BIOMARIN PHARMACEUTICAL INC
Form 10-Q
October 26, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission File Number: 000-26727

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

Delaware	68-0397820
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

770 Lindaro Street, San Rafael, California	94901
(Address of principal executive offices)	(Zip Code)

(415) 506-6700

(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.   Yes   No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).   Yes   No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.)   Yes   No

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 178,062,106 shares of common stock, par value $0.001, outstanding as of October 19, 2018.

BIOMARIN PHARMACEUTICAL INC.

TABLE OF CONTENTS

		Page
PART I.	FINANCIAL INFORMATION	3
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets as of September 30, 2018 (Unaudited) and December 31, 2017	3
	Condensed Consolidated Statements of Comprehensive Loss (Unaudited) for the three and nine months ended September 30, 2018 and 2017	4
	Condensed Consolidated Statement of Stockholders' Equity (Unaudited) for the nine months ended September 30, 2018	5
	Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2018 and 2017	6
	Notes to Condensed Consolidated Financial Statements (Unaudited)	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	27
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	39
Item 4.	Controls and Procedures	39
PART II.	OTHER INFORMATION	39
Item 1.	Legal Proceedings	39
Item 1A.	Risk Factors	40
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	62
Item 3.	Defaults Upon Senior Securities	62
Item 4.	Mine Safety Disclosures	62
Item 5.	Other Information	62
Item 6.	Exhibits	63
SIGNATURES		65

Unless the context suggests otherwise, references in this Quarterly Report on Form 10-Q to "BioMarin," the "Company," "we," "us," and "our" refer to BioMarin Pharmaceutical Inc. and, where appropriate, its wholly owned subsidiaries.

BioMarin®, Brineura®, Firdapse®, Kuvan®, Naglazyme®, Palynziq® and Vimizim® are our registered trademarks. Aldurazyme® is a registered trademark of BioMarin/Genzyme LLC. All other brand names and service marks, trademarks and other trade names appearing in this report are the property of their respective owners.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined under securities laws. Many of these statements can be identified by the use of terminology such as "believes," "expects," "intends," "anticipates," "plans," "m "will," "could," would," "projects," "continues," "estimates," "potential," "opportunity" or the negative versions of these terms other similar expressions. Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in "Risk Factors," in Part II, Item 1A of this Quarterly Report on Form 10-Q as well as information provided elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission (the SEC) on February 26, 2018. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these types of forward-looking statements, which speak only as of the date that they were made. These forward-looking statements are based on the beliefs and assumptions of the Company's management based on information currently available to management and should be considered in connection with any written or oral forward-looking statements that the Company may issue in the future as well as other cautionary statements the Company has made and may make. Except as required by law, the Company does not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the filing of this Quarterly Report on Form 10-Q to reflect later events or circumstances or the occurrence of unanticipated events.

The discussion of the Company's financial condition and results of operations should be read in conjunction with the Company's Condensed Consolidated Financial Statements and the related Notes thereto included in this Quarterly Report on Form 10-Q.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

September 30, 2018 and December 31, 2017

(In thousands, except share and per share amounts)

	September 30, 2018	December 31, 2017(1)
ASSETS	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 882,184	$ 598,028
Short-term investments	561,192	797,940
Accounts receivable, net	384,343	261,365
Inventory	508,482	475,775
Other current assets	71,652	74,036
Total current assets	2,407,853	2,207,144
Noncurrent assets:		
Long-term investments	204,883	385,785
Property, plant and equipment, net	924,033	896,700
Intangible assets, net	494,687	517,510
Goodwill	197,039	197,039
Deferred tax assets	429,194	399,095
Other assets	37,565	29,852
Total assets	$ 4,695,254	$ 4,633,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 378,226	$ 401,921
Short-term convertible debt, net	374,230	360,949
Short-term contingent acquisition consideration	86,204	53,648
Total current liabilities	838,660	816,518
Noncurrent liabilities:		
Long-term convertible debt, net	826,119	813,521
Long-term contingent acquisition consideration	58,160	135,318
Other long-term liabilities	57,370	59,105
Total liabilities	1,780,309	1,824,462
Stockholders' equity:		
Common stock, $0.001 par value: 500,000,000 shares authorized;	178	176

177,902,788 and 175,843,749 shares issued and outstanding, respectively.		
Additional paid-in capital	4,620,817	4,483,220
Company common stock held by Nonqualified Deferred Compensation Plan (the NQDC)	(13,415)	(14,224)
Accumulated other comprehensive loss	(2,160)	(22,961)
Accumulated deficit	(1,690,475)	(1,637,548)
Total stockholders' equity	2,914,945	2,808,663
Total liabilities and stockholders' equity	$ 4,695,254	$ 4,633,125

(1) December 31, 2017 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, 2017, filed with the SEC on February 26, 2018.

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

3

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Three and Nine Months Ended September 30, 2018 and 2017

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
REVENUES:				
Net product revenues	$386,320	$298,752	$1,123,205	$916,868
Royalty and other revenues	5,386	35,396	14,793	38,473
Total revenues	391,706	334,148	1,137,998	955,341
OPERATING EXPENSES:				
Cost of sales	78,893	59,480	240,245	165,791
Research and development	161,408	154,103	520,938	442,145
Selling, general and administrative	148,566	130,532	440,182	394,056
Intangible asset amortization and contingent consideration	18,580	3,760	42,009	26,096
Gain on sale of intangible assets	—	—	(20,000)	—
Total operating expenses	407,447	347,875	1,223,374	1,028,088
LOSS FROM OPERATIONS	(15,741)	(13,727)	(85,376)	(72,747)
Equity in the loss of BioMarin/Genzyme LLC	(468)	(253)	(507)	(996)
Interest income	6,338	3,976	17,141	10,031
Interest expense	(12,131)	(10,884)	(35,918)	(31,043)
Other income, net	2,589	267	5,266	4,282
LOSS BEFORE INCOME TAXES	(19,413)	(20,621)	(99,394)	(90,473)
Benefit from income taxes	(6,793)	(8,094)	(25,833)	(24,823)
NET LOSS	$(12,620)	$(12,527)	$(73,561)	$(65,650)
NET LOSS PER SHARE, BASIC AND DILUTED	$(0.07)	$(0.07)	$(0.42)	$(0.38)
Weighted average common shares outstanding, basic and diluted	177,481	175,103	176,767	174,071
COMPREHENSIVE LOSS	$(13,651)	$(19,303)	$(52,174)	$(99,900)

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS’ EQUITY

Nine Months Ended September 30, 2018

(In thousands)

(Unaudited)

	Common Stock		Additional	Company Common Stock	Accumulated Other		Total
	Shares	Amount	Paid-in Capital	Held by the NQDC	Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
Balance at December 31, 2017	175,844	$ 176	$ 4,483,220	$ (14,224)	$ (22,961)	$ (1,637,548)	$ 2,808,663
Impact of change in accounting principle - ASC 606	—	—	—	—	—	20,048	20,048
Impact of change in accounting principle - ASU 2018-02	—	—	—	—	(586)	586	—
Adjusted balance at January 1, 2018	175,844	$ 176	$ 4,483,220	$ (14,224)	$ (23,547)	$ (1,616,914)	$ 2,828,711
Net loss	—	—	—	—	—	(73,561)	(73,561)
Other comprehensive income	—	—	—	—	21,387	—	21,387
Issuances under equity incentive plans, net of tax	2,059	2	21,461	—	—	—	21,463
Common stock held by the NQDC	—	—	—	809	—	—	809
Stock-based compensation	—	—	116,136	—	—	—	116,136
Balance at September 30, 2018	177,903	$ 178	$ 4,620,817	$ (13,415)	$ (2,160)	$ (1,690,475)	$ 2,914,945

.

