Sarepta Therapeutics, Inc.
Form 10-Q
May 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 March 31, 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 001-14895

SAREPTA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	93-0797222
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
215 First Street, Suite 415	
Cambridge, MA	02142
(Address of principal executive offices)	(Zip Code)

Registrant’s telephone number, including area code: (617) 274-4000

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 (Check one):

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

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date.

Common Stock with $0.0001 par value	65,531,046
(Class)	(Outstanding as of April 30, 2018)

SAREPTA THERAPEUTICS, INC.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

SAREPTA THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands, except shares and per share amounts)

	As of March 31, 2018	As of December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$557,234	$599,691
Short-term investments	491,757	479,369
Accounts receivable	39,848	29,468
Inventory	99,375	83,605
Other current assets	31,203	36,511
Total current assets	1,219,417	1,228,644
Property and equipment, net of accumulated depreciation of $19,817 and $18,022 as of March 31, 2018 and December 31, 2017, respectively	53,927	43,156
Intangible assets, net of accumulated amortization of $4,659 and $4,145 as of March 31, 2018 and December 31, 2017, respectively	14,473	14,355
Other assets	12,466	21,809
Total assets	$1,300,283	$1,307,964
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$17,379	$8,467
Accrued expenses	65,648	68,982
Current portion of long-term debt	3,446	6,175
Other current liabilities	4,723	4,708
Total current liabilities	91,196	88,332
Long-term debt	427,365	424,876
Deferred rent and other	4,962	5,539
Total liabilities	523,523	518,747
Commitments and contingencies (Note 16)		
Stockholders' equity:		

Preferred stock, $0.0001 par value, 3,333,333 shares authorized; none issued and outstanding	—	—
Common stock, $0.0001 par value, 99,000,000 shares authorized; 65,493,293 and 64,791,670 issued and outstanding at March 31, 2018 and December 31, 2017, respectively	7	6
Additional paid-in capital	2,029,767	2,006,598
Accumulated other comprehensive loss	(643)	(379)
Accumulated deficit	(1,252,371)	(1,217,008)
Total stockholders' equity	776,760	789,217
Total liabilities and stockholders' equity	$1,300,283	$1,307,964

See accompanying notes to unaudited condensed consolidated financial statements.

SAREPTA THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited, in thousands, except per share amounts)

	For the Three Months Ended March 31,	
	2018	2017
Revenues:		
Product, net	$ 64,604	$ 16,342
Total revenues	64,604	16,342
Costs and expenses:		
Cost of sales (excluding amortization of in-licensed rights)	5,582	223
Research and development	46,204	29,119
Selling, general and administrative	43,341	26,216
Amortization of in-licensed rights	216	29
Total costs and expenses	95,343	55,587
Operating loss	(30,739)	(39,245)
Other (loss) income:		
Gain from sale of Priority Review Voucher	—	125,000
Interest (expense) income and other, net	(4,485)	335
Other (loss) income	(4,485)	125,335
(Loss) income before income tax expense	(35,224)	86,090
Income tax expense	139	2,000
Net (loss) income	(35,363)	84,090
Other comprehensive (loss) income:		
Unrealized (loss) gain on cash equivalents and short-term investments	(264)	65
Total other comprehensive (loss) income	(264)	65
Comprehensive (loss) income	$ (35,627)	$ 84,155
Net (loss) income per share		
Basic (loss) earnings per share	$ (0.55)	$ 1.53
Diluted (loss) earnings per share	$ (0.55)	$ 1.50
Weighted average number of shares of common stock used in computing:		
Basic (loss) earnings per share	64,631	54,850
Diluted (loss) earnings per share	64,631	56,012

See accompanying notes to unaudited condensed consolidated financial statements.

