

BioMarin Announces Full Year and Fourth Quarter 2018 Results

- Total Revenues for 2018 Grow 14% Year-over-Year to \$1.5 Billion
- As of February 15, 2019, 335 U.S. Commercial Patients Receiving Treatment with Palynziq®
- In Europe, CHMP Opinion for Palynziq Anticipated in First Quarter 2019
- Enrollment Complete for Accelerated Filing Requirements for Valoctocogene Roxaparvec for Hemophilia A
- Global Phase 3 Vosoritide Study in Children with Achondroplasia Enrollment Complete with Data Expected by Year-end 2019

SAN RAFAEL, Calif., Feb. 21, 2019 /PRNewswire/ --

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

	Three Months Ended December 31,			Twelve Months Ended December 31,		
	2018	2017	% Change	2018	2017	% Change
Total Revenues	\$ 353.2	\$ 358.3	(1)%	\$ 1,491.2	\$ 1,313.6	14%
Vimizim Net Product Revenues	114.0	114.0	0%	482.0	413.3	17%
Kuvan Net Product Revenues	112.2	107.4	4%	433.6	407.5	6%
Naglazyme Net Product Revenues	76.7	93.8	(18)%	345.9	332.2	4%
Aldurazyme Net Product Revenues	17.4	28.3	(39)%	135.1	90.0	50%
Brineura Net Product Revenues	12.2	5.2	135%	39.9	8.6	364%
Palynziq Net Product Revenues	8.1	—	n/a	12.2	—	n/a
GAAP Net Loss	\$ (3.6)	\$ (51.4)		\$ (77.2)	\$ (117.0)	
GAAP Net Loss per Share - Basic	\$ (0.02)	\$ (0.29)		\$ (0.44)	\$ (0.67)	
GAAP Net Loss per Share - Diluted	\$ (0.03)	\$ (0.30)		\$ (0.44)	\$ (0.67)	
Non-GAAP Income (Loss) ⁽¹⁾	\$ (10.8)	\$ 5.2		\$ 90.9	\$ 74.0	
	December 31, 2018	December 31, 2017				
Cash, cash equivalents and investments	\$ 1,320.2	\$ 1,781.7				

(1) Non-GAAP Income (Loss) is defined by the Company as reported GAAP Net Income (Loss), excluding net interest expense, provision for (benefit from) income taxes, depreciation expense, amortization expense, stock-based compensation expense, contingent consideration expense and, in certain periods, certain other specified items. Refer to Non-GAAP Information beginning on page 9 of this press release for a complete discussion of the Company's Non-GAAP financial information and reconciliations to the comparable information reported under Generally Accepted Accounting Principles in the United States (US GAAP).

BioMarin Pharmaceutical Inc. (NASDAQ: BMRN) (BioMarin or the Company) today announced financial results for the full year and fourth quarter of 2018. Net Loss for 2018 decreased \$39.8 million or 34%, to \$77.2 million, compared to \$117.0 million in 2017. Net Loss for the quarter ended December 31, 2018 decreased to \$3.6 million, compared to Net Loss of \$51.4 million, for same period in 2017.



The change in Net Loss for the full year and fourth quarter of 2018, compared to the same periods in 2017 was primarily due to the following:

- a year over year increase in gross profits of \$104.0 million driven by increased sales volume across all of our products, a \$4.1 million quarter over quarter decrease in gross profits driven by a decrease in Aldurazyme sales volume; and
- an increase in the benefit from income taxes. During 2018, the Company recognized a \$65.5 million benefit from income taxes primarily attributed to Orphan Drug Credits earned in the year, whereas in 2017 it recognized income tax expense of \$81.2 million primarily driven by U.S. tax reform; partially offset by
- higher research and development (R&D) expense for the expansion of BioMarin's clinical programs related to valoctocogene roxaparvec, vosoritide and tralesenidase alfa and higher selling, general and administrative (SG&A) expense in support of the U.S. commercial launch of Palynziq and European (EU) pre-launch activities, the continued commercial expansion of Brineura and market preparation activities related to the Company's valoctocogene roxaparvec product candidate; and
- a decrease in the gain on the sale of intangible assets. During the third and fourth quarters of 2018, the Company received milestone payments of \$20.0 million and \$30.0 million, respectively. The milestone payments were triggered by a third-party's attainment of development and regulatory approval milestones related to a previously sold intangible asset. In 2017, BioMarin sold the Priority Review Voucher it received in connection with the FDA approval of Brineura and recognized the \$125.0 million of proceeds as a gain on the sale of intangible assets.

