alternative corticosteroid regimen in late 2023, with an anticipated proof of concept by 2025, (v) BioMarin's plans to initiate a global clinical program with BMN 349 in 2024, (vi) BioMarin's plans to initiate a global clinical program with BMN 293 in 2024, and (vii) BioMarin's plans to initiate global clinical programs with BMN 365 and BMN 355 in 2025; the potential approval and commercialization of BioMarin's product candidates, including commercialization of ROCTAVIAN for the treatment of severe hemophilia A in the U.S. following FDA approval in June 2023, and the timing of such approval decisions and product launches, including (i) the anticipated start and growth of commercial sales of VOXZOGO in additional countries, and (ii) BioMarin's expectation that EU health authorities take action on its supplemental marketing application for VOXZOGO in the coming weeks and the number of additional children that will be eligible for VOXZOGO in the U.S. and, if such age expansions are accepted, in Europe; the expected benefits and availability of BioMarin's product candidates; and potential growth opportunities and trends, including that BioMarin expects accelerated growth of VOXZOGO revenues as the product launch continues in future quarters and that BioMarin expects growth of ROCTAVIAN revenues as the product's access is expanded in Europe and following commercial launch in the U.S.

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: BioMarin's success in the commercialization of its commercial products, impacts of macroeconomic and other external factors on BioMarin's operations; results and timing of current and planned preclinical studies and clinical trials and the release of data from those trials; BioMarin's ability to successfully manufacture its commercial products and product candidates; the content and timing of decisions by the FDA, the European Commission and other regulatory authorities concerning each of the described products and product candidates; the market for each of these products; actual sales of BioMarin's commercial products; the introduction of generic versions of BioMarin's commercial products, in particular generic versions of KUVAN; and those factors detailed in BioMarin's filings with the Securities and Exchange Commission (SEC), including, without limitation, the factors contained under the caption "Risk Factors" in BioMarin's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 as such factors may be updated by any subsequent reports. 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
September 30, 2023 and December 31, 2022
(In thousands of U.S. dollars, except per share amounts)

	September 30, 2023	December 31, 2022 [1]
ASSETS	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 785,414	$ 724,531
Short-term investments	340,431	567,006
Accounts receivable, net	572,498	461,316
Inventory	1,032,159	894,083
Other current assets	224,806	104,521
Total current assets	2,955,308	2,751,457
Noncurrent assets:		
Long-term investments	548,002	333,835
Property, plant and equipment, net	1,067,156	1,073,366
Intangible assets, net	302,476	338,569
Goodwill	196,199	196,199
Deferred tax assets	1,523,953	1,505,412
Other assets	165,069	176,236
Total assets	$ 6,758,163	$ 6,375,074
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 669,825	$ 572,959
Short-term convertible debt, net	493,398	—
Short-term contingent consideration	—	15,925
Total current liabilities	1,163,223	588,884
Noncurrent liabilities:		
Long-term convertible debt, net	592,586	1,083,019
Other long-term liabilities	105,457	100,015
Total liabilities	1,861,266	1,771,918
Stockholders' equity:		
Common stock, $0.001 par value: 500,000,000 shares authorized; 188,339,482 and 186,250,719 shares issued and outstanding, respectively	188	186
Additional paid-in capital	5,542,774	5,404,895
Company common stock held by the Nonqualified Deferred Compensation Plan (the NQDC)	(10,393)	(8,859)
Accumulated other comprehensive loss	6,257	(3,867)
Accumulated deficit	(641,929)	(789,199)
Total stockholders' equity	4,896,897	4,603,156
Total liabilities and stockholders' equity	$ 6,758,163	$ 6,375,074

(1) December 31, 2022 balances were derived from the audited Consolidated Financial Statements included in the company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission (SEC) on February 27, 2023.

BIOMARIN PHARMACEUTICAL INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Nine Months Ended September 30, 2023 and 2022
(In thousands of U.S. dollars, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
REVENUES:				
Net product revenues	$ 568,266	$ 493,348	$ 1,739,390	$ 1,516,533
Royalty and other revenues	13,063	11,996	33,629	41,968
Total revenues	581,329	505,344	1,773,019	1,558,501
OPERATING EXPENSES:				
Cost of sales	124,745	116,288	379,376	356,379
Research and development	191,314	157,829	540,523	476,855
Selling, general and administrative	223,928	216,816	662,267	608,270
Intangible asset amortization and contingent consideration	15,681	16,828	46,975	50,935
Gain on sale of nonfinancial assets, net	—	—	—	(108,000)
Total operating expenses	555,668	507,761	1,629,141	1,384,439
INCOME (LOSS) FROM OPERATIONS	25,661	(2,417)	143,878	174,062
Interest income	15,740	4,999	40,295	9,324
Interest expense	(3,779)	(4,679)	(11,237)	(12,344)
Other income (expense), net	4,047	193	(3,700)	(3,908)
INCOME (LOSS) BEFORE INCOME TAXES	41,669	(1,904)	169,236	167,134
Provision for income taxes	1,291	4,748	21,966	25,324
NET INCOME (LOSS)	$ 40,378	$ (6,652)	$ 147,270	$ 141,810
EARNINGS (LOSS) PER SHARE, BASIC	$ 0.21	$ (0.04)	$ 0.78	$ 0.77
EARNINGS (LOSS) PER SHARE, DILUTED	$ 0.21	$ (0.04)	$ 0.77	$ 0.75
Weighted average common shares outstanding, basic	188,219	185,597	187,617	185,009
Weighted average common shares outstanding, diluted	191,173	185,597	195,042	192,252

