DYNAVAX TECHNOLOGIES CORP
Form 10-Q
May 09, 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: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Delaware	33-0728374
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

(Address, including Zip Code, and telephone number, including area code, of the registrant's principal executive offices)

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 registration 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	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 Act). Yes No

As of May 4, 2018, the registrant had outstanding 62,274,096 shares of common stock.

INDEX

DYNAVAX TECHNOLOGIES CORPORATION

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our ability to successfully commercialize HEPLISAV-B®, our ability to successfully develop and timely obtain regulatory approval of SD-101 and DV281, and our other early stage compounds, our business, collaboration and regulatory strategy, our intellectual property position, our product development efforts, our ability to manufacture commercial supply and meet regulatory requirements, the timing of the introduction of our products, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds as well as our plans, objectives, strategies, expectations and intentions. These statements appear throughout this Quarterly Report on Form 10-Q and can be identified by the use of forward-looking language such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “future,” or “intend,” or the ne terms or other variations or comparable terminology.

Actual results may vary materially from those in our forward-looking statements as a result of various factors that are identified in “Item 1A—Risk Factors” and “Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this document. No assurance can be given that the risk factors described in this Quarterly Report on Form 10-Q are all of the factors that could cause actual results to vary materially from the forward-looking statements. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Readers should not place undue reliance on these forward-looking statements and are cautioned that any such forward-looking statements are not guarantees of future performance. We assume no obligation to update any forward-looking statements.

This Quarterly Report on Form 10-Q includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Quarterly Report on Form 10-Q may be trademarks or registered trademarks of their respective owners. References herein to “we,” “our,” “us,” “Dynavax” or the “Company” refer to Dynavax Technologies Corporation and its subsidiary.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
Dynavax Technologies Corporation

Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	March 31, 2018 (unaudited)	December 31, 2017 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$36,067	$26,584
Marketable securities available-for-sale	214,713	165,270
Accounts and other receivables	763	854
Inventories	550	312
Intangible assets, net	-	1,306
Prepaid expenses and other current assets	3,303	3,697
Total current assets	255,396	198,023
Property and equipment, net	17,064	16,619
Intangible assets, net	18,662	-
Goodwill	2,309	2,244
Restricted cash	635	629
Other assets	1,267	1,270
Total assets	$295,333	$218,785
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$2,279	$4,539
Accrued research and development	4,443	4,359
Accrued liabilities	9,820	9,695
Other current liabilities	7,000	-
Total current liabilities	23,542	18,593
Long-term debt, net	99,232	-
Other long-term liabilities	6,672	643
Total liabilities	129,446	19,236
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized at March 31, 2018 and December 31, 2017; no shares issued and outstanding at March 31, 2018 and December 31, 2017	-	-
Common stock: $0.001 par value; 139,000 shares authorized at	62	62

March 31, 2018 and December 31, 2017; 62,254 and 61,533 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively		
Additional paid-in capital	1,112,321	1,107,693
Accumulated other comprehensive loss	(213)	(881)
Accumulated deficit	(946,283)	(907,325)
Total stockholders' equity	165,887	199,549
Total liabilities and stockholders' equity	$295,333	$218,785

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2018	2017
Revenues:		
Product revenue, net	$165	$-
Grant revenue	-	148
Total revenues	165	148
Operating expenses:		
Cost of sales - product	205	-
Cost of sales - amortization of intangible assets	2,417	-
Research and development	18,966	16,345
Selling, general and administrative	16,891	6,472
Restructuring	-	2,783
Total operating expenses	38,479	25,600
Loss from operations	(38,314)	(25,452)
Other income (expense):		
Interest income	740	145
Interest expense	(1,161)	-
Other (expense) income, net	(223)	20
Net loss	$(38,958)	$(25,287)
Basic and diluted net loss per share	$(0.63)	$(0.60)
Weighted average shares used to compute basic and diluted net loss per share	61,744	41,830

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2018	2017

Net loss	$(38,958)	$(25,287)
Other comprehensive income (loss), net of tax:		
Unrealized loss on marketable securities available-for-sale	(22)	(29)
Cumulative foreign currency translation adjustments	690	303
Total other comprehensive income	668	274
Total comprehensive loss	$(38,290)	$(25,013)