Non-GAAP Income for 2018 increased \$16.9 million, or 23%, to \$90.9 million, compared to \$74.0 million in 2017. Non-GAAP Loss for the quarter ended December 31, 2018 was \$10.8 million, compared to Non-GAAP Income of \$5.2 million in the quarter ended December 31, 2017. The change in Non-GAAP Income/Loss for the full year 2018 was attributed to increased gross profit from sales partially offset by higher expenses as described above. The change in Non-GAAP Income/Loss quarter to quarter was attributed to decreased gross profit and higher expenses as described above.

Net product revenues for 2018 increased 14% to \$1.5 billion, compared to \$1.3 billion in 2017. The increase in net product revenues for the full year, is attributed to increased sales across all of our products despite quarter to quarter volatility driven by central government ordering patterns. The increase by product was:

- Vimizim: increased \$68.7 million, or 17%, primarily driven by new patients initiating therapy and government ordering patterns;
- Aldurazyme: increased \$45.1 million, or 50%, of which \$20.2 million is due to the different revenue recognition principles applied as a result of BioMarin's adoption of Accounting Standards Codification 606, Revenue from Contracts with Customers, (ASC 606), and \$24.9 million due an increase in sales volume;
- Brineura: contributed \$31.3 million to increased net product revenues, primarily attributed to new patients initiating therapy as the product was commercially launched in mid-2017;
- Kuvan: increased \$26.1 million, or 6%, primarily due to an increase in patients initiating therapy in North America;
- Naglazyme: increased \$13.7 million, or 4%, primarily driven by new patients initiating therapy in Turkey and North America and government ordering patterns in the Middle East, partially offset by a decrease due to the impact of government ordering patterns from certain Latin American countries; and
- Palynziq: received approval from the U.S. Food and Drug Administration (FDA) in May 2018, with commercial sales launching in the third quarter of 2018. Palynziq net product revenues in 2018 totaled \$12.2 million primarily driven by the conversion of clinical patients to commercial Palynziq in the U.S.

Net product revenues for the fourth quarter of 2018 were \$347.2 million, compared to \$353.6 million in the fourth quarter of 2017. The decrease in net product revenues in the fourth quarter of 2018 compared to the fourth quarter of 2017 was primarily attributed to decreased Naglazyme net product revenues driven by the volatility of central government ordering patterns and lower Aldurazyme sales volume driven by timing of shipments to Genzyme, partially offset by the first full quarter of Palynziq commercial sales and increased Brineura net product revenues.

As of December 31, 2018, BioMarin had cash, cash equivalents and investments totaling approximately \$1.3 billion, as compared to \$1.8 billion on December 31, 2017. On October 15, 2018, our 0.75% senior subordinated convertible notes matured and were settled with a combination of \$375.0 million in cash for the

full principal amount and cash in lieu of fractional shares plus the issuance of 190,220 common stock for the conversion value in excess of the principal.

Commenting on 2018 results, Jean-Jacques Bienaimé, Chairman and Chief Executive Officer of BioMarin, said, "BioMarin's achievements over the last 12 months have prepared us for a number of key catalysts across the product portfolio in 2019. In the second quarter of 2018, we received FDA approval of Palynziq, an important new therapy that helps address a significant unmet need in adults with phenylketonuria (PKU). As of February 15, 2019, 335 PKU patients were being treated in the U.S. with reimbursed Palynziq. Looking forward, we expect to hear the status of our European marketing authorization application in the first quarter of 2019. We are hopeful that PKU patients in the European Union will have the opportunity to benefit from Palynziq should we receive approval in that region later this year."