BIOMARIN PHARMACEUTICAL INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 2023 and 2022
(In thousands of U.S. dollars)
(unaudited)

	Nine Months Ended September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 147,270	$ 141,810
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	77,525	77,416
Non-cash interest expense	3,198	3,089
Amortization of premium (accretion of discount) on investments	(6,781)	3,741
Stock-based compensation	152,244	149,574
Gain on sale of nonfinancial assets, net	—	(108,000)
Loss on equity investment	12,650	—
Deferred income taxes	(20,137)	(743)
Unrealized foreign exchange loss (gain)	5,454	(16,075)
Non-cash changes in the fair value of contingent consideration	—	2,243
Other	(224)	(700)
Changes in operating assets and liabilities:		
Accounts receivable, net	(131,940)	(53,752)
Inventory	(97,948)	(27,419)
Other current assets	(59,389)	(8,558)
Other assets	(20,812)	12,140
Accounts payable and other short-term liabilities	56,333	(2,398)
Other long-term liabilities	14,333	(3,252)
Net cash provided by operating activities	131,776	169,116
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(67,774)	(85,271)
Maturities and sales of investments	751,677	477,244
Purchases of investments	(727,043)	(457,382)
Proceeds from sale of nonfinancial assets	—	110,000
Purchase of intangible assets	(3,141)	(9,910)
Net cash provided by (used in) investing activities	(46,281)	34,681
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercises of awards under equity incentive plans	54,548	43,866
Taxes paid related to net share settlement of equity awards	(72,399)	(50,696)
Payments of contingent consideration	(9,475)	(21,054)
Principal repayments of financing leases	(2,241)	(1,635)
Net cash used in financing activities	(29,567)	(29,519)
Effect of exchange rate changes on cash	4,955	(39)
NET INCREASE IN CASH AND CASH EQUIVALENTS	60,883	174,239
Cash and cash equivalents:		
Beginning of period	$ 724,531	$ 587,276
End of period	$ 785,414	$ 761,515

Non-GAAP Information

The results presented in this press release include both GAAP information and Non-GAAP information. Non-GAAP Income is defined by the company as GAAP Net Income (Loss) excluding amortization expense, stock-based compensation expense, contingent consideration expense, and, in certain periods, certain other specified items, as detailed below when applicable. The company also includes a Non-GAAP adjustment for the estimated tax impact of the reconciling items. Non-GAAP Diluted EPS is defined by the company as Non-GAAP Income divided by Non-GAAP diluted shares outstanding

BioMarin regularly uses both GAAP and Non-GAAP results and expectations internally to assess its financial operating performance and evaluate key business decisions related to its principal business activities: the discovery, development, manufacture, marketing and sale of innovative biologic therapies. Because Non-GAAP Income, Non-GAAP Diluted EPS and Non-GAAP Diluted Shares are important internal measurements for BioMarin, the company believes that providing this information in conjunction with BioMarin's GAAP information enhances investors' and analysts' ability to meaningfully compare the company's results from period to period and to its forward-looking guidance, and to identify operating trends in the company's principal business. BioMarin also uses Non-GAAP Income internally to understand, manage and evaluate its business and to make operating decisions, and compensation of executives is based in part on this measure.