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

5

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2018 and 2017

(In thousands)

(Unaudited)

	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(73,561)	$(65,650)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	70,955	59,197
Non-cash interest expense	26,099	23,792
Accretion of discount on investments	769	2,162
Stock-based compensation	112,261	106,678
Gain on sale of intangible assets	(20,000)	—
Gain on the sale of equity investments	—	(3,252)
Deferred income taxes	(32,735)	(36,150)
Unrealized foreign exchange gain	(11,997)	4,348
Non-cash changes in the fair value of contingent acquisition consideration	12,836	3,382
Other	(459)	4,657
Changes in operating assets and liabilities:		
Accounts receivable, net	(95,884)	(21,598)
Inventory	(10,232)	(80,885)
Other current assets	4,276	(20,787)
Other assets	(3,148)	(1,030)
Accounts payable and accrued liabilities	(12,090)	(1,732)
Other long-term liabilities	3,744	3,497
Net cash used in operating activities	(29,166)	(23,371)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(102,541)	(159,329)
Maturities and sales of investments	857,063	325,678
Purchases of available-for-sale securities	(439,198)	(609,794)
Proceeds from sale of intangible asset	20,000	—
Other	(10)	(1,560)
Net cash provided by (used in) investing activities	335,314	(445,005)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercises of awards under equity incentive plans	55,643	46,119
Taxes paid related to net share settlement of equity awards	(34,180)	(31,863)
Proceeds from convertible senior subordinated note offering, net	—	481,713
Payment of contingent acquisition consideration	(43,108)	(1,894)
Other	—	(26)
Net cash (used in) provided by financing activities	(21,645)	494,049
Effect of exchange rate changes on cash	(347)	(2,604)

NET INCREASE IN CASH AND CASH EQUIVALENTS	284,156	23,069
Cash and cash equivalents:		
Beginning of period	$598,028	$408,330
End of period	$882,184	$431,399
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Cash paid for income taxes	$15,791	$21,744
Cash paid for interest, net of interest capitalized into fixed assets	7,521	4,287
SUPPLEMENTAL CASH FLOW DISCLOSURES FOR NON CASH INVESTING AND FINANCING ACTIVITIES:		
Decrease in accounts payable and accrued liabilities related to fixed assets	$(7,678)	$(25,047)
Conversion of convertible debt	—	22,477

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(1) NATURE OF OPERATIONS

BioMarin Pharmaceutical Inc. (the Company) is a global biotechnology company that develops and commercializes innovative therapies for people with serious and life-threatening rare diseases and medical conditions. The Company selects product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market or offer a significant benefit over existing products. The Company's therapy portfolio consists of several commercial therapies and multiple clinical and pre-clinical product candidates. Palynziq (formerly known as pegvaliase) was granted marketing approval in the United States (U.S.) on May 24, 2018.

The Company expects to continue to finance future cash needs that exceed its operating activities primarily through its current cash, cash equivalents and investments and through proceeds from debt or equity offerings, commercial borrowing, or through collaborative agreements with corporate partners. If the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and other acquisitions of complementary technologies, products or companies, the Company may need additional capital.

(2) BASIS OF PRESENTATION

The accompanying Condensed Consolidated Financial Statements have been prepared pursuant to U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the SEC for Quarterly Reports on Form 10-Q and do not include all of the information and note disclosures required by U.S. GAAP for complete financial statements, although the Company believes that the disclosures herein are adequate to ensure that the information presented is not misleading. The Condensed Consolidated Financial Statements should therefore be read in conjunction with the Consolidated Financial Statements and Notes thereto for the fiscal year ended December 31, 2017 included in the Company's Annual Report on Form 10-K.

Effective 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 as discussed in Note 3 - Significant Accounting Policies. The Company recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of Accumulated Deficit. The comparative information for the periods prior to 2018 has not been restated and continue to be reported under the accounting standards in effect for those periods.

U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the Condensed Consolidated Financial Statements and accompanying disclosures. Although these estimates are based on management's best knowledge of current events and actions that the Company may undertake in the future, actual results may be different from those estimates. The Condensed Consolidated Financial Statements reflect all adjustments of a normal, recurring nature that are, in the opinion of management, necessary for a fair presentation of results for these interim periods. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018 or any other period.

Management performed an evaluation of the Company’s activities through the date of filing of this Quarterly Report on Form 10-Q, and has concluded that, except for the maturity and settlement of our convertible debt and execution of a new credit facility, as discussed in Note 10 – Debt, there were no subsequent events or transactions that occurred subsequent to the balance sheet date prior to filing this Quarterly Report on Form 10-Q that would require recognition or disclosure in the Condensed Consolidated Financial Statements.

(3) SIGNIFICANT ACCOUNTING POLICIES

Except as detailed below, there have been no material changes to the Company’s significant accounting policies during the nine months ended September 30, 2018, as compared to the significant accounting policies disclosed in Note 3 of the Consolidated Financial Statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

Effective January 1, 2018, the Company adopted the provisions of ASC 606 using the modified retrospective method for all contracts not completed as of the date of adoption. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price in accordance with available practical expedients. The reported results for 2018 reflect the application of ASC 606 guidance, while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition (ASC 605), which is also referred to herein as "previous guidance."

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, the Company performs the following five steps:

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(i) identification of the promised goods or services in the contract;
(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
(iii) measurement of the transaction price, including the constraint on variable consideration;
(iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and
(v) recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in ASC 606.

Net Product Revenues

In the U.S., the Company’s commercial products are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. Palynziq is distributed in the U.S. through certain qualified pharmacies under the Palynziq Risk Evaluation and Mitigation Strategy (REMS). Outside the U.S., the Company’s commercial products are sold to its authorized distributors or directly to government purchasers or hospitals, which act as the end-users. Revenues from product sales are recognized when the customer obtains control of the Company’s product, which occurs at a point in time, typically upon shipment to the customer. Amounts collected from customers and remitted to governmental authorities, which primarily consist of value-added taxes related to product sales in foreign jurisdictions, are presented on a net basis in the Company’s Condensed Consolidated Statements of Comprehensive Loss, in that taxes billed to customers are not included as a component of Net Product Revenues.

