BIOMARIN PHARMACEUTICAL INC
Form 10-Q
August 03, 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 June 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 (Do not check if a smaller reporting company) 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: 177,590,376 shares of common stock, par value $0.001, outstanding as of July 23, 2018.

BIOMARIN PHARMACEUTICAL INC.

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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.

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

June 30, 2018 and December 31, 2017

(In thousands, except share and per share amounts)

	June 30, 2018	December 31, 2017(1)
ASSETS	(unaudited)	
Current assets:		
Cash and cash equivalents	$427,411	$598,028
Short-term investments	935,662	797,940
Accounts receivable, net	363,566	261,365
Inventory	473,356	475,775
Other current assets	80,072	74,036
Total current assets	2,280,067	2,207,144
Noncurrent assets:		
Long-term investments	279,988	385,785
Property, plant and equipment, net	900,480	896,700
Intangible assets, net	502,295	517,510
Goodwill	197,039	197,039
Deferred tax assets	425,380	399,095
Other assets	39,430	29,852
Total assets	$4,624,679	$4,633,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$358,732	$401,921
Short-term convertible debt, net	369,752	360,949
Short-term contingent acquisition consideration	76,466	53,648
Total current liabilities	804,950	816,518
Noncurrent liabilities:		
Long-term convertible debt, net	821,871	813,521
Long-term contingent acquisition consideration	57,674	135,318
Other long-term liabilities	55,080	59,105
Total liabilities	1,739,575	1,824,462
Stockholders' equity:		
Common stock, $0.001 par value: 500,000,000 shares authorized;	178	176

177,508,135 and 175,843,749 shares issued and outstanding, respectively.		
Additional paid-in capital	4,577,300	4,483,220
Company common stock held by Nonqualified Deferred Compensation Plan (the NQDC)	(13,390)	(14,224)
Accumulated other comprehensive loss	(1,129)	(22,961)
Accumulated deficit	(1,677,855)	(1,637,548)
Total stockholders' equity	2,885,104	2,808,663
Total liabilities and stockholders' equity	$4,624,679	$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.

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

Three and Six Months Ended June 30, 2018 and 2017

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
REVENUES:				
Net product revenues	$367,786	$315,926	$736,885	$618,116
Royalty and other revenues	5,059	1,522	9,407	3,077
Total revenues	372,845	317,448	746,292	621,193
OPERATING EXPENSES:				
Cost of sales	79,019	56,305	161,352	106,311
Research and development	175,582	143,039	359,530	288,042
Selling, general and administrative	153,280	143,505	291,616	263,524
Intangible asset amortization and contingent consideration	10,227	13,411	23,429	22,336
Gain on sale of intangible assets	(20,000)	—	(20,000)	—
Total operating expenses	398,108	356,260	815,927	680,213
LOSS FROM OPERATIONS	(25,263)	(38,812)	(69,635)	(59,020)
Equity in the loss of BioMarin/Genzyme LLC	(107)	(220)	(39)	(743)
Interest income	5,569	2,983	10,803	6,055
Interest expense	(12,225)	(10,040)	(23,787)	(20,159)
Other income, net	2,849	543	2,677	4,015
LOSS BEFORE INCOME TAXES	(29,177)	(45,546)	(79,981)	(69,852)
Benefit from income taxes	(12,385)	(8,713)	(19,040)	(16,729)
NET LOSS	$(16,792)	$(36,833)	$(60,941)	$(53,123)
NET LOSS PER SHARE, BASIC AND DILUTED	$(0.09)	$(0.21)	$(0.35)	$(0.31)
Weighted average common shares outstanding, basic and diluted	176,873	174,374	176,405	173,547
COMPREHENSIVE INCOME (LOSS)	$10,624	$(56,511)	$(38,523)	$(80,597)

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

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Six Months Ended June 30, 2018

(In thousands)

(Unaudited)

	Common Stock		Additional Paid-in	Company Common Stock Held by the	Accumulated Other Comprehensive		Total Stockholders'
	Shares	Amount	Capital	NQDC	Income (Loss)	Accumulated Deficit	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	—	—	—	—	—	(60,941)	(60,941)
Other comprehensive income	—	—	—	—	22,418	—	22,418
Issuances under equity incentive plans, net of tax	1,664	2	16,310	—	—	—	16,312
Common stock held by the NQDC	—	—	—	834	—	—	834
Stock-based compensation	—	—	77,770	—	—	—	77,770
Balance at June 30, 2018	177,508	$ 178	$4,577,300	$(13,390)	$ (1,129)	$(1,677,855)	$2,885,104

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

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Six Months Ended June 30, 2018 and 2017

(In thousands)

(Unaudited)

	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(60,941)	$(53,123)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	44,610	38,497
Non-cash interest expense	17,300	15,601
Accretion of discount on investments	(41)	1,327
Stock-based compensation	75,214	70,775
Gain on sale of intangible assets	(20,000)	—
Gain on the sale of equity investments	—	(3,252)
Deferred income taxes	(29,681)	(22,770)
Unrealized foreign exchange gain	(5,693)	(4,870)
Non-cash changes in the fair value of contingent acquisition consideration	1,828	7,195
Other	1,772	3,806
Changes in operating assets and liabilities:		
Accounts receivable, net	(77,416)	(16,834)
Inventory	15,493	(60,369)
Other current assets	(2,037)	(3,710)
Other assets	(6,448)	(1,109)
Accounts payable and accrued liabilities	(32,989)	(36,286)
Other long-term liabilities	2,663	3,459
Net cash used in operating activities	(76,366)	(61,663)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(52,682)	(116,847)
Maturities and sales of investments	311,969	234,617
Purchases of available-for-sale securities	(345,458)	(130,986)
Proceeds from sale of intangible asset	20,000	—
Other	(841)	(1,560)
Net cash used in investing activities	(67,012)	(14,776)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercises of awards under equity incentive plans	44,926	40,659
Taxes paid related to net share settlement of equity awards	(28,614)	(26,624)
Payment of contingent acquisition consideration	(43,108)	(1,894)
Other	—	(28)
Net cash (used in) provided by financing activities	(26,796)	12,113
Effect of exchange rate changes on cash	(443)	10,860
NET DECREASE IN CASH AND CASH EQUIVALENTS	(170,617)	(53,466)