"In May, we provided two years of clinical data from the Phase 2 study with the 6e13 vg/kg dose of valoctocogene roxaparvovec gene therapy for severe hemophilia A that demonstrated the elimination of need for prophylaxis and no spontaneous bleeds. In addition, we amended the protocol of the global GENER8-1 (Phase 3) pivotal study by increasing the number of participants from 40 to 130 in order to evaluate superiority compared to the current standard of care. We now anticipate completing enrollment during the third quarter of 2019. Based on draft guidance from the FDA for hemophilia gene therapy products published in 2018, we communicated our interest in exploring a potential accelerated approval pathway with valoctocogene roxaparvovec. We plan to decide in the second half of 2019 whether we will pursue an accelerated approval path."

Mr. Bienaimé continued, "In November of 2018, we showcased a number of our other pipeline and research programs at BioMarin's annual Research and Development Day. Specifically, we provided a 42-month update on vosoritide for the treatment of achondroplasia that our ongoing Phase 2 study demonstrated an average additional cumulative height gain of 5.7 centimeters. Based on these results, we are encouraged that vosoritide could potentially be the first approved treatment option for children with achondroplasia. Finally, we were pleased to share initial pre-clinical data for BMN 307, our gene therapy product for PKU, which demonstrated lifetime normalization of Phe in a validated PKU mouse model. We plan to complete preclinical studies in the first half of 2019 with an anticipated IND filing planned for the second half of 2019."

Full-Year 2019 Financial Guidance (in millions, except %)

Item	2019 Guidance	
Total Revenues	\$1,680	to \$1,750
Vimizim Net Product Revenues	\$530	to \$570
Kuvan Net Product Revenues	\$420	to \$460
Naglazyme Net Product Revenues	\$350	to \$380
Palynziq Net Product Revenues	\$70	to \$100
Brineura Net Product Revenues	\$55	to \$75
Cost of Sales (% of Total Revenues)	20%	to 21%
Research and Development Expense	\$740	to \$780
Selling, General and Admin. Expense	\$650	to \$690
GAAP Net Loss	\$(45)	to \$(85)
Non-GAAP Income *	\$130	to \$170

*All Financial Guidance items are calculated based on U.S. GAAP with the exception of Non-GAAP Income/Loss. Refer to Non-GAAP Information beginning on page 9 of this press release for a complete discussion of the Company's Non-GAAP financial information and reconciliations to the comparable GAAP reported information.