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2018	2017 (As Adjusted)
Operating activities		
Net loss	$(38,958)	$(25,287)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	823	789
Gain on disposal of property and equipment	-	(21)
Accretion of discounts on marketable securities	(176)	(10)
Stock compensation expense	4,799	3,821
Cost of sales - amortization of intangible assets	2,417	-
Non-cash interest expense	348	-
Changes in operating assets and liabilities:		
Accounts and other receivables	91	(123)
Inventories	(238)	-
Prepaid expenses and other current assets	394	(39)
Other assets	3	(907)
Accounts payable	349	(2,110)
Accrued liabilities and other long term liabilities	276	(1,363)
Net cash used in operating activities	(29,872)	(25,250)
Investing activities		
Acquisition of technology licenses	(9,500)	-
Purchases of marketable securities	(141,103)	(44,652)
Proceeds from maturities of marketable securities	91,815	37,875
Purchases of property and equipment, net	(897)	(234)
Net cash used in investing activities	(59,685)	(7,011)
Financing activities		
Proceeds from long-term debt, net	99,000	-
Proceeds from issuance of common stock, net	-	29,535
Tax withholding from exercise of stock options and restricted stock awards, net	(426)	(303)
Proceeds from Employee Stock Purchase Plan	255	155
Net cash provided by financing activities	98,829	29,387
Effect of exchange rate changes on cash, cash equivalents and restricted cash	217	60
Net increase (decrease) in cash, cash equivalents and restricted cash	9,489	(2,814)
Cash, cash equivalents and restricted cash at beginning of period	27,213	24,891
Cash, cash equivalents and restricted cash at end of period	$36,702	$22,077
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$813	$-

Release of accrual for litigation settlement and insurance recovery (Note 6)	$ -	$ 4,050
Non-cash investing and financing activities:		
Disposal of fully depreciated property and equipment	$ 37	$ -
Non-cash acquisition of technology license	$ 12,773	$ -

See accompanying notes.

Dynavax Technologies Corporation

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation. Our first commercial product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted), was approved by the United States Food and Drug Administration ("FDA") in November 2017 for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We commenced commercial shipments of HEPLISAV-B in January 2018 and deployed our field sales force in late February 2018. Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents. Our lead investigational immuno-oncology products are SD-101, currently being evaluated in Phase 2 clinical studies, and DV281, in a Phase 1 safety study. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

Basis of Presentation

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which we consider necessary to present fairly our financial position and the results of our operations and cash flows. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted. Interim-period results are not necessarily indicative of results of operations or cash flows to be expected for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2017 has been derived from audited financial statements at that date, but excludes disclosures required by GAAP for complete financial statements.

The unaudited condensed consolidated financial statements and these notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (the "SEC").

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiary, Dynavax GmbH. All significant intercompany accounts and transactions among these entities have been eliminated from the condensed consolidated financial statements. We operate in one business segment: the discovery, development and commercialization of biopharmaceutical products.

Liquidity and Financial Condition

As of March 31, 2018, we had cash, cash equivalents and marketable securities of $250.8 million. On February 20, 2018, we entered into a $175.0 million term loan agreement ("Loan Agreement") with CRG Servicing LLC. The Loan Agreement provides for a $175.0 million term loan facility, $100.0 million of which was borrowed at closing and, subject to the satisfaction of certain market capitalization and other borrowing conditions, up to an additional $75.0 million is available for borrowing at our option on or before July 17, 2019. During the three months ended March 31,

2018, we used $29.9 million of cash in operating activities and paid $9.5 million in fees under patent license agreements relating to HEPLISAV-B.

We have incurred significant operating losses and negative cash flows from our operations since our inception and we expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B, clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates and discovery research and development. Until we can generate a sufficient amount of revenue from product sales, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Management's estimates are based on historical information available as of the date of the condensed consolidated financial statements and various other assumptions we believe are reasonable under the circumstances. Actual results could differ materially from these estimates.