Cash and cash equivalents:		
Beginning of period	$598,028	$408,330
End of period	$427,411	$354,864
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Cash paid for income taxes	$14,858	$16,341
Cash paid for interest, net of interest capitalized into fixed assets	5,831	4,519
SUPPLEMENTAL CASH FLOW DISCLOSURES FOR NON CASH INVESTING AND FINANCING ACTIVITIES:		
Decrease in accounts payable and accrued liabilities related to fixed assets	$(7,734)	$(29,300)
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 seven commercial products 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 have 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 six months ended June 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 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 six months ended June 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. 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 Income (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 Income (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.

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, as such 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. 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 Kuvan or Brineura therapy. The branded co-pay assistance programs assist commercially insured patients who have coverage for Kuvan or Brineura and are intended to reduce each participating patient's portion of the financial responsibility for Kuvan's or Brineura'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 utilizes 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 six months ended June 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

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, Leases (ASU 2016-02). 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. ASU 2016-02 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. ASU 2016-02 will be effective for the Company's fiscal year beginning January 1, 2019. The amendments require a modified retrospective approach with optional practical expedients.

As of June 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. After completing the analysis of the accounting for the Company's lease contracts under the standard, management will assess the required changes to the Company's accounting policies, systems and internal control over

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

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

financial reporting. Based on management's preliminary analysis, the Company 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 equity. 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 December 31, 2017	Aldurazyme (1)	Tax Provision (2)	Adjusted 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 Income (Loss) for the three and six months ended June 30, 2018 was as follows:

	Three Months Ended June 30, 2018		
	As Reported	Adjustments [1]	Balance without Adoption of ASC 606
Net product revenues	$367,786	$ 48	$367,834
Benefit from income taxes	$(12,385)	$ 11	$(12,374)
Net loss	$(16,792)	$ 37	$(16,755)

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

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

	Six Months Ended June 30, 2018		
	As Reported	Adjustments [1]	Balance without Adoption of ASC 606
Net product revenues	$736,885	$ (27,150)	$709,735
Benefit from income taxes	$(19,040)	$ (6,225)	$(25,265)
Net loss	$(60,941)	$ (20,925)	$(81,866)

(1) The adoption of ASC 606 resulted in additional revenues recognized in the first half 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 six months ended June 30, 2018 was as follows:

	As Reported	Adjustments [1]	Balance without Adoption of ASC 606
Net loss	$(60,941)	$ (20,925)	$(81,866)
Deferred income taxes	$(29,681)	$ (6,225)	$(35,906)
Changes in operating assets and liabilities:			
Accounts receivable, net	$(77,416)	$ 27,150	$(50,266)
Net cash used in operating activities	$(76,366)	$ —	$(76,366)

(1) The adoption of ASC 606 resulted in decreased Net Loss and increased Accounts Receivable, Net due to additional revenues recognized in the first quarter of 2018, which in turn generated additional deferred tax liabilities that reduced the Company's net Deferred Tax Assets. The Deferred Income Taxes amount 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 Income (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.

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 presents potential shares of common stock that were excluded from the computation of basic and 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 Six Months Ended June 30,	
	2018	2017
Options to purchase common stock	7,829	8,440
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	—
Unvested restricted stock units	3,544	3,041
Common stock potentially issuable for ESPP purchases	433	387
Common stock held by the NQDC	208	224
Total number of potentially issuable shares	23,950	20,058

In connection with the issuance of to 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 June 29, 2018 (the last trading day before June 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 six months ended June 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 six months ended June 30, 2017 as the Company’s closing stock price on June 30, 2017 did not exceed the conversion price.

(6) FINANCIAL INSTRUMENTS

All marketable securities were classified as available-for-sale at June 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 June 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	$209,062	$ —	$ —	$209,062	$ 209,062	$ —	$ —
Level 2:							
Money market instruments	177,882	—	—	177,882	177,882	—	—
Corporate debt securities	643,979	136	(3,452)	640,663	7,708	411,185	221,770
Commercial paper	51,818	1	—	51,819	18,947	32,871	—
U.S. government agency securities	532,066	4	(1,597)	530,473	11,312	461,143	58,019
Foreign and other	33,035	150	(23)	33,162	2,500	30,463	199
Subtotal	1,438,780	291	(5,072)	1,433,999	218,349	935,662	279,988
Total	$1,647,842	$ 291	$ (5,072)	$1,643,061	$ 427,411	$ 935,662	$ 279,988

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

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

	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.

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 to these Condensed Consolidated Financial Statements 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 June 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:

	June 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	(127,362)	(112,147)
Net carrying value	$502,295	$ 517,510

Indefinite-Lived Intangible Assets

Intangible assets related to in-process research and development (IPR&D) assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development (R&D) efforts. During the second quarter of 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 in milestone payments 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 Income (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)

(8) PROPERTY, PLANT AND EQUIPMENT

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

	June 30, 2018	December 31, 2017
Building and improvements	$674,682	$ 663,347
Manufacturing and laboratory equipment	316,331	294,521
Computer hardware and software	152,010	144,268
Leasehold improvements	38,352	42,572
Furniture and equipment	30,833	31,515
Land improvements	5,977	5,331
Land	62,369	62,369
Construction-in-progress	60,582	59,511
	1,341,136	1,303,434
Accumulated depreciation	(440,656)	(406,734)
Total property, plant and equipment, net	$900,480	$ 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.