Key Program Highlights

- Palynziq for PKU:** With the approval in May 2018 of Palynziq in the United States, an injection to reduce blood Phe concentrations in adult patients with PKU, BioMarin added its seventh commercial product to its portfolio. As of February 15, 2019, 335 patients were on reimbursed Palynziq, with an additional 131 patients enrolled and awaiting their first treatment with commercial Palynziq. Of the 125 PKU clinics in the U.S., 80 had at least one complete patient enrollment in the REMS program as of February 15, 2019. BioMarin anticipates an opinion from the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), on Palynziq in the first quarter of 2019. If the CHMP provides a positive opinion in the first quarter of 2019, then in the second quarter of 2019, it is possible that the European Commission (EC) could provide marketing authorization in the European Union.
- Valoctocogene roxaparvovec gene therapy for hemophilia A:** In May 2018, the Company updated the protocol for the Phase 3 GENER8-1 study evaluating the 6e13 vg/kg dose and has statistically powered the study results to evaluate superiority to the current standard of care, Factor VIII prophylaxis. The Phase 3 GENER8-1 study will include 130 participants and is expected to be fully enrolled in the third quarter of 2019. Draft guidelines published by the FDA in 2018 on the development of gene therapy products for the treatment of hemophilia outlined a potential accelerated approval path forward applicable to valoctocogene roxaparvovec. The Company announced in January 2019 that it had completed enrollment of the initial cohort of patients in its Phase 3 program that would be included in a potential accelerated submission. The Company plans to decide in the second half of 2019 whether it will submit a Biologics License Application through an accelerated approval pathway.
- Vosoritide for children with achondroplasia:** On November 7, 2018, the Company provided a 42-month update for vosoritide at R&D Day 2018. Data from the children in the ongoing Phase 2 study demonstrated an average of 5.7 centimeters of cumulative additional height gained at 42 months. BioMarin expects to have over 5 years of clinical data from this study to corroborate maintenance of effect at the time of possibly filing for marketing authorization. The vosoritide development program includes four distinct areas of focus to support global approval, including a large contemporaneous natural History study which is underway. The global Phase 3 study, which is fully enrolled, is a randomized, placebo-controlled study of vosoritide in approximately 110 children with achondroplasia between the ages of 5 to 14 years. BioMarin expects top line results from the 52-week Phase 3 study by year end 2019. Also in 2018, BioMarin began its global Phase 2 study with vosoritide in infants and young (less than 60 months old) children with achondroplasia, to determine the impact of treatment in this age group.
- Tralesinidase alfa (formerly referred to as BMN 250) for MPS IIIB (Sanfilippo Syndrome, Type B):** In February 2019, the Company provided an update at the Society for the Study of Inborn Errors of Metabolism (SSIEM) meeting from the Phase 1/2 trial with tralesinidase alfa. Of the seven subjects who have been treated with the 300 mg/kg weekly dose, heparan sulfate levels were normalized in the brain fluid. All subjects also experienced normalization of the enlargement of their liver and spleen. Development Quotient (DQ), a measure of cognitive function normalized to age, was also monitored. Five of the seven subjects have experienced encouraging trends in brain function based on DQ measures.
- BMN 307 gene therapy product candidate for phenylketonuria (PKU):** The Company expects to submit an investigational new drug application (IND) and/or a clinical trial application (CTA) for a gene therapy product for the treatment of PKU in the second half of 2019. At R&D Day 2018, BioMarin shared data with BMN 307 that demonstrated a lifetime Phe correction sustained at 80 weeks in preclinical mouse models. BMN 307 is an AAV vector containing the DNA sequence that codes for the phenylalanine hydroxylase enzyme that is deficient in people with PKU.
- BMN 290 for Friedreich's Ataxia:** BMN 290 is a selective chromatin modulation therapy intended for the treatment of Friedreich's ataxia. Currently, there are no approved disease modifying therapies for Friedreich's ataxia. The Company is currently conducting additional pre-clinical work on BMN 290 and will decide in the first half of 2019 whether to file an IND based on the outcome of those data.

BioMarin will host a conference call and webcast to discuss fourth quarter 2018 financial results today, Thursday, February 21, 2019 at 4:30 p.m. ET. This event can be accessed on the investor section of the BioMarin website at www.biomin.com.

U.S. / Canada Dial-in Number: 866.502.9859	Replay Dial-in Number: 855.859.2056
International Dial-in Number: 574.990.1362	Replay International Dial-in Number: 404.537.3406
Conference ID: 8265006	Conference ID: 8265006

About BioMarin

BioMarin is a global biotechnology company that develops and commercializes innovative therapies for patients with serious and life-threatening rare and ultra-

rare genetic diseases. The Company's portfolio consists of several approved products and multiple clinical and pre-clinical product candidates. 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 and expenses for BioMarin's commercial products, GAAP Net Loss, Non-GAAP Income (Loss) and other specified income statement guidance; the financial performance of BioMarin as a whole; BioMarin's potential for growth, BioMarin's commercial prospects, including the timing of (i) decisions by regulators, including the European Commission's decision regarding BioMarin's Marketing Authorization Application for Palynziq, (ii) BioMarin's clinical studies and trials, (iii) completion of enrollment of those studies and trials including enrollment in BioMarin's Phase 3 program with valoctocogene roxaparovec, and (iv) announcements of data from those studies and trials, including BioMarin's Phase 3 program and Phase 1/2 study with valoctocogene roxaparovec; the ongoing Phase 2 and Phase 3 studies of vosoritide and the Phase 1/2 study of traleseninase alfa (formerly referred to as BMN 250); the continued clinical development and commercialization of BioMarin's commercial products and product candidates, including (i) BioMarin's plans to potentially decide in the first half of 2019 whether to file an IND for BMN 290 and potentially file an IND and/or a CTA for its new gene therapy candidate for the treatment of PKU in the second half of 2019; (ii) statements regarding the timing of BioMarin's decision on whether or not to pursue an accelerated approval pathway for valoctocogene roxaparovec and (iii) statements regarding BioMarin's encouragement that vosoritide could potentially be the first approved treatment option for children with achondroplasia; the possible approval and commercialization of BioMarin's product candidates. 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; Genzyme Corporation's success in continuing the commercialization of Aldurazyme; results and timing of current and planned preclinical studies and clinical 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 September 30, 2018 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.