SAREPTA THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	For the Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net (loss) income	$ (35,363)	$ 84,090
Adjustments to reconcile net loss to cash flows from operating activities:		
Gain from sale of Priority Review Voucher	—	(125,000)
Depreciation and amortization	2,252	1,637
Amortization of investment discount	(1,259)	(100)
Non-cash interest expense	4,940	82
Loss on disposal of assets	10	485
Stock-based compensation	10,526	5,712
Changes in operating assets and liabilities, net:		
Net increase in accounts receivable	(10,380)	(7,050)
Net increase in inventory	(15,770)	(17,632)
Net decrease in other assets	4,672	774
Net increase (decrease) in accounts payable, accrued expenses, deferred revenue and other liabilities	4,704	(886)
Net cash used in operating activities	(35,668)	(57,888)
Cash flows from investing activities:		
Purchase of property and equipment	(12,166)	(4,465)
Purchase of intangible assets	(673)	(1,245)
Purchase of available-for-sale securities	(91,514)	—
Proceeds from sale of Priority Review Voucher	—	125,000
Maturity of restricted investment	—	10,695
Maturity and sale of available-for-sale securities	90,093	80,000
Net cash (used in) provided by investing activities	(14,260)	209,985
Cash flows from financing activities:		
Proceeds from revolving line of credit	96,235	—
Payments on mortgage loans	(1,265)	(43)
Payment of term loan	—	(2,500)
Payments on revolving line of credit	(100,142)	—
Proceeds from exercise of options and purchase of stock under the Employee Stock Purchase Program	12,643	2,749
Net cash provided by financing activities	7,471	206
(Decrease) increase in cash and cash equivalents	(42,457)	152,303
Cash, cash equivalents and restricted cash:		

Beginning of period	599,827	122,556
End of period	557,370	274,859
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 853	$ 291
Supplemental schedule of non-cash investing activities and financing activities:		
Shares withheld for taxes	$ —	$ 165
Reclassification of long term investments to short term investments	$ 9,980	$ —
Intangible assets included in accrued expenses	$ 202	$ 179
Accrual for debt issuance costs related to the term loans	$ —	$ 400
Property and equipment included in accrued expenses	$ 2,980	$ 330

See accompanying notes to unaudited condensed consolidated financial statements.

SAREPTA THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. ORGANIZATION AND NATURE OF BUSINESS

Sarepta Therapeutics, Inc. (together with its wholly-owned subsidiaries, "Sarepta" or the "Company") is a commercial-stage biopharmaceutical company focused on the discovery and development of unique RNA-targeted therapeutics, gene therapy and other genetic medicine approaches for the treatment of rare neuromuscular diseases. Applying its proprietary, highly-differentiated and innovative platform technologies, the Company is able to target a broad range of diseases and disorders. Its first commercial product in the U.S., EXONDYS 51® (eteplirsen) Injection ("EXONDYS 51"), was granted accelerated approval by the United States Food and Drug Administration ("FDA") on September 19, 2016. EXONDYS 51 is indicated for the treatment of Duchenne muscular dystrophy ("DMD") in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

In addition to advancing its exon-skipping product candidates for DMD, including eteplirsen, golodirsen, casimersen and SRP-5051, the Company is working with several strategic partners under various agreements to research and develop multiple treatment approaches to DMD, which include Nationwide Children's Hospital, Genethon, Duke University and Summit (Oxford) Ltd. ("Summit").

In November 2016, the Company submitted a marketing authorization application ("MAA") for eteplirsen to the European Medicines Agency ("EMA") and the application was validated in December 2016. The Company continues to work with the EMA during their review process and anticipate they will complete their review and make a final decision on the approvability of the Company's MAA for eteplirsen in the first half of 2018.

The Company has also initiated a market access program ("MAP") for eteplirsen in select countries in Europe, North America, South America and Asia where it currently has not been approved. The MAP provides a mechanism through which physicians can prescribe eteplirsen, within their professional responsibility, to patients who meet pre-specified medical and other criteria and can secure funding. The Company has commenced shipments through the MAP and continue to expand the MAP to include more countries. In addition, the Company contracted with third party distributors and service providers to distribute eteplirsen in certain areas outside the U.S., such as Israel and certain countries in the Middle East, on a named patient basis.