Depreciation expense for the three and six months ended June 30, 2018 was $20.1 million and $40.1 million, respectively, of which $6.6 million and $10.5 million, respectively, was capitalized into inventory. Depreciation expense for the three and six months ended June 30, 2017 was $17.9 million and $35.4 million, respectively, of which $6.2 million and $11.8 million, respectively, was capitalized into inventory. Capitalized interest related to the Company’s property, plant and equipment purchases for each of the three and six months ended June 30, 2018 and 2017 was insignificant.

(9) SUPPLEMENTAL BALANCE SHEET INFORMATION

Inventory consisted of the following:

June 30, 2018	December 31, 2017

Raw materials	$46,537	$ 49,877
Work-in-process	234,370	234,674
Finished goods	192,449	191,224
Total inventory	$473,356	$ 475,775

Accounts Payable and Accrued Liabilities consisted of the following:

	June 30, 2018	December 31, 2017
Accounts payable and accrued operating expenses	$166,416	$ 166,616
Accrued compensation expense	94,954	140,781
Accrued rebates payable	50,944	36,472
Accrued royalties payable	18,620	18,820
Value added taxes payable	9,191	9,740
Forward foreign currency exchange contracts	7,165	14,464
Accrued income taxes	2,658	5,528
Other	8,784	9,500
Total accounts payable and accrued liabilities	$358,732	$ 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 June 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:

	June 30, 2018	December 31, 2017
0.75% senior subordinated convertible notes due in October 2018	$374,980	$ 374,980
Unamortized discount	(4,659)	(12,488)
Unamortized deferred offering costs	(569)	(1,543)
Convertible Notes due in 2018, net	369,752	360,949
1.50% senior subordinated convertible notes due in October 2020	374,993	374,993
Unamortized discount	(33,531)	(40,287)
Unamortized deferred offering costs	(2,983)	(3,631)
Convertible Notes due in 2020, net	338,479	331,075
0.599% senior subordinated convertible notes due in August 2024	495,000	495,000
Unamortized discount	(8,651)	(9,355)
Unamortized deferred offering costs	(2,957)	(3,199)
Convertible Notes due in 2024, net	483,392	482,446
Total convertible debt, net	$1,191,623	$ 1,174,470
Fair value of fixed rate convertible debt		
Convertible Notes due in 2018 [1]	$398,874	$ 403,955
Convertible Notes due in 2020 [1]	442,240	446,470
Convertible Notes due in 2024 [1]	502,509	493,894
Total	$1,343,623	$ 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Coupon interest expense	$3,527	$2,194	$6,488	$4,558
Amortization of debt issuance costs	1,006	886	2,010	1,772
Accretion of discount on convertible notes	7,692	6,960	15,289	13,829
Total interest expense on convertible debt	$12,225	$10,040	$23,787	$20,159

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.

Revolving Credit Facility

The Company maintains a senior unsecured revolving credit facility (Credit Facility) that provides revolving credit of up to $100.0 million in revolving loans (the Revolving Credit Facility), a $10.0 million letter of credit subfacility and a $15.0 million swingline loan subfacility. The maturity date of the Revolving Credit Facility will occur on November 29, 2018. As of June 30, 2018 and December 31, 2017, there were no outstanding amounts due on nor any usage of the Credit Facility. As of June 30, 2018, the Company and certain of its subsidiaries that serve as guarantors were in compliance with all covenants.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

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

(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 June 30, 2018 (notional amounts in millions):

Foreign Exchange Contracts	Number of Contracts	Aggregate Notional Amount in Foreign Currency	Maturity
Brazilian Reais – Sell	2	143.8	Aug. 2018
Canadian Dollars – Sell	12	15.0	Jul. 2018 - Dec. 2018
Colombian Pesos – Sell	6	48,000.0	Jul. 2018 - Dec. 2018
Euros – Purchase	108	134.4	Jul. 2018 - Jun. 2021
Euros – Sell	394	488.2	Jul. 2018 - Jun. 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 $2.2 million from Accumulated Other Comprehensive Loss to earnings as the forecasted revenue and operating expense transactions occur.

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

Foreign Exchange Contracts	Number of Contracts	Aggregate Notional Amount in Foreign Currency	Maturity
Brazilian Reais – Purchase	5	52.2	Aug. 2018
British Pounds – Sell	1	2.6	Jul. 2018
Colombian Pesos – Sell	1	34,000.0	Jul. 2018
Euros – Purchase	3	52.2	Jul. 2018
Total	10		

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

	Asset Derivatives June 30, 2018		Liability Derivatives June 30, 2018	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Level 2[(1)]				
Forward foreign currency exchange contracts	Other current assets	$ 8,599	Accounts payable and accrued liabilities	$ 6,608

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

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

Forward foreign currency exchange contracts	Other assets	5,852	Other long- term liabilities	4,571
Total		14,451		11,179
Derivatives not designated as hedging instruments:				
Level 2[1]				
Forward foreign currency exchange contracts	Other current assets	1,440	Accounts payable and accrued liabilities	557
Total		1,440		557
Total value of derivative contracts		$15,891		$11,736

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Derivatives Designated as Hedging Instruments:				

Net gain (loss) recognized in accumulated other comprehensive loss [1]	$23,582	$(19,165)	$14,356	$(23,364)
Net gain (loss) reclassified from accumulated other comprehensive income (loss) into earnings [2]	(2,659)	695	(8,444)	3,211
Net gain recognized in net loss [3]	2,700	826	2,322	1,706
Derivatives Not Designated as Hedging Instruments:				
Net gain (loss) recognized in net loss [4]	(4,238)	5,373	2,985	5,631

(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.