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BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

December 31, 2018 and 2017

(In thousands of U.S. dollars, except share and per share amounts)

	December 31, 2018 ⁽¹⁾	December 31, 2017 ⁽²⁾
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 493,982	\$ 598,028
Short-term investments	590,326	797,940
Accounts receivable, net	342,633	261,365
Inventory	530,871	475,775
Other current assets	98,403	74,036
Total current assets	<u>2,056,215</u>	<u>2,207,144</u>
Noncurrent assets:		
Long-term investments	235,864	385,785
Property, plant and equipment, net	948,682	896,700
Intangible assets, net	491,808	517,510
Goodwill	197,039	197,039
Deferred tax assets	460,952	399,095
Other assets	36,568	29,852
Total assets	<u>\$ 4,427,128</u>	<u>\$ 4,633,125</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 437,290	\$ 401,921
Short-term convertible debt, net	—	360,949
Short-term contingent consideration	85,951	53,648
Total current liabilities	<u>523,241</u>	<u>816,518</u>
Noncurrent liabilities:		
Long-term convertible debt, net	830,417	813,521
Long-term contingent consideration	46,883	135,318
Other long-term liabilities	58,647	59,105
Total liabilities	<u>1,459,188</u>	<u>1,824,462</u>
Stockholders' equity:		
Common stock, \$0.001 par value: 500,000,000 shares authorized; 178,252,954 and 175,843,749 shares issued and outstanding, respectively.	178	176
Additional paid-in capital	4,669,926	4,483,220
Company common stock held by Nonqualified Deferred Compensation Plan	(13,301)	(14,224)
Accumulated other comprehensive income (loss)	5,271	(22,961)
Accumulated deficit	(1,694,134)	(1,637,548)
Total stockholders' equity	<u>2,967,940</u>	<u>2,808,663</u>
Total liabilities and stockholders' equity	<u>\$ 4,427,128</u>	<u>\$ 4,633,125</u>

(1) As of January 1, 2018, the Company adopted the requirements of Accounting Standards Codification 606, *Revenue from Contracts with Customers* (ASC 606), using the modified retrospective method, and as a result, Accounts Receivable and Deferred Tax Assets are not comparable to the prior periods presented.

(2) December 31, 2017 balances were derived from the audited Consolidated Financial Statements included in the Company's Annual Report on Form 10-K

