

Sarepta Therapeutics, Inc.  
Form 10-Q  
August 08, 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 001-14895

SAREPTA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	93-0797222
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	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

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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	66,442,402
(Class)	(Outstanding as of August 3, 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 share and per share amounts)

	As of June 30, 2018	As of December 31, 2017
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$410,375	\$599,691
Short-term investments	538,769	479,369
Accounts receivable	42,985	29,468
Inventory	104,126	83,605
Other current assets	42,989	36,511
Total current assets	1,139,244	1,228,644
Property and equipment, net of accumulated depreciation of \$22,124 and \$18,022 as of June 30, 2018 and December 31, 2017, respectively	57,624	43,156
Intangible assets, net of accumulated amortization of \$5,100 and \$4,145 as of June 30, 2018 and December 31, 2017, respectively	14,857	14,355
Other assets	35,435	21,809
Total assets	\$1,247,160	\$1,307,964
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$17,382	\$8,467
Accrued expenses	72,477	68,982
Current portion of long-term debt	9,514	6,175
Deferred revenue	3,303	3,316
Other current liabilities	2,011	1,392
Total current liabilities	104,687	88,332
Long-term debt	429,925	424,876
Deferred rent and other	13,501	5,539
Total liabilities	548,113	518,747
Commitments and contingencies (Note 16)		

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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; 66,346,248

and 64,791,670 issued and outstanding at June 30, 2018 and

December 31, 2017, respectively

7 6

Additional paid-in capital

2,061,039 2,006,598

Accumulated other comprehensive loss

(361 ) (379 )

Accumulated deficit

(1,361,638) (1,217,008)

Total stockholders' equity

699,047 789,217

Total liabilities and stockholders' equity

\$1,247,160 \$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		For the Six Months Ended	
	June 30, 2018	2017	June 30, 2018	2017
<b>Revenues:</b>				
Product, net	\$ 73,529	\$ 35,011	\$ 138,133	\$ 51,353
Total revenues	73,529	35,011	138,133	51,353
<b>Costs and expenses:</b>				
<b>Cost of sales (excluding amortization of in-licensed rights)</b>				
	\$ 6,735	506	\$ 12,317	729
Research and development	122,848	58,908	169,052	88,027
Selling, general and administrative	47,156	36,069	90,497	62,285
EXONDYS 51 litigation and license charges	—	2,839	—	2,839
Amortization of in-licensed rights	217	28	433	57
Total costs and expenses	176,956	98,350	272,299	153,937
Operating loss	(103,427 )	(63,339 )	(134,166 )	(102,584 )
<b>Other (loss) income:</b>				
Gain from sale of Priority Review Voucher	—	—	—	125,000
Interest (expense) income and other, net	(5,218 )	184	(9,703 )	519
Other (loss) income	(5,218 )	184	(9,703 )	125,519
(Loss) income before income tax expense (benefit)	(108,645 )	(63,155 )	(143,869 )	22,935
Income tax expense (benefit)	622	(109 )	761	1,891
Net (loss) income	(109,267 )	(63,046 )	(144,630 )	21,044
<b>Other comprehensive (loss) income:</b>				
<b>Unrealized gain on cash equivalents and short-term investments</b>				
	282	17	18	82
Total other comprehensive income	282	17	18	82
Comprehensive (loss) income	\$ (108,985 )	\$ (63,029 )	\$ (144,612 )	\$ 21,126
<b>Net (loss) income per share</b>				
Basic (loss) earnings per share	\$ (1.67 )	\$ (1.15 )	\$ (2.22 )	\$ 0.38
Diluted (loss) earnings per share	\$ (1.67 )	\$ (1.15 )	\$ (2.22 )	\$ 0.37
<b>Weighted average number of shares of common stock used in computing:</b>				
Basic (loss) earnings per share	65,484	54,976	65,060	54,913
Diluted (loss) earnings per share	65,484	54,976	65,060	56,176

See accompanying notes to unaudited condensed consolidated financial statements.