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 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.

(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 June 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	$—	$ 1,018	$ —	$1,018
Restricted investments [1]	—	7,721	—	7,721
Total other current assets	—	8,739	—	8,739
Other assets:				
NQDC Plan assets	—	12,832	—	12,832
Restricted investments [1]	—	6,889	—	6,889
Strategic investments [2]	1,616	—	—	1,616
Total other assets	1,616	19,721	—	21,337
Total assets	$1,616	$ 28,460	$ —	$30,076
Liabilities:				
Current liabilities:				
NQDC Plan liability	$1,050	$ 1,018	$ —	$2,068

Contingent acquisition consideration	—	—	76,466	76,466
Total current liabilities	1,050	1,018	76,466	78,534
Other long-term liabilities:				
NQDC Plan liability	$18,588	$ 12,832	—	31,420
Contingent acquisition consideration	—	—	57,674	57,674
Total other long-term liabilities	18,588	12,832	57,674	89,094
Total liabilities	$19,638	$ 13,850	$ 134,140	$167,628

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 June 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 six months ended June 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	8,284
Milestone payments to Ares Trading S.A. (Merck Serono)	(61,607)
Foreign exchange remeasurement of Euro denominated contingent acquisition consideration	(1,503)
Contingent acquisition consideration at June 30, 2018	$134,140

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 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 June 30, 2018 and December 31, 2017, the balance of the asset retirement obligation liability was $4.2 million at each period.

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 Income (Loss) for all stock-based compensation arrangements was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Cost of sales	$3,246	$2,510	$6,386	$4,796
R&D	15,573	14,647	28,842	26,141
Selling, general and administrative	19,787	22,944	39,986	39,838
Total stock-based compensation expense	$38,606	$40,101	$75,214	$70,775

Stock-based compensation expense of $5.4 million and $9.0 million was capitalized into inventory for the three and six months ended June 30, 2018, respectively, compared to stock-based compensation expense of $4.4 million and $7.6 million that was capitalized into inventory for the three and six months ended June 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Expected volatility	38.4%	37.8 – 39.6%	37.8 – 38.4%	37.6 – 39.7%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected life	5.7 years	5.0 – 6.6 years	4.6 – 5.7 years	5.0 – 6.6 years
Risk-free interest rate	2.7%	1.8 – 1.9%	2.3 – 2.7%	1.8 – 2.2%

During the six months ended June 30, 2018, the Company granted options to purchase 775,380 shares of common stock with a weighted-average fair value of $33.34 per share.

The Company issued new stock purchase rights under the ESPP during the three and six months ended June 30, 2018, using the following assumptions to estimate the per share fair value:

	Three and Six Months Ended June 30,	
	2018	2017
Expected volatility	29.7 - 33.3%	30.7 - 42.3%
Dividend yield	0.0%	0.0%
Expected life	6-24 months	6-24 months
Risk-free interest rate	1.2 - 2.5%	1.0 - 1.3%

During the six months ended June 30, 2018, the Company granted 1,519,780 RSUs with service-based vesting conditions with a weighted-average fair value of $84.19 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 INCOME (LOSS)

The following table summarizes amounts reclassified out of AOCI and their effect on the Company’s Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended June 30, 2018 and 2017.

Details about AOCI Components	Three Months Ended June 30, 2018	2017	Six Months Ended June 30, 2018	2017	Condensed Consolidated Statement of Comprehensive Loss Classification
Gains (losses) on cash flow hedges:					
Forward foreign currency exchange contracts	$(4,062)	$1,119	$(11,708)	$4,661	Net product revenues
Forward foreign currency exchange contracts	1,403	(424)	3,264	(1,450)	Operating expenses
Total gain (loss) on cash flow hedges	(2,659)	695	(8,444)	3,211	
Gain on sale of available-for-sale debt securities	—	—	—	3,252	Other income
Income tax effect of the above	—	—	—	(1,181)	Benefit from income taxes
Total gain on available-for-sale debt securities	—	—	—	2,071	
	$(2,659)	$695	$(8,444)	$5,282	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 six months ended June 30, 2018 and 2017.

	Three Months Ended June 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 March 31, 2018	$(23,673)	$ (4,866)	$ (6)	$(28,545)
Other comprehensive income (loss) before reclassifications	23,582	1,531	(5)	25,108
Less: net loss reclassified from AOCI	(2,659)	—	—	(2,659)
Tax effect	—	(351)	—	(351)
Net current-period other comprehensive income (loss)	26,241	1,180	(5)	27,416
AOCI balance at June 30, 2018	$2,568	$ (3,686)	$ (11)	$(1,129)

	Three Months Ended June 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 March 31, 2017	$6,291	$ (1,258)	$ (13)	$5,020
Other comprehensive income (loss) before reclassifications	(19,165)	267	4	(18,894)
Less: gain reclassified from AOCI	695	—	—	695
Tax effect	—	(89)	—	(89)
Net current-period other comprehensive income (loss)	(19,860)	178	4	(19,678)
AOCI balance at June 30, 2017	$(13,569)	$ (1,080)	$ (9)	$(14,658)

Six Months Ended June 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	14,356	(490)	(4)	13,862
Less: loss reclassified from AOCI	(8,444)	—	—	(8,444)
Tax effect	—	112	—	112
Net current-period other comprehensive income (loss)	22,800	(378)	(4)	22,418
AOCI balance at June 30, 2018	$2,568	$ (3,686)	$ (11)	$(1,129)