As of March 31, 2018, the Company had approximately $1,049.8 million of cash, cash equivalents and investments, consisting of $557.2 million of cash and cash equivalents, $491.8 million of short-term investments, and $0.8 million of restricted cash and investments. The Company believes that its balance of cash, cash equivalents and investments as of the date of the issuance of this report is sufficient to fund its current operational plan for at least the next twelve months, though it may pursue additional cash resources through public or private debt and equity financings, seek additional government contracts and establish collaborations with or license its technology to other companies.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND RECENT ACCOUNTING PRONOUNCEMENTS

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"), reflect the accounts of Sarepta Therapeutics, Inc. and its wholly-owned subsidiaries. All intercompany transactions between and among its consolidated subsidiaries have been eliminated. Management has determined that the Company operates in one segment: discovering, developing, manufacturing and delivering therapies to patients with DMD. The Company's CEO, as the chief operating decision-maker, manages and allocates resources to the operations of the Company on a total company basis. The Company's research and development organization is responsible for the research and discovery of new product candidates and supports development and registration efforts for potential future products. The Company's supply chain organization manages the development of the manufacturing processes, clinical trial supply and commercial product supply. The Company's commercial organization is responsible for commercialization of EXONDYS 51 in the U.S. and internationally. The Company is supported by other back-office general and administration functions. Consistent with this decision-making process, the Company's CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets.

Estimates and Uncertainties

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue, expenses and

the disclosure of contingent assets and liabilities. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include revenue recognition, inventory, convertible debt, valuation of stock-based awards, research and development expenses and income tax.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of accounts receivable from customers and cash, cash equivalents and investments held at financial institutions.

As of March 31, 2018, the majority of the Company's accounts receivable arose from product sales in the U.S. and all customers have standard payment terms which generally require payment within 30 to 60 days. Outside of the U.S., the payment terms range between 45 and 120 days. Three individual customers accounted for 44%, 34% and 18% of net product revenues and 60%, 22% and 9% of accounts receivable from product sales, respectively. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profile. As of March 31, 2018, the Company believes that such customers are of high credit quality.

As of March 31, 2018 the Company's cash equivalents and investments were concentrated at a single financial institution, which potentially exposes the Company to credit risks. However, the Company does not believe that there is significant risk of non-performance by the financial institution.

Significant Accounting Policies

For details about the Company's accounting policies, please read Note 2, Summary of Significant Accounting Policies and Recent Accounting Pronouncements of the Annual Report on Form 10-K for the year ended December 31, 2017.

The Company has adopted Accounting Standards Codification Topic 606, "Revenue from Contracts with Customers" ("ASC 606") effective as of January 1, 2018. The Company has chosen to use the full retrospective transition method, under which it is required to revise its consolidated financial statements for the years ended December 31, 2016 and 2017 as well as any applicable interim periods within those years, as if ASC 606 had been effective for those periods. Under ASC 606, the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for the goods or services provided. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when or as the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. For all contracts that fall into the scope of ASC 606, only one performance obligation has been identified by the Company: to timely deliver drug products to the customer's designated warehouses.

Product Revenues

The Company distributes its product principally through a limited number of specialty distributor and specialty pharmacies in the U.S. and certain distributors in the European Union ("EU"), Israel and Middle East (collectively, "Customers"). The Customers subsequently resell the product to patients and health care providers. The Company provides no right of return to the Customers except in cases of shipping error or product defect. Product revenues are recognized when the Customers take control of the product, which typically occurs upon delivery to the Customers. For the three months ended March 31, 2018, majority of the revenues recognized were generated by the specialty distributor and specialty pharmacies in the U.S.