Non-GAAP Income and its components are not meant to be considered in isolation or as a substitute for, or superior to comparable GAAP measures and should be read in conjunction with the consolidated financial information prepared in accordance with GAAP. Investors should note that the Non-GAAP information is not prepared under any comprehensive set of accounting rules or principles and does not reflect all of the amounts associated with the company's results of operations as determined in accordance with GAAP. Investors should also note that these Non-GAAP financial measures have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. In addition, from time to time in the future there may be other items that the company may exclude for purposes of its Non-GAAP financial measures; likewise, the company may in the future cease to exclude items that it has historically excluded for purposes of its Non-GAAP financial measures. Because of the non-standardized definitions, the Non-GAAP financial measure as used by BioMarin in this press release and the accompanying tables may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

The following tables present the reconciliation of GAAP reported to Non-GAAP adjusted financial information:

Reconciliation of GAAP Reported Net Income to Non-GAAP Income[1]
(In millions of U.S. dollars)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP Reported Net Income (Loss)	**$ 40.4**	**$ (6.7)**	**$ 147.3**	**$ 141.8**
Adjustments				
Stock-based compensation expense - COS	4.0	4.4	13.1	13.4
Stock-based compensation expense - R&D	14.5	17.1	49.4	47.9
Stock-based compensation expense - SG&A	29.9	33.2	89.8	88.2
Amortization of intangible assets	15.7	15.9	47.0	47.1
Contingent consideration	—	0.9	—	3.8
Gain on sale of non-financial assets [2]	—	—	—	(108.0)
Severance and employee termination benefits [3]	(0.4)	4.8	(0.5)	4.8
Loss on investment in equity securities [4]	—	—	12.6	—
Income tax effect of adjustments	(14.6)	(17.6)	(48.2)	(11.4)
Non-GAAP Income	$ 89.5	$ 52.0	$ 310.5	$ 227.6

Reconciliation of Certain GAAP Reported Information to Non-GAAP Information

(in millions, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP Diluted EPS	**$ 0.21**	**$ (0.04)**	**$ 0.77**	**$ 0.75**
Adjustments				
Stock-based compensation expense	0.24	0.28	0.76	0.78
Amortization of intangible assets	0.08	0.08	0.24	0.24
Contingent consideration	—	—	—	0.02
Gain on sale of non-financial assets [2]	—	—	—	(0.56)
Severance and employee termination benefits [3]	—	0.02	—	0.02
Loss on investment in equity securities [4]	—	—	0.06	—
Income tax effect of adjustments	(0.07)	(0.09)	(0.23)	(0.05)
Non-GAAP Diluted EPS	$ 0.46	$ 0.27	$ 1.60	$ 1.20

(1) Certain amounts may not sum or recalculate due to rounding.

(2) Represents the net gain in the first quarter of 2022 on the sale to a third party of the PRV the company received from the FDA in connection with the U.S. approval of VOXZOGO.

(3) Represents change in estimates to severance and employee termination benefit charges in SG&A related to the company's organizational redesign announced in October 2022. Related to this October 2022 reorganization plan, the company recognized $23.0 million of expense related to severance and employee termination benefits in 2022, the majority of which was recognized in the fourth quarter.

(4) Represents the impairment loss on investment in non-marketable equity securities recorded in Other income (expense), net in the first quarter of 2023.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP Weighted-Average Dilutive Shares Outstanding	**191.2**	**185.6**	**195.0**	**192.3**
Adjustments				
Issuances under equity incentive plans	—	3.5	—	—
Common stock issuable under Company's convertible debt [1]	8.4	4.0	4.4	—
Non-GAAP Weighted-Average Dilutive Shares Outstanding	199.6	193.1	199.4	192.3

(1) Common stock issuable under the company's convertible debt was excluded from the computation of GAAP Weighted-Average Dilutive Shares Outstanding when they were anti-dilutive. If converted, the company would issue 4.0 million shares under the convertible notes due in 2024 and 4.4 million shares under the convertible notes due in 2027.

	Guidance for the Year Ended December 31, 2023 [1][2]		
	Net Income	Diluted Shares	Diluted EPS
GAAP Net Income and Diluted EPS	**$ 170 to $ 210**	200	**$0.85 to $1.05**
Amortization of intangible assets	60		0.30
Stock-based compensation expense	200		1.00
Severance and employee termination benefits	(0.5)		—
Loss on investment in equity securities	12.6		0.06
Income tax effect of adjustments [3]	(67)		(0.34)
Non-GAAP Income and Diluted EPS	$ 380 to $ 410	200	$1.90 to $2.05

(1) The adjustments/reconciling items included in this table are presented to facilitate the reconciliation of Non-GAAP Income and Non-GAAP Diluted EPS to their closest GAAP financial metrics, GAAP Net Income and GAAP Diluted EPS. The specific amounts included in each reconciling line item above represent approximations of the underlying adjustments from GAAP Net Income to Non-GAAP Income and from GAAP Diluted EPS to Non-GAAP Diluted EPS. Actual 2023 results for each reconciling line item may be different, in some cases materially, than the amounts listed above as a result of uncertainty regarding, and the potential variability of, those items.

(2) Amounts will sum when using midpoint of ranges provided

(3) Income tax adjustments represent the estimated income tax impact of each pre-tax non-GAAP adjustment based on the applicable statutory income tax rate.

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