(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)

	Six Months Ended June 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	(23,364)	1,834	3	(21,527)
Less: gain reclassified from AOCI	3,211	3,252	—	6,463
Tax effect	—	516	—	516
Net current-period other comprehensive income (loss)	(26,575)	(902)	3	(27,474)
AOCI balance at June 30, 2017	$(13,569)	$ (1,080)	$ (9)	$(14,658)

(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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017

Total revenues by geographic region:				
United States	$162,788	$141,611	$353,360	$274,095
Europe	107,221	87,672	212,871	171,577
Latin America	58,158	66,739	96,633	112,035
Rest of world	44,678	21,426	83,428	63,486
Total revenues	$372,845	$317,448	$746,292	$621,193

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net product revenues by product:				
Aldurazyme	$24,003	$19,985	$90,059	$39,340
Brineura	10,890	254	17,807	254
Firdapse	5,177	4,855	10,103	8,965
Kuvan	109,045	101,944	208,160	194,290
Naglazyme	91,086	85,751	166,082	166,309
Vimizim	127,585	103,137	244,674	208,958
Total net product revenues	$367,786	$315,926	$736,885	$618,116

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 Brineura, Firdapse, Kuvan, Naglazyme, and Vimizim, which are 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
United States	$138,411	$121,256	$262,552	$233,962
Europe	104,262	87,672	207,419	171,577
Latin America	58,158	66,738	96,633	112,032
Rest of world	42,952	20,275	80,222	61,205
Total net product revenue marketed by the Company	343,783	295,941	646,826	578,776
Aldurazyme net product revenues marketed by Genzyme	24,003	19,985	90,059	39,340
Total net product revenues	$367,786	$315,926	$736,885	$618,116

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 six months ended June 30, 2018 and 2017.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Customer A	18%	17 %	18%	17 %
Customer B	7 %	6 %	12%	6 %
Customer C	12%	14 %	12%	13 %
Customer D	10%	10 %	9 %	10 %
Customer E	4 %	10 %	2 %	7 %
Total	51%	57 %	53%	53 %

On a consolidated basis, the Company's two largest customer accounts receivable balances accounted for 30% and 15% of the June 30, 2018 total accounts receivable balance, respectively, compared to December 31, 2017, when the two largest customer accounts receivable balances accounted for 21% and 18% of the total accounts receivable balance, respectively. As of June 30, 2018, and December 31, 2017, the accounts receivable balance for Genzyme included $85.0 million and $18.1 million, respectively, of unbilled accounts receivable, which become payable to the Company when the product is sold through by Genzyme. The Company does not require collateral from its customers,

but does perform periodic credit evaluations of its customers' financial condition and requires immediate payment in certain circumstances.

The Company sells its products in countries that face economic volatility and weakness. Although the Company has historically collected receivables from customers in such countries, sustained weakness or further deterioration of the local economies and currencies may cause customers in those countries to be unable to pay for the Company's products. The Company has not historically experienced a significant level of uncollected receivables and has received continued payments from its more aged accounts in these countries. The Company believes that the allowances for doubtful accounts related to these countries, if any, is adequate based on its analysis of the specific business circumstances and expectations of collection for each of the underlying accounts in these countries.

(16) COMMITMENTS AND CONTINGENCIES

Contingencies

From time to time the Company is involved in legal actions arising in the normal course of its business. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters could adversely affect the Company, its results of operations, financial condition and cash flows. The Company's general practice is to expense legal fees as services are rendered in connection with legal matters, and to accrue for liabilities when losses are probable and reasonably estimable.

Contingent Payments

As of June 30, 2018, the Company is subject to contingent payments totaling approximately $540.4 million upon achievement of certain development and regulatory activities and commercial sales and licensing milestones if they occur before certain dates in the future. Of this amount, $158.0 million relates to the acquisition of certain rights and other assets with respect to Kuvan and Palynziq from Merck Serono and $53.2 million relates to programs that are no longer being developed.

As of June 30, 2018, the Company has recorded a total of $134.1 million of contingent acquisition consideration on its Condensed Consolidated Balances Sheet. The Company paid $61.6 million of contingent acquisition consideration in April 2018 related to the filing of the European Marketing Authorization Application for Palynziq.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

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

See Note 12 to these Condensed Consolidated Financial Statements for further information regarding the Company's contingent acquisition consideration.

Other Commitments

In the normal course of business, the Company enters into various firm purchase commitments primarily related to active pharmaceutical ingredients and certain inventory related items. As of June 30, 2018, these commitments for the next five years were approximately $62.0 million. The amounts primarily represent minimum purchase requirements for active pharmaceutical ingredients and post-marketing commitments related to the Company's commercial products.

(17) BENEFIT FROM INCOME TAXES

The 2017 Tax Act, which became effective on January 1, 2018 resulted in significant changes to the U.S. corporate income tax system including a federal statutory rate reduction from 35% to 21% and the elimination or reduction of certain domestic deductions and credits. The 2017 Tax Act changed U.S. international taxation from a worldwide basis to a modified territorial system that includes base erosion prevention measures on foreign earnings. This will result in the Company's foreign subsidiaries being subject to U.S. taxation in the future.

U.S. and foreign tax expense was computed using a forecasted annual effective tax rate for the three and six months ended June 30, 2018. Prior to the 2017 Tax Act, the Company's effective tax rate was highly sensitive to minor fluctuations in U.S. forecasted income, as such, the Company computed the U.S. component of the consolidated benefit from income taxes for the three and six months ended June 30, 2017 using an actual year-to-date tax calculation. Foreign tax expense was computed using a forecasted annual effective tax rate for the three and six months ended June 30, 2017.