For Aldurazyme revenues, the Company receives a payment ranging from 39.5% to 50% on worldwide net Aldurazyme sales by Genzyme Corporation (Genzyme) depending on sales volume, which is included in Net Product Revenues in the Company’s Condensed Consolidated Statements of Comprehensive Loss. Under the previous guidance the Company only recognized a portion of this amount as product transfer revenue when the product was released to Genzyme because all of the Company’s performance obligations were fulfilled at that point, the prices were substantially fixed or determinable and title to, and risk of loss for, the product had transferred to Genzyme. The product transfer revenue only represented the fixed amount per unit of Aldurazyme that Genzyme was required to pay the Company if the product was unsold by Genzyme. The amount of product transfer revenue was eventually deducted from the calculated royalty recognized when the product was subsequently sold by Genzyme. The Company recorded the Aldurazyme revenues based on net sales information provided by Genzyme and recorded product transfer revenues based on the fulfillment of Genzyme purchase orders in accordance with the terms of the related agreements with Genzyme.

Under ASC 606, the Company recognizes its best estimate of the entire revenue that it expects to receive when the product is released and control is transferred to Genzyme. The Company records Aldurazyme net product revenues based on the estimated variable consideration payable when the product is sold through by Genzyme. Actual amounts of consideration ultimately received may differ from the Company’s estimates, however the Company does not expect any such difference to be material. If actual results in the future vary from the Company’s estimates, the Company will make adjustments, which would affect Net Product Revenues and earnings in the period such variances become known. The adoption of ASC 606 did not have an impact on the timing or amount of revenues from other sources.

Revenue Reserves

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from government rebates, sales returns, and other incentives that are offered within contracts between the Company and its customers, such as specialty pharmacies, hospitals, authorized distributors and government purchasers. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company’s historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company’s best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company’s estimates, however the Company does not expect any such difference to be material. If actual results in the future vary from the Company’s estimates, the Company will adjust its estimates, which would affect net product revenue and earnings in the period such variances become known.

Government Rebates: The Company records reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product revenues are recorded. The Company’s reserve calculations require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. The Company updates its estimates and assumptions on a quarterly basis and records any necessary adjustments to its reserves.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

Sales Returns: The Company records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including market exclusivity of the products based on their orphan drug status, the patient population, the customers' limited return rights and the Company's historical experience with returns. Because of the pricing of the Company's commercial products, the limited number of patients and the customers' limited return rights, most customers and retailers carry a limited inventory. The Company relies on historical return rates to estimate returns. Based on these factors and the fact that the Company has not experienced significant product returns to date, management has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns change, an allowance for product returns may be required.

Other Incentives: Other incentives include fees paid to the Company's distributors, discounts for prompt payment and the estimated costs of the Company's patient co-payment assistance programs. Beginning in 2018, the Company also offers a branded co-pay assistance program for eligible patients with commercial insurance in the U.S. who are on Brineura, Kuvan or Palynziq therapy. The branded co-pay assistance programs assist commercially insured patients who have coverage for Brineura, Kuvan or Palynziq and are intended to reduce each participating patient's portion of the financial responsibility for Brineura's, Kuvan's or Palynziq's purchase price up to a specified dollar amount of assistance. The Company records fees paid to distributors, cash discounts and amounts paid under the branded specific co-pay assistance program for each patient as a reduction of revenue.

Royalty and Other Revenues

Royalties: For arrangements that include the receipt of sales-based royalties, including milestone payments based on the level of sales when the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company uses judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes developmental, regulatory or commercial milestone payments, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission by the Company) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized from the satisfaction of performance obligations in the amount billable to the customer.

(4) RECENT ACCOUNTING PRONOUNCEMENTS

Except as described below, there have been no new accounting pronouncements or changes to accounting pronouncements during the nine months ended September 30, 2018, as compared to the recent accounting pronouncements described in Note 4 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2017, that the Company believes are of significance or potential significance to the Company.

Accounting Pronouncements Not Yet Adopted

Effective January 1, 2019, the Company will adopt the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 842, Leases (ASC Topic 842). The amended guidance requires balance sheet recognition of lease right-of-use (ROU) assets and liabilities by lessees for leases classified as operating leases, with an option to not recognize lease ROU assets and lease liabilities for leases with a term of 12 months or less. The amendments also require new disclosures providing additional qualitative and quantitative information about the amounts recorded in the financial statements. Lessor accounting is largely unchanged. ASC Topic 842 is effective for the Company’s fiscal year beginning January 1, 2019. Early adoption is permitted, but the Company has not made the election to do so. The Company plans to adopt ASC Topic 842 using the modified retrospective approach with the cumulative effect of adoption recognized to retained earnings on January 1, 2019.

As of September 30, 2018, the Company’s task force formed in connection with the adoption of ASU 2016-02 was in the process of analyzing the Company’s lease contracts and the potential impact the standard may have on its Condensed Consolidated Financial Statements and related disclosures. Concurrently, management continues to assess the required changes to the Company’s accounting policies, systems and internal control over financial reporting. Based on management’s preliminary analysis, the Company

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

anticipates the standard may have a material impact on the Company's Condensed Consolidated Balance Sheets due to the requirement to recognize lease ROU assets and corresponding liabilities related to leases on the Company's Condensed Consolidated Balance Sheets, however it is not anticipated to have a material impact on the Company's other Condensed Consolidated Financial Statements.

Accounting Pronouncements Adopted

Effective January 1, 2018, the Company adopted ASC 606, which provides principles for recognizing revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 on a modified retrospective basis through a cumulative adjustment to Accumulated Deficit. See Note 3 – Significant Accounting Policies and Note 15 – Revenue, Credit Concentrations and Geographic Information for additional disclosures related to the adoption of ASC 606.

The cumulative effect of applying the new guidance of ASC 606 to all contracts with customers that were not completed as of January 1, 2018 was recorded as an adjustment to Accumulated Deficit as of the adoption date. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the Condensed Consolidated Balance Sheet as of January 1, 2018:

	As Reported			Adjusted
	December 31, 2017	Aldurazyme (1)	Tax Provision (2)	January 1, 2018
Balance Sheet				
Assets:				
Accounts receivable, net	$261,365	$ 26,012	$ —	$287,377
Deferred tax assets	$399,095	$ —	$ (5,964)	$393,131
Total assets	$4,633,125	$ 26,012	$ (5,964)	$4,653,173
Equity:				
Accumulated deficit	$(1,637,548)	$ 26,012	$ (5,964)	$(1,617,500)
Total liabilities and stockholders' equity	$4,633,125	$ 26,012	$ (5,964)	$4,653,173

(1) This adjustment represents management's estimate of the variable consideration to be earned on worldwide sales of Aldurazyme by Genzyme in excess of the product transfer revenue previously recognized for Genzyme's ending inventory at December 31, 2017. The product transfer revenue previously recognized as revenue represents the fixed amount per unit of Aldurazyme that Genzyme was required to pay the Company if the product was unsold by Genzyme.

(2) The adoption of ASC 606 primarily resulted in an acceleration of the variable consideration components of revenue as of December 31, 2017, which in turn generated additional deferred tax liabilities that ultimately reduced the Company's net deferred tax asset position. The tax provision amount has been calculated using the Company's estimated statutory rate.