Variable Consideration

Product revenues are recorded at the net sales price ("transaction price") which includes estimated reserves for variable consideration, such as Medicaid rebates, governmental chargebacks, including Public Health Service ("PHS") chargebacks, prompt payment discounts, co-pay assistance and distribution fees. 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 no payment is required by the Company) or a current liability (if a payment is required by the Company). These reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contracts. Additional details relating to variable consideration follows:

- Medicaid rebates relate to the Company's estimated obligations to states under established reimbursement arrangements. Rebate reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses.
- Governmental chargebacks, including PHS chargebacks, relate to the Company's estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices that the Company charges to wholesalers. The wholesaler charges the Company for the difference between what the wholesaler pays for the products and the ultimate selling price to the qualified healthcare providers. Chargeback reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider from the wholesaler, and the Company generally issues credits for such amounts within a few weeks of receiving notification of resale from the wholesaler.
- Prompt payment discounts relate to the Company's estimated obligations for credits to be granted to a specialty pharmacy for remitting payment on its purchases within established incentive periods. Reserves for prompt payment discounts are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.
- Co-pay assistance relates to financial assistance provided to qualified patients, whereby the Company may assist them with prescription drug co-payments required by the patient's insurance provider. Reserves for co-pay assistance are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses.
- Distribution fees relate to fees paid to Customers in the distribution channel that provide the Company with inventory management, data and distribution services and are generally accounted for as a reduction of revenue. To the extent that the services received are distinct from the Company's sale of products to the Customer, these payments are accounted for as selling, general and administrative expenses.

The impact of adopting ASC 606 was not material. There have not been any other material changes to the Company's accounting policies as of March 31, 2018.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, "Leases (Topic 842)", which supersedes Topic 840, "Leases". Under the new guidance, a lessee should recognize assets and liabilities that arise from its leases and disclose qualitative and quantitative information about its leasing arrangements. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. ASU No. 2016-02 will be effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The adoption of this standard is expected to have an impact on the amount of the Company's assets and liabilities. As of March 31, 2018, the Company has not elected to early adopt this guidance or determined the effect that the adoption of this guidance will have on its consolidated financial statements.

In March 2017, the Financial Accounting Standards Board issued ASU No. 2017-08, "Receivables - Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities". This new

standard amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period for the premium to the earliest call date. ASU No. 2017-02 will be effective for fiscal years beginning after December 15, 2018, with early adoption permitted. As of March 31, 2018, we are currently evaluating the potential impact that this new standard may have on our financial position and results of operations.

Reclassification

The Company has revised the presentation as well as the caption of certain items within the unaudited condensed consolidated balance sheets to conform to the current period presentation. “Restricted cash and investments” of $0.8 million and

“deferred revenue” of $3.3 million as December 31, 2017 are grouped into “other assets” and “other current liabilities”, respectively. These revisions had no impact on total assets nor total liabilities.

Additionally, the Company has revised the presentation as well as caption of certain items within the unaudited condensed consolidated statements of operations and comprehensive loss to conform to the current period presentation. “Amortization of in-licensed rights” of less than $0.1 million was reclassified from “cost of sales” and presented separately in the unaudited condensed consolidated statements of operations and comprehensive loss. The reclassification had no impact on operating loss or net income.

Furthermore, the Company has also revised the presentation as well as caption of certain items within the unaudited condensed consolidated statements of cash flows to conform to the current period presentation. “Accretion of discount on available-for-sale securities” of $0.1 million and “Non-cash interest expense” of approximately $0.1 million are presented separately in the unaudited condensed consolidated statements of cash flows. These revisions had no impact on the net cash used in operating activities or cash, cash equivalents and restricted cash at end of period.

3. FAIR VALUE MEASUREMENTS

The Company has certain financial assets that are recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- Level 1 — quoted prices for identical instruments in active markets;
- Level 2 — quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets; and
- Level 3 — valuations derived from valuation techniques in which one or more significant value drivers are unobservable.

The tables below present information about the Company’s financial assets that are measured and carried at fair value and indicate the level within the fair value hierarchy of valuation techniques it utilizes to determine such fair value:

	Fair Value Measurement as of March 31, 2018			
	Total	Level 1	Level 2	Level 3