The Company included a provisional estimate of the impact of the 2017 Tax Act in its 2017 tax provision in accordance with its interpretation of the 2017 Tax Act and Staff Accounting Bulletin 118. During the first quarter of 2018, the Company refined its estimates for certain provisional amounts and recorded a tax benefit of $4.6 million associated with the remeasurement of its deferred taxes. The Company may refine its estimates of provisional amounts as further guidance is issued from the U.S. Treasury, SEC and the FASB. The Company has not yet elected an accounting method regarding whether to record deferred tax assets and liabilities for expected amounts of Global Intangible Low-Taxed Income inclusions or whether to treat such amounts as a period cost.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our Condensed Consolidated Financial Statements and the related Notes thereto included in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that could impact our business. In particular, we encourage you to review the risks and uncertainties described in "Risk Factors" in Part II, Item 1A in this Quarterly Report on Form 10-Q. These risks and uncertainties could cause actual results to differ significantly from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations. See the section titled "Forward-Looking Statements" that appears at the beginning of this Quarterly Report on Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and, except as required by law, we undertake no obligation to update or revise these statements in light of future developments.

Overview

We are a global biotechnology company that develops and commercializes innovative therapies for people with serious and life-threatening rare diseases and medical conditions. We select 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.

Our portfolio consists of several commercial therapies and multiple clinical and pre-clinical product candidates. A summary of our major commercial products, including key metrics as of June 30, 2018, is provided below:

Commercial Products	Indication	U.S. Orphan Drug Exclusivity Expiration	U.S. Biologic Exclusivity Expiration	EU Orphan Drug Exclusivity Expiration
Aldurazyme (laronidase)	MPS I [1]	Expired	Expired	Expired
Brineura (cerliponase alfa)	CLN2 [2]	2024	2029	2027
Kuvan (sapropterin dihydrochloride)	PKU [3]	Expired	NA	2020 [3]
Naglazyme (galsulfase)	MPS VI [4]	Expired	Expired	Expired
Palynziq (pegvaliase-pqpz)	PKU [5]	2025	2030	NA [5]
Vimizim elosulfase alpha)	MPS IVA [6]	2021	2026	2024

(1) For the treatment of Mucopolysaccharidosis I (MPS I).
(2) For the treatment of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2).
(3) For the treatment of phenylketonuria (PKU). Kuvan has been granted orphan drug status in the EU, which together with pediatric exclusivity, confers 12 years of market exclusivity in the EU that expires in 2020.
(4) For the treatment of Mucopolysaccharidosis VI (MPS VI).
(5) For adult patients with PKU. Palynziq (formerly referred to as pegvaliase) was approved by the U.S. Food and Drug Administration (FDA) in May 2018 and our European Marketing Authorization Application (MAA) submission for Palynziq was accepted by the European Medicines Agency (EMA) in March 2018.
(6) For the treatment of Mucopolysaccharidosis IV Type A (MPS IV A).

A summary of our ongoing major development programs, including key metrics as of June 30, 2018, is provided below:

Major Product Candidates in Development	Target Indication	U.S. Orphan Designation	EU Orphan Designation	Stage
Palynziq [1]	PKU	Yes	Yes	EU MAA regulatory review
Valoctocogene roxaparvovec	Hemophilia A [2]	Yes	Yes	Clinical Phase 3
Vosoritide	Achondroplasia	Yes	Yes	Clinical Phase 3
Tralesinidase alfa (formerly referred to as BMN 250)	MPS IIIB [3]	Yes	Yes	Clinical Phase 1/2
BMN 290	Friedreich's Ataxia	Not applicable	Not applicable	Preclinical

(1) In May 2018, the FDA granted marketing approval for Palynziq in the U.S.
(2) Hemophilia A is also called factor VIII deficiency or classic hemophilia.
(3) Sanfilippo Syndrome Type B, or mucopolysaccharidosis type IIIB (MPS IIIB).

Management’s Discussion and Analysis of Financial Condition and Results of Operations (continued)

(In millions, except as otherwise disclosed)

Business Developments

We continued to grow our commercial business and advance our product candidate pipeline during 2018. We believe that the combination of our internal research programs, acquisitions and partnerships will allow us to continue to develop and commercialize innovative therapies for people with serious and life-threatening rare diseases and medical conditions. Below is a summary of key business developments in 2018 to date:

Product Approvals

- In May 2018, the FDA approved Palynziq, a PEGylated recombinant phenylalanine ammonia lyase enzyme product, for the treatment of adults with PKU who have inadequate blood phenylalanine control despite prior management with available treatment options including sapropterin. We have begun marketing Palynziq in the U.S. and the product was made available in the U.S. in July 2018. The EMA accepted our MAA submission in March 2018.