The impact of adoption on the Company's Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2018 was as follows:

	Three Months Ended September 30, 2018		
	As Reported	Adjustments [1]	Balance without Adoption of ASC 606
Net product revenues	$386,320	$ (1,515)	$384,805
Benefit from income taxes	$(6,793)	$ (347)	$(7,140)
Net loss	$(12,620)	$ (1,168)	$(13,788)

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

	Nine Months Ended September 30, 2018		
	As Reported	Adjustments (1)	Balance without Adoption of ASC 606
Net product revenues	$1,123,205	$ (28,229)	$1,094,976
Benefit from income taxes	$(25,833)	$ (6,473)	$(32,306)
Net loss	$(73,561)	$ (21,756)	$(95,317)

(1) The adoption of ASC 606 resulted in additional revenues recognized in the first nine months of 2018, which in turn generated additional deferred tax liabilities that reduced the Company’s benefit from income taxes. The benefit from income taxes amount has been calculated using the Company’s estimated statutory rate.

The impact of adoption on the Company’s Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2018 was as follows:

	As Reported	Adjustments (1)	Balance without Adoption of ASC 606
Net loss	$(73,561)	$ (21,756)	$(95,317)
Deferred income taxes	$(32,735)	$ (6,473)	$(39,208)
Changes in operating assets and liabilities:			
Accounts receivable, net	$(95,884)	$ 28,229	$(67,655)
Net cash used in operating activities	$(29,166)	$ —	$(29,166)

(1) The adoption of ASC 606 resulted in decreased Net Loss and increased Accounts Receivable, Net due to additional revenues recognized in the first nine months of 2018, which in turn generated additional deferred tax liabilities that reduced net Deferred Tax Assets. The amount of deferred income taxes has been calculated using the Company’s estimated statutory rate.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (ASU 2018-02). The amendments allow a reclassification from Accumulated Other Comprehensive Loss (AOCI) to Accumulated Deficit for stranded tax effects resulting from the change in the U.S. federal corporate income tax rate on the gross deferred tax amounts at the date of enactment of the Tax Cuts and Jobs Act of 2017 (the 2017 Tax Act). ASU 2018-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company elected to early adopt ASU 2018-02 using the modified retrospective approach on an aggregate portfolio basis on January 1, 2018. As a result of adoption ASU 2018-02, the Company reclassified $0.6 million from AOCI to Accumulated Deficit in the first quarter of 2018.

(5) NET LOSS PER COMMON SHARE

Potentially issuable shares of common stock include shares issuable upon the exercise of outstanding employee stock option awards, common stock issuable under the Company’s Employee Stock Purchase Plan (ESPP), unvested restricted stock units (RSUs), common stock held by the NQDC and contingent issuances of common stock related to convertible debt.

The table below presents potential shares of common stock that were excluded from the computation of diluted earnings per common share as they were anti-dilutive using the if-converted or treasury stock method (in thousands of common shares):

	Three and Nine Months Ended September 30,	
	2018	2017
Options to purchase common stock	7,517	8,328
Common stock issuable under the 2018 Notes	3,983	3,983
Common stock issuable under the 2020 Notes	3,983	3,983
Common stock issuable under the 2024 Notes	3,970	3,970
Unvested restricted stock units	3,411	2,923
Common stock potentially issuable for ESPP purchases	407	365
Common stock held by the NQDC	208	224
Total number of potentially issuable shares	23,479	23,776

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

In connection with the issuance of the Company's 0.75% senior subordinated convertible notes due in 2018 (the 2018 Notes) and the Company's 1.50% senior subordinated convertible notes due in 2020 (the 2020 Notes), the Company entered into capped call transactions with respect to 50% of the principal amount of the 2018 Notes and 50% of the principal amount of the 2020 Notes with certain hedge counterparties with conversion price of $94.15 per share. Although the Company's stock price on September 30, 2018 exceeded the conversion price, the potential effect of the capped call transactions and potential shares issuable under the 2018 Notes and the 2020 Notes were excluded from the calculation of diluted loss per share in the three and nine months ended September 30, 2018 as they were anti-dilutive using the if-converted method. The potential effect of the capped call transactions with respect to the 2018 Notes and the 2020 Notes was excluded from the diluted net loss per share in the three and nine months ended September 30, 2017 as the Company's closing stock price on September 30, 2017 did not exceed the conversion price.

(6) FINANCIAL INSTRUMENTS

All marketable securities were classified as available-for-sale at September 30, 2018 and December 31, 2017.

The following tables show the Company's cash, cash equivalents and available-for-sale securities by significant investment category as of September 30, 2018 and December 31, 2017, respectively:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities (1)	Long-term Marketable Securities (2)
Level 1:							
Cash	$208,562	$ —	$ —	$208,562	$ 208,562	$ —	$ —
Level 2:							
Money market instruments	657,334	—	—	657,334	657,334	—	—
Corporate debt securities	506,054	133	(2,498)	503,689	—	350,109	153,580
Commercial paper	70,784	—	—	70,784	16,288	54,496	—
U.S. government agency securities	201,706	—	(1,087)	200,619	—	149,512	51,107
Foreign and other	7,126	146	(1)	7,271	—	7,075	196
Subtotal	1,443,004	279	(3,586)	1,439,697	673,622	561,192	204,883

Total	$1,651,566	$ 279	$ (3,586)	$1,648,259	$ 882,184	$ 561,192	$ 204,883

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities (1)	Long-term Marketable Securities (2)
Level 1:							
Cash	$340,253	$ —	$ —	$340,253	$ 340,253	$ —	$ —
Level 2:							
Money market instruments	215,441	—	—	215,441	215,441	—	—
Corporate debt securities	707,652	150	(2,553)	705,249	3,096	406,188	295,965
Commercial paper	24,566	—	—	24,566	2,751	21,815	—
U.S. government agency securities	472,593	—	(1,975)	470,618	35,497	345,501	89,620
Foreign and other	25,540	150	(64)	25,626	990	24,436	200
Subtotal	1,445,792	300	(4,592)	1,441,500	257,775	797,940	385,785
Total	$1,786,045	$ 300	$ (4,592)	$1,781,753	$ 598,028	$ 797,940	$ 385,785

(1)The Company's short-term marketable securities mature in one year or less.

(2) The Company's long-term marketable securities mature between one and five years.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

The Company's cash equivalents and marketable securities are classified within Level 2 in the fair value hierarchy because they are valued using third-party pricing sources and remeasured on a recurring basis. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. The Company validates the prices provided by its third-party pricing services by understanding the models used, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming those securities traded in active markets. See Note 12 – Fair Value Measurements for additional information related to the Company's fair value measurements.

Impairment assessments are made at the individual security level each reporting period. When the fair value of an investment is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in earnings equal to the difference between the investment's amortized cost and fair value at such date. As of September 30, 2018, the Company's investments in an unrealized loss position were not significant and were considered to be temporary in nature. The Company has the ability and intent to hold all investments that have been in a continuous loss position until maturity or recovery, thus no other-than-temporary impairment is deemed to have occurred.