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Twelve Months Ended December 31, 2018 and 2017
(In thousands of U.S. dollars, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018 (1)	2017	2018 (1)	2017 (2)
	(unaudited)	(unaudited)	(unaudited)	
REVENUES:				
Net product revenues	\$ 347,151	\$ 353,577	\$ 1,470,356	\$ 1,270,445
Royalty and other revenues	6,063	4,728	20,856	43,201
Total revenues	<u>353,214</u>	<u>358,305</u>	<u>1,491,212</u>	<u>1,313,646</u>
OPERATING EXPENSES:				
Cost of sales	75,019	75,995	315,264	241,786
Research and development	175,390	168,608	696,328	610,753
Selling, general and administrative	164,171	160,280	604,353	554,336
Intangible asset amortization and contingent consideration	6,782	20,375	48,791	46,471
Gain on sale of intangible assets	(30,000)	(125,000)	(50,000)	(125,000)
Total operating expenses	<u>391,362</u>	<u>300,258</u>	<u>1,614,736</u>	<u>1,328,346</u>
INCOME (LOSS) FROM OPERATIONS	<u>(38,148)</u>	<u>58,047</u>	<u>(123,524)</u>	<u>(14,700)</u>
Equity in the loss of BioMarin/Genzyme LLC	(46)	(295)	(553)	(1,291)
Interest income	5,690	4,822	22,831	14,853
Interest expense	(7,746)	(11,664)	(43,664)	(42,707)
Other income, net	(3,061)	3,688	2,205	7,970
LOSS BEFORE INCOME TAXES	<u>(43,311)</u>	<u>54,598</u>	<u>(142,705)</u>	<u>(35,875)</u>
Provision for (benefit from) income taxes	(39,661)	105,990	(65,494)	81,167
NET LOSS	<u>\$ (3,650)</u>	<u>\$ (51,392)</u>	<u>\$ (77,211)</u>	<u>\$ (117,042)</u>
NET LOSS PER SHARE, BASIC	<u>\$ (0.02)</u>	<u>\$ (0.29)</u>	<u>\$ (0.44)</u>	<u>\$ (0.67)</u>
NET LOSS PER SHARE, DILUTED	<u>\$ (0.03)</u>	<u>\$ (0.30)</u>	<u>\$ (0.44)</u>	<u>\$ (0.67)</u>
Weighted average common shares outstanding, basic	177,936	175,485	177,061	174,427
Weighted average common shares outstanding, dilutive	178,143	175,705	177,268	174,427

- (1) As of January 1, 2018, the Company adopted the requirements of ASC 606 using the modified retrospective method, and as a result, Net Product Revenues are not comparable to the prior periods presented.
- (2) December 31, 2017 totals 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, 2017, filed with the SEC on February 26, 2018.

Non-GAAP Information

The results presented in this press release include both GAAP information and Non-GAAP information. As used in this release, Non-GAAP Income (Loss) is defined by the Company as GAAP Net Loss excluding net interest expense, provision for (benefit from) income taxes, depreciation expense, amortization expense, stock-based compensation expense, contingent consideration expense and, in certain periods, certain other specified items, as detailed below when applicable. In addition, BioMarin includes in this press release the effects of these adjustments on certain components of GAAP Net Loss for each of the periods presented. In this regard, Non-GAAP Income (Loss) and its components, including Non-GAAP Cost of Sales, Non-GAAP Research and Development expenses, Non-GAAP Selling, General and Administrative expense, Non-GAAP Intangible Asset Amortization and Contingent Consideration, Non-GAAP Gain on the Sale of Intangible Asset and Non-GAAP Benefit From Income Taxes are statement of operations line items prepared on the same basis as, and therefore components of, the overall Non-GAAP measures.

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 (Loss) and its components 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 (Loss) 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 (Loss) and its components are not meant to be considered in isolation, 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 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 measures; likewise, the Company may in the future cease to exclude items that it has historically excluded for purposes of its Non-GAAP measures. Because of the non-standardized definitions, the Non-GAAP 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 table presents the reconciliation of GAAP Net Loss to Non-GAAP Income (Loss):

Reconciliation of GAAP Net Loss to Non-GAAP Income (Loss)
(In millions of U.S. dollars)
(unaudited)

	Three Months Ended		Twelve Months Ended		Guidance	
	December 31,	December 31,	December 31,	December 31,	Year Ending	
	2018	2017	2018	2017	December 31, 2019	
GAAP Net Loss	\$ (3.6)	\$ (51.4)	\$ (77.2)	\$ (117.0)	\$ (45.0)	– \$ (85.0)
Interest expense, net	2.1	6.8	20.8	27.9	-	10.0
Provision for (Benefit from) income taxes	(39.7)	106.0	(65.5)	81.2	(50.0)	(30.0)
Depreciation expense	17.1	14.8	65.2	51.7	45.0	60.0
Amortization expense	7.6	13.4	30.3	36.2	40.0	55.0
Stock-based compensation expense	36.5	33.6	148.8	140.2	150.0	175.0
Contingent consideration expense	(0.8)	7.0	18.5	10.3	20.0	30.0
Gain on sale of intangible assets	(30.0)	(125.0)	(50.0)	(125.0)	(30.0)	(45.0)