Summary of Significant Accounting Policies

Revenue Recognition

On January 1, 2018, we adopted Accounting Standards Codification, ("ASC") 606, Revenue from Contracts with Customers, using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Under the modified retrospective method, results for the reporting period beginning January 1, 2018 are presented under ASC 606, while the cumulative effect of initially applying the guidance is reflected as an adjustment to the opening balance of retained earnings at January 1, 2018. Adoption of this ASU did not have a material impact on our consolidated financial statements as there were no remaining performance obligations under our license and collaboration agreements as of the adoption date.

While results for reporting periods beginning after January 1, 2018 are presented under ASC 606, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The accounting policy for revenue recognition for periods prior to January 1, 2018 is described in Note 1 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

We sell our product to a limited number of wholesalers and specialty distributors in the U.S. (collectively, our "Customers"). Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product upon delivery to the Customer. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Because our standard credit terms are short-term and we expect to receive payment in less than one-year, there is no financing component on the related receivables. Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration 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. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts and other fees that are offered within contracts between us and our Customers, health care providers, and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the amount is due to the Customer) or as an accrued liability (if the amount is payable to a party other than a Customer). Variable consideration requires significant estimates, judgment andinformation obtained from external sources. The amount of variable consideration 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. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment.

Product Returns: Consistent with industry practice, we offer our Customers a limited right of return based on the product's expiration date for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We consider several factors in the estimation of potential product returns including expiration dates of the product shipped, the limited product return rights, available information about Customers' inventory, shelf life of the product and other relevant factors.

Chargebacks: Our Customers subsequently resell our product to health care providers. In addition to distribution agreements with Customers, we enter into arrangements with health care providers that provide for chargebacks and discounts with respect to the purchase of our product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that 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 by Customers, and we issue credits for such amounts generally within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consists of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers, and chargebacks that Customers have claimed but for which we have not yet issued credit.

Trade Discounts and Allowances: We provide our Customers with discounts which include early payment incentives that are explicitly stated in our contracts, and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Distribution fees: Distribution fees include fees paid to certain Customers for sales order management, data and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

Inventories

Inventory is stated at the lower of cost or estimated net realizable value. We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but are expensed as research and development costs. We begin capitalization of these inventory related costs once regulatory approval is obtained.

HEPLISAV-B was approved by the FDA on November 9, 2017, at which time we began to capitalize inventory costs associated with HEPLISAV-B. Prior to FDA approval of HEPLISAV-B, all costs related to the manufacturing of HEPLISAV-B that could potentially be available to support the commercial launch of our products, were charged to research and development expense in the period incurred as there was no alternative future use. We periodically analyze our inventory levels, and will write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements. Expired inventory will be disposed of and the related costs written off.

Intangible Assets

We record definite-lived intangible assets related to certain capitalized milestone and license payments. After determining that the pattern of future cash flows associated with intangible asset could not be reliably estimated with a high level of precision, these assets are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If our estimate of HEPLISAV-B's useful life is shorter than the remaining patent life, then the shorter period is used. We assess our intangible assets for impairment if indicators are present or

changes in circumstance suggest that impairment may exist. No impairment of intangible assets has been identified during the three months ended March 31, 2018.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under contracts with third parties may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. Our accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties. We estimate our research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to us at that time. There have been no material adjustments to the prior period accrued estimates for clinical trial activities through March 31, 2018.

Restructuring

Restructuring costs are comprised of severance costs related to workforce reductions. We recognize restructuring charges when the liability is incurred. Employee termination benefits are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments.

Income Taxes

We account for income taxes using the asset and liability method, under which deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Tax law and rate changes are reflected in income in the period such changes are enacted. The Company includes interest and penalties related to income taxes, including unrecognized tax benefits, within income tax expense.