(7) INTANGIBLE ASSETS

Intangible assets consisted of the following:

	September 30, 2018	December 31, 2017
Intangible assets:		
Finite-lived intangible assets	$ 303,298	$ 303,298
Indefinite-lived intangible assets	326,359	326,359
Gross intangible assets:	629,657	629,657
Less: Accumulated amortization	(134,970)	(112,147)
Net carrying value	$ 494,687	$ 517,510

Indefinite-Lived Intangible Assets

Intangible assets related to in-process research and development assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development (R&D) efforts. During the three and nine months ended September 30, 2018, no amounts have been reclassified to definite-lived and no impairment charges were recorded.

During the second quarter of 2018, the Company received $20.0 million due to the achievement by a third party of regulatory milestones related to a previously sold intangible asset, which the Company recorded as a gain on the sale in the Condensed Consolidated Statements of Comprehensive Loss.

(8) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net consisted of the following:

	September 30, 2018	December 31, 2017
Building and improvements	$ 686,939	$ 663,347
Manufacturing and laboratory equipment	333,756	294,521
Computer hardware and software	154,632	144,268
Leasehold improvements	44,086	42,572
Furniture and equipment	32,215	31,515
Land improvements	6,535	5,331
Land	74,185	62,369
Construction-in-progress	52,684	59,511
	1,385,032	1,303,434
Accumulated depreciation	(460,999)	(406,734)
Total property, plant and equipment, net	$ 924,033	$ 896,700

The construction-in-process balance primarily includes costs related to the Company's significant in-process projects at its facilities in Marin County, California, and in Shanbally, Ireland.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

Depreciation expense for the three and nine months ended September 30, 2018 was $26.6 million and $66.7 million, respectively, of which $8.1 million and $18.6 million, respectively, was capitalized into inventory. Depreciation expense for the three and nine months ended September 30, 2017 was $19.4 million and $54.8 million, respectively, of which $6.1 million and $17.9 million, respectively, was capitalized into inventory. Capitalized interest related to the Company's property, plant and equipment purchases for each of the three and nine months ended September 30, 2018 and 2017 was insignificant.

(9) SUPPLEMENTAL BALANCE SHEET INFORMATION

Inventory consisted of the following:

	September 30, 2018	December 31, 2017
Raw materials	$ 49,428	$ 49,877
Work-in-process	248,151	234,674
Finished goods	210,903	191,224
Total inventory	$ 508,482	$ 475,775

Accounts Payable and Accrued Liabilities consisted of the following:

	September 30, 2018	December 31, 2017
Accounts payable and accrued operating expenses	$ 177,396	$ 166,616
Accrued compensation expense	114,536	140,781
Accrued rebates payable	42,354	36,472
Accrued royalties payable	19,255	18,820
Value added taxes payable	8,612	9,740
Forward foreign currency exchange contracts	6,438	14,464
Accrued income taxes	—	5,528
Other	9,635	9,500
Total accounts payable and accrued liabilities	$ 378,226	$ 401,921

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(10) DEBT

Convertible Notes

As of September 30, 2018, the Company had outstanding fixed-rate notes with varying maturities for an aggregate principal amount of $1.2 billion (collectively the Notes). The Notes are senior subordinated convertible obligations, and interest is payable in arrears, quarterly. The following table summarizes information regarding the Company's convertible debt:

	September 30, 2018	December 31, 2017
0.75% senior subordinated convertible notes due October 2018 (the 2018 Notes)	$ 374,980	$ 374,980
Unamortized discount	(669)	(12,488)
Unamortized deferred offering costs	(81)	(1,543)
Convertible Notes due in 2018, net	374,230	360,949
1.50% senior subordinated convertible notes due in October 2020	374,993	374,993
Unamortized discount	(30,080)	(40,287)
Unamortized deferred offering costs	(2,659)	(3,631)
Convertible Notes due in 2020, net	342,254	331,075
0.599% senior subordinated convertible notes due in August 2024	495,000	495,000
Unamortized discount	(8,299)	(9,355)
Unamortized deferred offering costs	(2,836)	(3,199)
Convertible Notes due in 2024, net	483,865	482,446
Total convertible debt, net	$ 1,200,349	$ 1,174,470
Fair value of fixed rate convertible debt		
Convertible Notes due October 2018 (1)	$ 387,459	$ 403,955
Convertible Notes due in October 2020 (1)	447,577	446,470
Convertible Notes due in August 2024 (1)	521,953	493,894
Total	$ 1,356,989	$ 1,344,319

(1) The fair value of the Company's fixed-rate convertible debt is based on open market trades and is classified as Level 1 in the fair value hierarchy. See Note 12 to these Condensed Consolidated Financial Statements for additional information related to the Company's fair value measurements.

Interest expense on the Company's convertible debt consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Coupon interest expense	$3,331	$2,692	$9,819	$7,250
Amortization of debt issuance costs	1,008	1,138	3,018	2,910
Accretion of discount on convertible notes	7,792	7,054	23,081	20,883
Total interest expense on convertible debt	$12,131	$10,884	$35,918	$31,043

See Note 13 to the Consolidated Financial Statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 for additional information related to the Company’s convertible debt.

The Company’s 2018 Notes matured on October 15, 2018, subsequent to quarter-end. Substantially all holders of the 2018 Notes converted at maturity and the 2018 Notes were settled with a combination of cash and shares of the Company’s common stock, consisting of approximately $375.0 million in cash and 190,220 in shares. The shares issued represented the value of the 2018 Notes in excess of the conversion price of $94.15, as measured over a 25-day averaging period. The cash payment was comprised of the principal, the value of fractional shares and the value of unconverted 2018 Notes. Subsequent to quarter-end and pursuant to a capped call transaction, which was entered into concurrently with the issuance of the 2018 Notes, the Company received from the capped call counterparties 95,127 shares of the Company’s common stock, which were accounted for as treasury shares and subsequently retired. The Company incurred no gain or loss upon the extinguishment of the 2018 Notes.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

Revolving Credit Facilities

In November 2016, the Company entered into a senior unsecured revolving credit facility (the 2016 Credit Facility) that provided revolving credit of up to $100.0 million in revolving loans, a $10.0 million letter of credit subfacility and a $15.0 million swingline loan subfacility. The maturity date of the 2016 Credit Facility would have occurred on November 29, 2018, but the Company terminated the 2016 Credit Facility before maturity as described below. As of September 30, 2018 and December 31, 2017, there were no outstanding amounts due on nor any usage of the 2016 Credit Facility. As of September 30, 2018, the Company and certain of its subsidiaries that served as guarantors were in compliance with all covenants.