Continued Emphasis on Research and Development

- We announced 104 weeks of clinical data in 6e13 vg/kg dose and 52 weeks of data for the 4e13 vg/kg dose from our ongoing Phase 1/2 study in valoctocogene roxaparvovec gene therapy for severe hemophilia A. We now have six clinical studies underway in our gene therapy program for the treatment of severe hemophilia A, including two global Phase 3 studies: GENEr8-1, amended to evaluate superiority compared to standard of care, and GENEr8-2, as well as the Phase 1/2 study with the 6E13kg/vg dose, which began enrolling patients in May 2018 to evaluate patients with pre-existing AAV5 antibodies.
- We announced that we dosed the first participant in a global Phase 2 study for vosoritide, an analog of C-type Natriuretic Peptide (CNP), in infants and young children with achondroplasia, the most common form of disproportionate short stature in humans. The Phase 2 study is a randomized, placebo-controlled study of vosoritide in approximately 70 infants and young children with achondroplasia ages zero to less than 60 months for 52 weeks. Continuing studies include our Phase 3 study of vosoritide in approximately 110 children with achondroplasia for 52 weeks and a long-term open-label Phase 2 study of approximately 23 children.
- We announced positive, preliminary results from a multicenter, international Phase 1/2 clinical trial for tralesinidase alfa (formerly referred to as BMN 250), which began enrolling patients in April 2016. The study demonstrated that tralesinidase alfa reduced heparan sulfate levels to normal range in cerebral spinal fluid of MPS IIIB patients and indicated that ICV-administered tralesinidase alfa is well-tolerated by MPS IIIB patients. A complementary observational study was also initiated to study the progression of MPS IIIB over time.
- We announced that we expect to submit an Investigational New Drug (IND) application for a gene therapy product for the treatment of PKU in 2019. We expect to complete IND-enabling evaluations with a view to submitting an IND application for BMN 290 for the treatment of Friedreich's ataxia during the second half of 2018.
- We announced updated results from a multi-center, open-label, dose-escalation and ongoing extension study evaluating the efficacy and safety of Brineura in children with CLN2 disease, noting the new data demonstrated that treatment with Brineura resulted in less decline in motor and language function compared to historical controls. The updated results were published in the May 2018 issue of The New England Journal of Medicine.

Financial Highlights

Key components of our results of operations include the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Total revenues	$372.8	$317.4	$746.3	$621.2
Research and development (R&D) expense	175.6	143.0	359.5	288.0
Selling, general and administrative (SG&A) expense	153.3	143.5	291.6	263.5
Gain on sale of intangible assets	(20.0)	-	(20.0)	-
Total operating expenses	398.1	356.3	815.9	680.2
Net loss	(16.8)	(36.8)	(60.9)	(53.1)

The decrease in net loss for the three months ended June 30, 2018 was primarily attributed to the following:

- increased gross profit primarily driven by increased Brineura, Kuvan and Vimizim net product revenues; and
- the gain on the sale of intangible assets from the receipt of $20.0 million triggered by the achievement of a regulatory milestone by a third party; partially offset by
- increased in R&D expense for the expansion of our clinical programs related to tralesinidase alfa; valoctocogene roxaparvovec and vosoritide; and

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

(In millions, except as otherwise disclosed)

- increased SG&A expense primarily due to pre-launch activities related to Palynziq, which was approved by the FDA in the U.S. in May 2018.

The increase in net loss for the six months ended June 30, 2018 was primarily attributed to the following:

- increased R&D expense for the expansion of our clinical programs related to tralesinidase alfa, valoctocogene roxaparvovec and vosoritide; and
- increased SG&A expense primarily due to pre-launch activities related to Palynziq; partially offset by
- increased gross profit primarily driven by increased Aldurazyme and Brineura net product revenues; and
- the $20.0 million gain on the sale of intangible assets.

On January 1, 2018, we adopted Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers (ASC 606) using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under ASC 605, Revenue Recognition. See Note 4 to our accompanying Condensed Consolidated Financial Statements for additional information.

Our cash, cash equivalents and investments totaled approximately $1.6 billion as of June 30, 2018, compared to $1.8 billion as of December 31, 2017. We have historically financed our operations primarily through our cash flows from operating activities and the issuance of common stock and convertible debt. We will be highly dependent on our net product revenues to supplement our current liquidity and fund our operations for the foreseeable future. We may in the future elect to supplement this with further debt or equity offerings or commercial borrowing. Further, depending on market conditions, our financial position and performance and other factors, we may in the future choose to use a portion of our cash, cash equivalents or investments to repurchase our convertible debt or other securities. See "Financial Position, Liquidity and Capital Resources" below for a further discussion of our liquidity and capital resources.

Critical Accounting Policies and Estimates

In preparing our Condensed Consolidated Financial Statements in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and pursuant to the rules and regulations promulgated by the Securities and Exchange Commission (the SEC), we make assumptions, judgments and estimates that can have a significant impact on our net income/loss and affect the reported amounts of certain assets, liabilities, revenue and expenses, and related

disclosures. On an ongoing basis, we evaluate our estimates and discuss our critical accounting policies and estimates with the Audit Committee of our Board of Directors. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions.

Except as described in Note 3 to our accompanying Condensed Consolidated Financial Statements with respect to changes in our revenue recognition policy related to our adoption of the requirements of ASC 606, there have been no significant changes to our critical accounting policies and estimates during the six months ended June 30, 2018, compared to the critical accounting policies and estimates disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Recent Accounting Pronouncements

See Note 4 to our accompanying Condensed Consolidated Financial Statements for a description of recent accounting pronouncements and our expectation of their impact on our results of operations and financial condition.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

(In millions, except as otherwise disclosed)

Results of Operations

Total Revenues

Net product revenues consisted of the following:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Aldurazyme	$24.0	$19.9	$ 4.1	$90.1	$39.3	$50.8
Brineura	10.9	0.3	10.6	17.8	0.3	17.5
Firdapse	5.2	4.8	0.4	10.1	8.9	1.2
Kuvan	109.0	102.0	7.0	208.1	194.3	13.8
Naglazyme	91.1	85.7	5.4	166.1	166.3	(0.2)
Vimizim	127.6	103.2	24.4	244.7	209.0	35.7
Total net product revenues	$367.8	$315.9	$ 51.9	$736.9	$618.1	$118.8

Total Revenues include Net Product Revenues and Royalty and Other Revenues. Net Product Revenues include revenues generated from our approved products. In the U.S., our commercial products are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. Outside the U.S., our commercial products are sold to our authorized distributors or directly to government purchasers or hospitals, which act as intermediaries between us and end-users and generally do not stock significant quantities of our products. However, in certain countries, such as in Latin America, governments place large periodic orders for Naglazyme and Vimizim. The timing of these large government orders can be inconsistent and can create significant quarter to quarter variation in our revenues. Genzyme Corporation (Genzyme) is our sole customer for Aldurazyme and is responsible for marketing and selling Aldurazyme to third parties. Royalty and Other Revenues include royalties on net sales of products to licensees or sublicensees, collaborative agreement revenues and rental income associated with the tenants in our San Rafael, California facility.