## SAREPTA THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	For the Six Months Ended June 30,	
	2018	2017
<b>Cash flows from operating activities:</b>		
Net (loss) income	\$ (144,630 )	\$ 21,044
<b>Adjustments to reconcile net (loss) income to cash flows from operating activities:</b>		
Gain from sale of Priority Review Voucher	—	(125,000 )
Depreciation and amortization	5,125	3,409
Amortization of investment discount	(2,828 )	(260 )
Non-cash interest expense	9,958	117
Loss on disposal of assets	37	604
Stock-based compensation	25,805	16,177
<b>Changes in operating assets and liabilities, net:</b>		
Net increase in accounts receivable	(13,517 )	(12,563 )
Net increase in inventory	(20,521 )	(28,941 )
Net increase in other assets	(29,866 )	(9,285 )
Net increase (decrease) in accounts payable, accrued expenses, deferred revenue and other liabilities	17,515	(8,337 )
<b>Net cash used in operating activities</b>	<b>(152,922 )</b>	<b>(143,035 )</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(20,863 )	(7,336 )
Purchase of intangible assets	(1,556 )	(1,601 )
Purchase of available-for-sale securities	(295,823 )	(100,348 )
Proceeds from sale of Priority Review Voucher	—	125,000
Purchases of restricted investment	(353 )	—
Maturity of restricted investment	—	10,695
Maturity of available-for-sale securities	249,243	163,521
<b>Net cash (used in) provided by investing activities</b>	<b>(69,352 )</b>	<b>189,931</b>
<b>Cash flows from financing activities:</b>		
Proceeds from revolving line of credit	173,354	—
Payments on mortgage loans	(1,265 )	—
Payments on revolving line of credit	(173,653 )	—
<b>Proceeds from exercise of options and purchase of stock under the Employee Stock Purchase Program</b>		
	34,386	4,086
Repayments of long-term debt	—	(5,054 )
<b>Net cash provided by (used in) financing activities</b>	<b>32,822</b>	<b>(968 )</b>
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(189,452 )</b>	<b>45,928</b>

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Cash, cash equivalents and restricted cash:		
Beginning of period	599,827	122,556
End of period	\$ 410,375	\$ 168,484
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 410,375	\$ 168,348
Restricted cash in other assets	—	136
Total cash, cash equivalents and restricted cash	\$ 410,375	\$ 168,484
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 6,058	\$ 538
Supplemental schedule of non-cash investing activities and financing activities:		
Shares withheld for taxes	\$ 5,750	\$ 309
Reclassification of long term investments to short term investments	\$ 9,980	\$ —
Intangible assets included in accrued expenses	\$ 294	\$ 265
Asset held for sale	\$ —	\$ 1,529
Accrual for debt issuance costs related to the term loans	\$ 600	\$ 400
Property and equipment included in accrued expenses	\$ 289	\$ —

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<sup>®</sup> (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. On June 1, 2018, the Committee for Medicinal Products for Human Use (“CHMP”) of the EMA, adopted a negative opinion for eteplirsen. The Company has requested a re-examination of the opinion, and that a Scientific Advisory Group (“SAG”) on DMD be called so that neuromuscular specialists, experienced with working with treatments for these patients, can provide expert guidance and insight into, among other things, the validity of the external controls used and the importance of certain functional endpoints, including for instance, the relevance of meaningful slowing pulmonary decline in patients with this disease that is difficult to treat. The re-examination process is expected to be completed by year-end 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 commenced shipments through the MAP. 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 June 30, 2018, the Company had approximately \$950.2 million of cash, cash equivalents and investments, consisting of \$410.4 million of cash and cash equivalents, \$538.8 million of short-term investments, and \$1.0 million of restricted investment. 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 June 30, 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%, 35% and 19% of net product revenues for the six months ended June 30, 2018 and 61%, 26% and 11% of accounts receivable from product sales as of June 30, 2018. 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 June 30, 2018, the Company believes that such customers are of high credit quality.

As of June 30, 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 both the three and six months ended June 30, 2018, the majority of the revenues recognized were generated by the specialty distributor and specialty pharmacies in the U.S.

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## 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 June 30, 2018.

## Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) 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 June 30, 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 FASB 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 June 30, 2018, the Company is currently evaluating the potential impact that this new standard may have on its financial position and results of operations.

In June 2018, the FASB issued ASU 2018-07, "Compensation - Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting." This ASU expands the scope of Topic 718 to include share based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. ASU No. 2018-07



will be effective for fiscal years beginning after December 15, 2018, with early adoption permitted, although no earlier than the adoption date of Topic 606. The Company elected to early adopt this ASU in the quarter ended June 30, 2018, which did not have a material impact on its consolidated financial statements.

### 3. COLLABORATION, LICENSE AND MANUFACTURING AGREEMENTS

#### Myonexus Warrant Agreement

In May 2018, the Company entered into a Warrant to Purchase Common Stock Agreement (“Warrant Agreement”) with Myonexus Therapeutics, Inc. (“Myonexus”). Pursuant to the terms of the Warrant Agreement, the Company made an up-front payment of \$60.0 million to purchase an exclusive option to acquire Myonexus at a pre-negotiated, fixed price plus sales-related and regulatory-related contingent payments. Prior to the exercise of the option to acquire Myonexus, the Company may be required to make additional development milestone payments to Myonexus of up to \$45.0 million over an approximately two-year evaluation period.

The up-front payment of \$60.0 million to Myonexus provides the Company with rights to potential future benefits associated with Myonexus’s ongoing research and development activities, which have not reached technological feasibility and have no alternative future use. Accordingly, the up-front payment of \$60.0 million was expensed as incurred and classified as research and development expense in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss during the three and six months ended June 30, 2018. The additional development milestones payments of up to \$45.0 million will also be recorded to research and development expense when (and if) incurred.

The Company considered whether it would have to consolidate the operations of Myonexus and concluded that, while Myonexus is a variable interest entity, the Company is not the primary beneficiary as it does not have the power to direct the activities that would most significantly impact the economic performance of Myonexus.

#### Brammer Manufacturing Agreement

In June 2018, the Company entered into a Development, Commercial Manufacturing and Supply Agreement (“Brammer Manufacturing Agreement”), with Brammer Bio MA, LLC (“Brammer”). Pursuant to the terms of the Brammer Manufacturing Agreement, Brammer agreed to provide the Company with access to clinical and commercial manufacturing capacity for its gene therapy programs.

As part of the Brammer Manufacturing Agreement, the Company will purchase product in batches from Brammer, subject to minimum and maximum annual purchase requirements. Further, the Company: (i) was required to make a \$20.0 million advance payment to Brammer upon execution of the agreement, (ii) is required to make two non-refundable payments of \$5.0 million each to Brammer in the third and fourth quarter of 2018 to be used in the specification, selection, and procurement of the related process equipment to be utilized under the agreement, and (iii) is required to make a \$10.0 million quarterly capacity access fee payment to Brammer throughout the term of the agreement. However, through June 30, 2019, a reduced quarterly capacity access fee will be in effect as Brammer works towards achieving full capacity at its facility. In addition, one-tenth of the \$20.0 million advance payment will be applied as a credit to the quarterly capacity access fees due and payable from July 1, 2019 through December 31, 2021, resulting in a net capacity access fee of \$8.0 million.

The term of the Brammer Manufacturing Agreement will continue for a period of six years following the first regulatory approval of a product manufactured under the agreement. The term will automatically renew for successive two years unless the Company notifies Brammer of its intention not to renew (no less than twenty-four months prior to the expiration of the term). The Company also has the ability to terminate the agreement prior to expiration but would be required to continue remitting capacity access fees to Brammer for up to eight additional quarters.

The Company has determined that the Brammer Manufacturing Agreement does not contain an embedded lease because it does not convey the right to control the use of the facility or related equipment. This conclusion was based on the Company's inability or right to control physical access to Brammer's facility and the related equipment, and the ability of one or more parties, other than the Company, to take more than a minor amount of the output that will be produced during the term of the agreement.

As of June 30, 2018, the \$20.0 million advance payment was recorded as an other non-current asset in the accompanying unaudited condensed consolidated balance