On October 19, 2018, subsequent to quarter end, the Company entered into an unsecured revolving credit facility of $200.0 million (the 2018 Credit Facility) and terminated the 2016 Credit Facility. The 2018 Credit Facility includes a letter of credit subfacility and a swingline loan subfacility and is also intended to finance ongoing working capital needs and for other general corporate purposes. Borrowings under the 2018 Credit Facility bear interest, at the Company’s option, at a rate equal to either (a) the LIBOR rate, or LIBOR successor rate, plus an applicable margin ranging from 1.00% to 1.95% per annum, based upon the Company’s net leverage ratio and EBITDA for each of the two most recently ended four-quarter measurement periods, or (b) the Base Rate, generally the prime lending rate, plus an applicable margin ranging from 0.00% to 0.95%, based upon the Company’s net leverage ratio and EBITDA for each of the two most recently ended four-quarter measurement periods. Commitment fees payable on the undrawn amount range from 0.15% to 0.35% per annum based upon the Company’s net leverage ratio and EBITDA for each of the two most recently ended four-quarter measurement periods. The 2018 Credit Facility matures on October 19, 2021 at which time all outstanding amounts become due and payable, except that if at least $100.0 million aggregate principal amount of the 2020 Notes remain outstanding on August 1, 2020 and certain other conditions have not been met, the Company may be required to repay all amounts borrowed under the 2018 Credit Facility on August 1, 2020. The Company incurred approximately $1.0 million of issuance costs, which will be amortized to Interest Expense over the term of the 2018 Credit Facility. The Company incurred no gain or loss upon the termination of the 2016 Credit facility. The 2018 Credit Facility contains financial covenants requiring the Company to maintain a minimum interest coverage ratio and a minimum liquidity requirement.

(11) DERIVATIVE INSTRUMENTS AND HEDGING STRATEGIES

The Company uses forward foreign currency exchange contracts to hedge certain operational exposures resulting from potential changes in foreign currency exchange rates. Such exposures result from portions of the Company’s monetary assets and liabilities and forecasted revenues and operating expenses being denominated in currencies other than the U.S. Dollar (USD), primarily the Euro.

The Company designates certain of these forward foreign currency exchange contracts as cash flow hedges and expects them to be highly effective in offsetting fluctuations in operating expenses denominated in Euros and revenues denominated in currencies other than the USD related to changes in foreign currency exchange rates. The Company also enters into some forward foreign currency exchange contracts that are not designated as hedging instruments. Whether designated or undesignated, these forward foreign currency exchange contracts protect against the reduction in value of forecasted foreign currency cash flows resulting from product revenues, royalty revenues, operating expenses and asset or liability positions designated in currencies other than the USD. The fair values of forward foreign currency exchange contracts are estimated using current exchange rates and interest rates, and take into consideration the current creditworthiness of the counterparties or the Company, as applicable. Information regarding the specific instruments used by the Company to hedge its exposure to foreign currency exchange rate fluctuations is provided below.

The following table summarizes the Company's designated forward foreign currency exchange contracts outstanding as of September 30, 2018 (notional amounts in millions):

Foreign Exchange Contracts	Number of Contracts	Aggregate Notional Amount in Foreign Currency	Maturity
Canadian Dollars – Sell	6	7.5	Oct. 2018 - Dec. 2018
Colombian Pesos – Sell	3	26,000.0	Oct. 2018 - Dec. 2018
Euros – Purchase	112	135.9	Oct. 2018 - Sep. 2021
Euros – Sell	401	498.5	Oct. 2018 - Sep. 2021
Total	522		

The maximum length of time over which the Company is hedging its exposure to the reduction in value of forecasted foreign currency revenues through forward foreign currency exchange contracts is through June 2021. Over the next twelve months, the Company expects to reclassify unrealized losses of $1.1 million from Accumulated Other Comprehensive Loss to earnings as the forecasted revenue and operating expense transactions occur.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

The following table summarizes the Company’s non-designated forward foreign currency exchange contracts outstanding as of September 30, 2018 (notional amounts in millions):

Foreign Exchange Contracts	Number of Contracts	Aggregate Notional Amount in Foreign Currency	Maturity
Colombian Pesos – Sell	1	35,000.0	Oct. 2018
Euros – Purchase	3	55.5	Oct. 2018
Rubles – Sell	1	340.0	Oct. 2018
Total	5		

The fair value carrying amounts of the Company’s derivative instruments, as classified within the fair value hierarchy, were as follows:

	Asset Derivatives September 30, 2018 Balance Sheet Location	Fair Value	Liability Derivatives September 30, 2018 Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Level 2[(1)]				
Forward foreign currency exchange contracts	Other current assets	$ 8,022	Accounts payable and accrued liabilities	$ 5,414
Forward foreign currency exchange contracts	Other assets	6,902	Other long-term liabilities	4,070
Total		14,924		9,484
Derivatives not designated as hedging instruments:				
Level 2[(1)]				
Forward foreign currency exchange contracts	Other current assets	—	Accounts payable and accrued liabilities	1,024
Total		—		1,024
Total value of derivative contracts		$ 14,924		$ 10,508

	Asset Derivatives December 31, 2017 Balance Sheet Location	Fair Value	Liability Derivatives December 31, 2017 Balance Sheet Location	Fair Value

Derivatives designated as hedging instruments:				
Level 2[1]				
Forward foreign currency exchange contracts	Other current assets	$ 4,015	Accounts payable and accrued liabilities	$ 14,420
Forward foreign currency exchange contracts	Other assets	4,973	Other long-term liabilities	12,686
Total		8,988		27,106
Derivatives not designated as hedging instruments:				
Level 2[1]				
Forward foreign currency exchange contracts	Other current assets	675	Accounts payable and accrued liabilities	44
Total		675		44
Total value of derivative contracts		$ 9,663		$ 27,150

(1) See Note 12 to these Condensed Consolidated Financial Statements for additional information related to the Company’s fair value measurements.

17

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

The effect of the Company's derivative instruments on the Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2018 and 2017 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Derivatives Designated as Hedging Instruments:				
Net gain (loss) recognized in accumulated other comprehensive loss [1]	$3,355	$(10,569)	$17,711	$(33,933)
Net gain (loss) reclassified from accumulated other comprehensive income (loss) into earnings [2]	5,523	(3,700)	(2,921)	(489)
Net gain recognized in net loss [3]	2,224	689	4,545	2,395
Derivatives Not Designated as Hedging Instruments:				
Net gain (loss) recognized in net loss[4]	(381)	1,655	(3,366)	7,286

(1) Net change in the fair value of the effective portion classified as accumulated other comprehensive loss.
(2) Effective portion classified as Net Product Revenues and Operating expenses.
(3) Ineffective portion and amount excluded from effectiveness testing classified as Operating expenses.
(4) Classified as Operating expenses.

The Company is exposed to counterparty credit risk on all of its derivative financial instruments. The Company has established and maintains strict counterparty credit guidelines and enters into hedges only with financial institutions that are investment grade or better to minimize the Company's exposure to potential defaults. The Company does not require collateral to be pledged under these agreements.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(12) FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value on a recurring basis. In addition to available-for-sale debt securities, debt and foreign currency derivatives, which are disclosed in Notes 6, 10 and 11, respectively, the following tables below present the classification within fair value hierarchy of financial assets and liabilities not disclosed elsewhere.