The following is additional discussion of our Net Product Revenue results for our major products:

- Aldurazyme: Aldurazyme net product revenues for the three months ended June 30, 2018 compared to 2017 increased primarily due to an increase in volume. The increase in Aldurazyme net product revenues for the six months ended June 30, 2018 compared to 2017 is attributed to an increase in volume and the adoption of ASC 606, which contributed $27.2 million as we now recognize the estimated variable consideration that we expect to receive when the product is sold through by Genzyme at the time our performance obligation is met. Our performance obligation is met when the product is delivered and the required quality certification documentation is issued. We believe any differences between the estimated variable consideration to be received from Genzyme and actual payments will be insignificant. Prior to the adoption of ASC 606, we recognized product transfer revenues, representing the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if they do not sell the product, at the time of fulfillment of Genzyme purchase orders. Product transfer revenue was subsequently deducted from the calculated variable consideration recognized when the product was sold by Genzyme to third parties. Although Genzyme sells Aldurazyme worldwide, the net product revenues earned by us on Genzyme's net sales are denominated in U.S. Dollar (USD).

- Brineura: The increase in Brineura net product revenues for the three and six months ended June 30, 2018 compared to 2017 was primarily attributable to new patients initiating therapy as the product was launched in mid-2017.
- Kuvan: The increase in Kuvan net product revenues for the three and six months ended June 30, 2018 compared to 2017 was primarily attributable to an increase in patients on Kuvan therapy, the majority of which were in the U.S.
- Naglazyme: The increase in Naglazyme net product revenues for the three months ended June 30, 2018 compared to 2017 was mainly due to increased sales in the U.S. and Middle East. Naglazyme net product revenues for both the three and six months ended June 30, 2018 were impacted by government ordering patterns in certain Latin American countries. During the six months ended June 30, 2018, the effect of government ordering patterns in certain Latin American countries was partially offset by increased sales in the Middle East.
- Vimizim: The increase in Vimizim net product revenues for the three and six months ended June 30, 2018 compared to 2017 was primarily attributed to new patients initiating therapy.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

(In millions, except as otherwise disclosed)

We face exposure to movements in foreign currency exchange rates, primarily the Euro. We use foreign currency exchange contracts to hedge a percentage of our foreign currency exposure. The following table shows our Net Product Revenues denominated in USD and foreign currencies:

	For the Three Months Ended June 30,			For the Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Sales denominated in USD	$219.8	$187.3	$ 32.5	$456.2	$366.5	$89.7
Sales denominated in foreign currencies	148.0	128.6	19.4	280.7	251.6	29.1
Total net product revenues	$367.8	$315.9	$ 51.9	$736.9	$618.1	$118.8

The net impact of foreign currency exchange rates on product sales denominated in currencies other than USD during the three and six months ended June 30, 2018 was positive by $3.4 million and $9.5 million, respectively, compared to a positive impact of $1.5 million and $2.4 million during the three and six months ended June 30, 2017, respectively. The currency primarily driving the positive impact was the Euro, partially offset by a negative impact related to the Brazilian Real.

Cost of Sales and Product Gross Margin

Cost of Sales includes raw materials, personnel and facility and other costs associated primarily with manufacturing Aldurazyme, Brineura, Naglazyme and Vimizim at our production facilities. Cost of Sales also includes third-party manufacturing costs related to the active ingredient in Kuvan and Firdapse and third-party production costs related to final formulation and packaging services for all products and cost of royalties payable to third parties for all products.

The following table summarizes our cost of goods sold and product gross margin:

	For the Three Months Ended June 30,			For the Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Total net product revenues	$367.8	$315.9	$ 51.9	$736.9	$618.1	$118.8
Cost of sales	79.0	56.3	22.7	161.4	106.3	55.1
Product gross margin	79 %	82 %	(3.0)%	78 %	83 %	(5.0)%

Our Cost of Sales increased and gross margins decreased for the three and six months ended June 30, 2018 compared to 2017 primarily due to higher Naglazyme and Vimizim manufacturing costs and higher volume of Aldurazyme and Vimizim product sales. We expect product gross margin to remain near 80 percent over the next twelve months.

Research and Development

R&D expense includes costs associated with the research and development of product candidates and post-marketing research commitments related to our approved products. R&D expense primarily includes preclinical and clinical studies, personnel and cost to manufacture our product candidates, and related quality control and assurance, research and development, facilities and regulatory costs.

We manage our R&D expense by identifying the R&D activities we anticipate will be performed during a given period and then prioritizing efforts based on scientific data, probability of successful development, market potential, available human and capital resources and other similar considerations. We continually review our product pipeline and the development status of product candidates and, as necessary, reallocate resources among the research and development portfolio that we believe will best support the future growth of our business.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

(In millions, except as otherwise disclosed)

R&D expense increased to $175.6 million for the three months ended June 30, 2018 from $143.0 million for the three months ended June 30, 2017. R&D expense increased to $359.5 million for the six months ended June 30, 2018 from $288.0 million for the six months ended June 30, 2017. R&D Expense consisted of the following:

	Three Months Ended June 30,			Six Months Ended June 30,	
	2018	2017	Change	2018	2017