Royalty and other revenues	—	—	—	(31.5)	—	—
Non-GAAP Income (Loss)	<u>\$ (10.8)</u>	<u>\$ 5.2</u>	<u>\$ 90.9</u>	<u>\$ 74.0</u>	<u>\$ 130.0</u>	<u>— \$ 170.0</u>

The following reconciliation of the GAAP reported to the Non-GAAP information provides the details of the effects of the Non-GAAP adjustments on certain components of the Company's operating results for each of the periods presented.

Reconciliation Of Certain GAAP Reported Information To Non-GAAP Information
(In millions of U.S. dollars)
(Unaudited)

Three Months Ended December 31,

	2018				2017			
	GAAP Reported	Adjustments			GAAP Reported	Adjustments		
		Interest, Taxes, Depreciation and Amortization	Stock-Based Compensation, Contingent Consideration and Other Adjustments	Non-GAAP		Interest, Taxes, Depreciation and Amortization	Stock-Based Compensation, Contingent Consideration and Other Adjustments	Non-GAAP
Cost of sales	\$ 75.0	\$ —	\$ (3.1)	\$ 71.9	\$ 76.0	\$ —	\$ (2.8)	\$ 73.2
Research and development	175.4	(11.2)	(14.5)	149.7	168.6	(8.0)	(13.2)	147.4
Selling, general and administrative	164.2	(5.9)	(18.9)	139.4	160.3	(6.8)	(17.6)	135.9
Intangible asset amortization and contingent consideration	6.8	(7.6)	0.8	—	20.4	(13.4)	(7.0)	—
Gain on sale of intangible assets	(30.0)	—	30.0	—	(125.0)	—	125.0	—
Interest expense, net	(2.1)	2.1	—	—	(6.8)	6.8	—	—
Provision for (Benefit from) income taxes	(39.7)	39.7	—	—	106.0	(106.0)	—	—
GAAP Net Loss/ Non-GAAP Income (Loss)	(3.6)	(12.9)	5.7	(10.8)	(51.4)	141.0	(84.4)	5.2

Twelve Months Ended December 31,

	2018				2017			
	GAAP Reported	Adjustments			GAAP Reported	Adjustments		
		Interest, Taxes, Depreciation and Amortization	Stock-Based Compensation, Contingent Consideration and Other Adjustments	Non-GAAP		Interest, Taxes, Depreciation and Amortization	Stock-Based Compensation, Contingent Consideration and Other Adjustments	Non-GAAP
Royalty and other revenues	\$ 20.9	\$ —	\$ —	\$ 20.9	\$ 43.2	\$ —	\$ (31.5)	\$ 11.7
Cost of sales	315.3	—	(13.5)	301.8	241.8	—	(10.6)	231.2
Research and development	696.3	(36.6)	(57.6)	602.1	610.8	(28.2)	(53.1)	529.5
Selling, general and administrative	604.4	(28.6)	(77.7)	498.1	554.3	(23.5)	(76.5)	454.3
Intangible asset amortization and contingent consideration	48.8	(30.3)	(18.5)	—	46.5	(36.2)	(10.3)	—
Gain on sale of intangible assets	(50.0)	—	50.0	—	(125.0)	—	125.0	—
Interest expense, net	(20.8)	20.8	—	—	(27.9)	27.9	—	—
Provision for (Benefit from) income taxes	(65.5)	65.5	—	—	81.2	(81.2)	—	—
GAAP Net Loss/Non-GAAP Income	(77.2)	50.8	117.3	90.9	(117.0)	197.0	(6.0)	74.0

SOURCE BioMarin Pharmaceutical Inc.

<https://investors.biopharm.com/2019-02-21-BioMarin-Announces-Full-Year-and-Fourth-Quarter-2018-Results>