	Fair Value Measurements at September 30, 2018			
	Quoted Price in Active Markets For Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Other current assets:				
NQDC Plan assets	$—	$ 426	$ —	$426
Restricted investments [1]	—	11,217	—	11,217
Total other current assets	—	11,643	—	11,643
Other assets:				
NQDC Plan assets	—	13,928	—	13,928
Restricted investments [1]	—	2,336	—	2,336
Strategic investments [2]	2,934	—	—	2,934
Total other assets	2,934	16,264	—	19,198
Total assets	$2,934	$ 27,907	$ —	$30,841
Liabilities:				
Current liabilities:				
NQDC Plan liability	$1,219	$ 426	$ —	$1,645
Contingent acquisition consideration	—	—	86,204	86,204
Total current liabilities	1,219	426	86,204	87,849
Other long-term liabilities:				
NQDC Plan liability	$19,020	$ 13,928	—	32,948
Contingent acquisition consideration	—	—	58,160	58,160

Total other long-term liabilities	19,020	13,928	58,160	91,108
Total liabilities	$20,239	$ 14,354	$ 144,364	$178,957

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

	Fair Value Measurements at December 31, 2017			
	Quoted Price in Active Markets For Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Other current assets:				
NQDC Plan assets	$—	$ 967	$ —	$967
Restricted investments (1)	—	15,647	—	15,647
Total other current assets	—	16,614	—	16,614
Other assets:				
NQDC Plan assets	—	11,859	—	11,859
Total other assets	—	11,859	—	11,859
Total assets	$—	$ 28,473	$ —	$28,473
Liabilities:				
Current liabilities:				
NQDC Plan liability	$1,356	$ 967	$ —	$2,323
Contingent acquisition consideration	—	—	53,648	53,648
Total current liabilities	1,356	967	53,648	55,971
Other long-term liabilities:				
NQDC Plan liability	18,272	11,859	—	30,131
Contingent acquisition consideration	—	—	135,318	135,318
Total other long-term liabilities	18,272	11,859	135,318	165,449
Total liabilities	$19,628	$ 12,826	$ 188,966	$221,420

(1) The restricted investments at September 30, 2018 and December 31, 2017 secure the Company's irrevocable standby letters of credit obtained in connection with certain commercial agreements.

(2) The Company has investments in marketable equity securities measured using quoted prices in an active market that are considered strategic investments and included in other assets on the Company's Consolidated Balance Sheets.

There were no transfers between levels during the three and nine months ended September 30, 2018.

The Company's Level 2 instruments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. The Company validates the prices provided by its third-party pricing services by understanding the models used, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming those securities traded in active markets.

Liabilities measured at fair value using Level 3 inputs consisted of contingent acquisition consideration and asset retirement obligations. The following tables represent a roll-forward of contingent acquisition consideration.

Contingent acquisition consideration at December 31, 2017	$188,966
Changes in the fair value of other contingent acquisition consideration	19,293
Milestone payments to Ares Trading S.A. (Merck Serono)	(61,607)
Foreign exchange remeasurement of Euro denominated contingent acquisition consideration	(2,288)
Contingent acquisition consideration at September 30, 2018	$144,364

Under certain of the Company’s lease agreements, the Company is contractually obligated to return leased space to its original condition upon termination of the applicable lease agreement. The Company records an asset retirement obligation liability and a corresponding capital asset in an amount equal to the estimated fair value of the obligation, when estimable. In subsequent periods, for each such lease, the Company records interest expense to accrete the asset retirement obligation liability to full value and depreciates each capitalized asset retirement obligation asset, both over the term of the associated lease agreement. As of September 30, 2018 and December 31, 2017, the balance of the asset retirement obligation liability was $4.4 million and $4.2 million, respectively.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

The Company acquired intangible assets as a result of various business acquisitions. The estimated fair value of these long-lived assets was measured using Level 3 inputs as of the acquisition date. Refer to Note 3 – Significant Accounting Policies in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 for details on valuation.

(13) STOCK-BASED COMPENSATION

Compensation expense included in the Company's Condensed Consolidated Statements of Comprehensive Loss for all stock-based compensation arrangements was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of sales	$3,974	$3,007	$10,360	$7,803
R&D	14,257	13,832	43,099	39,973
Selling, general and administrative	18,815	19,064	58,802	58,902
Total stock-based compensation expense	$37,046	$35,903	$112,261	$106,678

Stock-based compensation expense of $5.3 million and $14.3 million was capitalized into inventory for the three and nine months ended September 30, 2018, respectively, compared to stock-based compensation expense of $4.5 million and $12.1 million that was capitalized into inventory for the three and nine months ended September 30, 2017, respectively. Capitalized stock-based compensation is recognized as cost of sales when the related product is sold.

Equity Awards with Service-Based Vesting Conditions

The assumptions used to estimate the per share fair value of stock options granted under the Company's 2017 Equity Incentive Plan and the Company's Amended and Restated 2006 Share Incentive Plan were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected volatility	36.8%	38.0 – 39.7%	36.8 – 38.4%	37.6 – 39.7%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected life	5.7 years	4.9 – 6.6 years	4.6 – 5.7 years	4.9 – 6.6 years

Risk-free interest rate	2.8%	1.8 – 2.1%	2.3 – 2.8%	1.8 – 2.2%

During the nine months ended September 30, 2018, the Company granted options to purchase 782,240 shares of common stock with a weighted-average fair value of $33.40 per share.

The Company did not issue any new stock purchase rights under the ESPP during the three months ended September 30, 2018.

During the nine months ended September 30, 2018, the Company granted 1,596,820 RSUs with service-based vesting conditions with a weighted-average fair value of $84.97 per share.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

Restricted Stock Unit Awards with Performance Conditions

The Compensation Committee of the Board (with respect to awards to certain executive officers other than the Chief Executive Officer) and the Board (with respect to awards to the Chief Executive Officer) may grant RSUs with performance-based vesting conditions to certain executive officers. In March 2018, the Compensation Committee and Board approved the grant of 129,680 RSUs (base RSUs) with performance-based vesting conditions. This award is contingent upon the achievement of a 2018 revenue target and the awarded RSUs, if any, vest ratably over a three-year service period. The number of shares that may be earned range between 50% and 200% of the base RSUs, dependent on the percentage of 2018 "managed revenues" (defined as the Company's net product revenues, excluding net revenues attributable to Aldurazyme, and determined using fixed foreign currency exchange rates) achieved against the target managed revenues, with a threshold achievement level of 70% of target and a ceiling achievement level of 125% of target. RSUs with performance-based vesting conditions with similar performance conditions were granted in 2017, 2016 and 2015. The following table details the base RSUs granted, RSUs earned and expected to vest and the performance multiplier achieved for the RSUs with performance-based vesting conditions for the years ended December 31, 2017, 2016 and 2015, respectively, as well as the base RSUs granted in March 2018:

Date of Grant	Base RSUs Granted	Grant Date Fair Value per RSU	Multiplier Achieved	RSUs Earned
March 2018	129,680	$83.57	(a)	(a)
March 2017	133,250	$87.42	1.03	132,548
March 2016	130,310	$83.43	1.03	134,219
March 2015	58,300	$108.36	1.11	64,713

(a) The Company's Compensation Committee is expected to approve the multiplier and total earned RSUs in the first quarter of 2019 based on the Company's performance against the 2018 managed revenue target. The Company evaluated the 2018 revenue target in the context of its current 2018 revenue forecast, and related confidence level in the forecast, and determined that attainment of the revenue target was probable for accounting purposes commencing in the first quarter of 2018.

(14) ACCUMULATED OTHER COMPREHENSIVE LOSS

The following table summarizes amounts reclassified out of AOCI and their effect on the Company's Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2018 and 2017.

Details about AOCI Components	Three Months Ended September 30, 2018	2017	Nine Months Ended September 30, 2018	2017	Condensed Consolidated Statement of Comprehensive Loss Classification
Gains (losses) on cash flow hedges:					
Forward foreign currency exchange contracts	$5,025	$(4,643)	$(6,683)	$18	Net product revenues
Forward foreign currency exchange contracts	498	943	3,762	(507)	Operating expenses
Total gain (loss) on cash flow hedges	5,523	(3,700)	(2,921)	(489)	
Gain (loss) on sale of available-for-sale debt securities	—	—	—	3,252	Other income
Income tax effect of the above	—	—	—	(1,176)	Benefit from income taxes
Total gain (loss) on available-for-sale debt securities	—	—	—	2,076	
	$5,523	$(3,700)	$(2,921)	$1,587	Net loss

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

The following tables summarize changes in the accumulated balances for each component of AOCI, including current period other comprehensive income (loss) and reclassifications out of AOCI for the three and nine months ended September 30, 2018 and 2017.

	Three Months Ended September 30, 2018			
	Unrealized Gains (Losses) on Cash Flow Hedges	Unrealized Gains (Losses) on Available-for-Sale Debt Securities	Foreign Currency Items	Total
AOCI balance at June 30, 2018	$2,568	$ (3,686)	$ (11)	$(1,129)
Other comprehensive income before reclassifications	3,355	1,475	—	4,830
Less: net gain (loss) reclassified from AOCI	5,523	—	—	5,523
Tax effect	—	(338)	—	(338)
Net current-period other comprehensive income (loss)	(2,168)	1,137	—	(1,031)
AOCI balance at September 30, 2018	$400	$ (2,549)	$ (11)	$(2,160)

	Three Months Ended September 30, 2017			
	Unrealized Gains (Losses) on Cash Flow Hedges	Unrealized Gains (Losses) on Available-for-Sale Debt Securities	Foreign Currency Items	Total
AOCI balance at June 30, 2017	$(13,569)	$ (1,080)	$ (9)	$(14,658)
Other comprehensive income (loss) before reclassifications	(10,569)	147	2	(10,420)
Less: gain (loss) reclassified from AOCI	(3,700)	—	—	(3,700)
Tax effect	—	(56)	—	(56)
Net current-period other comprehensive income (loss)	(6,869)	91	2	(6,776)
AOCI balance at September 30, 2017	$(20,438)	$ (989)	$ (7)	$(21,434)

Nine Months Ended September 30, 2018

	Unrealized Gains (Losses) on Cash Flow Hedges	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Items	Total
AOCI balance at December 31, 2017	$(20,232)	$ (2,722)	$ (7)	$(22,961)
Impact of change in accounting principle (1)	—	$ (586)	—	$(586)
AOCI balance at January 1, 2018	$(20,232)	$ (3,308)	$ (7)	$(23,547)
Other comprehensive income (loss) before reclassifications	17,711	985	(4)	18,692
Less: gain (loss) reclassified from AOCI	(2,921)	—	—	(2,921)
Tax effect	—	(226)	—	(226)
Net current-period other comprehensive income (loss)	20,632	759	(4)	21,387
AOCI balance at September 30, 2018	$400	$ (2,549)	$ (11)	$(2,160)

(1) As of January 1, 2018, the Company early adopted the requirements of ASU 2018-02. The amount represents the reclassification from Accumulated Other Comprehensive Income (Loss) to Accumulated Deficit in the first quarter of 2018 related to the adoption of ASU 2018-02. See Note 4 for additional discussion.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

	Nine Months Ended September 30, 2017			
	Unrealized Gains (Losses) on Cash Flow Hedges	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Items	Total
AOCI balance at December 31, 2016	$13,006	$ (178)	$ (12)	$12,816
Other comprehensive income (loss) before reclassifications	(33,933)	1,981	5	(31,947)
Less: gain (loss) reclassified from AOCI	(489)	3,252	—	2,763
Tax effect	—	460	—	460
Net current-period other comprehensive income (loss)	(33,444)	(811)	5	(34,250)
AOCI balance at September 30, 2017	$(20,438)	$ (989)	$ (7)	$(21,434)

(15) REVENUE, CREDIT CONCENTRATIONS AND GEOGRAPHIC INFORMATION

The Company operates in one business segment, which primarily focuses on the development and commercialization of innovative therapies for people with serious and life-threatening rare diseases and medical conditions. The Company considers there to be revenue concentration risks for regions where net product revenues exceed 10% of consolidated net product revenues. The concentration of the Company’s net product revenues within the regions below may have a material adverse effect on the Company’s revenues and results of operations if sales in the respective regions experience difficulties.

The Company adopted the requirements of ASC 606 on January 1, 2018 using the modified retrospective method, therefore there is a lack of comparability to the prior periods presented. See Note 4 – Recent Accounting Pronouncements for additional discussion.

The following table disaggregates Total Revenues from external customers and collaborative partners by geographic region. Net product revenues by geographic region are based on patient location for the Company’s commercial products, except for Aldurazyme. Although Genzyme sells Aldurazyme worldwide, the revenues earned by the Company based on Genzyme’s net sales are included in the U.S. region, as the transactions are with Genzyme whose headquarters is located in the U.S.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017

Total revenues by geographic region:				
United States	$174,722	$151,012	$528,082	$425,107
Europe	111,069	121,268	323,940	292,845
Latin America	55,322	9,546	151,955	121,581
Rest of world	50,593	52,322	134,021	115,808
Total revenues	$391,706	$334,148	$1,137,998	$955,341

The following table disaggregates total Net Product Revenues from external customers by product.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net product revenues by product:				
Aldurazyme	$27,593	$22,341	$117,652	$61,681
Brineura	9,936	3,107	27,743	3,361
Firdapse	4,977	5,086	15,080	14,051
Kuvan	113,254	105,837	321,414	300,127
Naglazyme	103,089	72,083	269,171	238,392
Palynziq	4,129	—	4,129	—
Vimizim	123,342	90,298	368,016	299,256
Total net product revenues	$386,320	$298,752	$1,123,205	$916,868

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

The table below disaggregates total Net Product Revenues based on patient location for products sold directly by the Company, and global sales of Aldurazyme, which is marketed by Genzyme. Genzyme is the Company’s sole customer for Aldurazyme and is responsible for marketing and selling Aldurazyme to third-parties.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
United States	$146,742	$127,302	$409,294	$361,264
Europe	107,851	88,646	315,270	260,223
Latin America	55,322	9,549	151,955	121,581
Rest of world	48,812	50,914	129,034	112,119
Total net product revenue marketed by the Company	358,727	276,411	1,005,553	855,187
Aldurazyme net product revenues marketed by Genzyme	27,593	22,341	117,652	61,681
Total net product revenues	$386,320	$298,752	$1,123,205	$916,868

The following table illustrates the percentage of the Company’s total Net Product Revenues attributed to the Company’s largest customers for the three and nine months ended September 30, 2018 and 2017.