On December 22, 2017, President Trump signed U.S. tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”), which became effective January 1, 2018. The Tax Act significantly changes the fundamentals of U.S. corporate income taxation by, among many other things, reducing the U.S. federal corporate income tax rate to 21%, converting to a territorial tax system, and creating various income inclusion and expense limitation provisions. We have performed a review of the Tax Act, and based on information available at March 31, 2018, recorded certain provisional amounts related to the revaluation of our deferred taxes and the realization of certain tax credit carryforwards. The accounting for these provisional amounts is expected to be completed within the one year measurement period allowed under Staff Accounting Bulletin 118. Due to insufficient guidance on certain aspects of the Tax Act, such as officer’s compensation, as well as uncertainty around the GAAP treatment associated with many other parts of the Tax Act, such as the implementation of certain international provisions, we cannot be certain that all deferred tax assets and liabilities have been established for the future effects of the legislation. Therefore, the final accounting for these provisions is subject to change as further information becomes available and further analysis is complete. Additionally, given the uncertainty and complexity of these new international tax regimes, we are continuing to evaluate how these provisions will be accounted for under U.S. generally accepted accounting principles; therefore, we have not yet adopted an accounting policy for treating the effects of these provisions as either a component of income tax expense in the period the tax arises, or through adjusting our deferred tax assets and liabilities to account for the estimated future impact of the special international tax regimes.

Recent Accounting Pronouncements

Accounting Standards Update 2016-02

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, Leases (Topic 842) which outlines a comprehensive lease accounting model and supersedes the current lease

guidance. The ASU requires companies to recognize lease right-of-use assets and lease liabilities by lessees for all operating leases with lease terms greater than 12 months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The ASU is effective for annual periods beginning after December 15, 2018 and interim periods therein on a modified retrospective basis with early adoption permitted. We are currently evaluating the impact this guidance will have on our consolidated financial statements and believe the adoption will modify our analyses and disclosures of lease agreements considering operating leases are a significant portion of the Company’s total lease commitments.

Accounting Standards Update 2017-04

In January 2017, the FASB issued ASU No. 2017-04, Intangibles – Goodwill and Other (Topic 350), which simplifies the test for goodwill impairment by eliminating a previous requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2016-18

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force). This ASU requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. The amendments in this update is applied using a retrospective transition method to each period presented. The ASU is effective for annual periods beginning after December 15, 2017. We adopted ASU 2016-18 on January 1, 2018 and have presented comparable prior period cash, cash equivalents and restricted cash balances in the consolidated statements of cash flows reflecting the retrospective impact of this ASU. See Note 3.

2. Fair Value Measurements

We measure fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities;
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities; therefore, requiring an entity to develop its own valuation techniques and assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy.

The carrying amounts of cash equivalents, accounts and other receivables, accounts payable and accrued liabilities are considered reasonable estimates of their respective fair value because of their short-term nature.

As of March 31, 2018, we measured the fair value of our $7.0 million payment to Merck Sharpe & Dohme Corp., which is due in the first quarter of 2020, based on Level 3 inputs due to the use of unobservable inputs that cannot be corroborated by observable market data. We estimated the fair value of the liability using a discounted cash flow technique using the effective interest rate on our term loan. The liability had a fair value of $5.8 million as of March 31, 2018.

Recurring Fair Value Measurements

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
March 31, 2018				
Money market funds	$25,923	$-	$ -	$25,923

U.S. treasuries	-	49,206	-	49,206
U.S. government agency securities	-	54,644	-	54,644
Corporate debt securities	-	119,099	-	119,099
Total	$25,923	$222,949	$ -	$248,872

	Level 1	Level 2	Level 3	Total
December 31, 2017				
Money market funds	$22,543	$-	$ -	$22,543
U.S. treasuries	-	45,534	-	45,534
U.S. government agency securities	-	86,820	-	86,820
Corporate debt securities	-	32,916	-	32,916
Total	$22,543	$165,270	$ -	$187,813

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

U.S. treasuries, U.S. government agency securities and corporate debt securities are measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

There were no transfers between Level 1 and Level 2 during the three months ended March 31, 2018.

3. Cash, Cash Equivalents, Restricted Cash and Marketable Securities

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheet that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows:

	March 31, 2018	December 31, 2017
Cash and cash equivalents	$36,067	$26,584
Restricted cash	635	629
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$36,702	$27,213

Due to the adoption of ASU 2016-18, we have presented below, comparable prior period cash, cash equivalents and restricted cash balances as presented in the condensed consolidated statement of cash flows:

	March 31, 2017	December 31, 2016
Cash and cash equivalents	$21,472	$24,289
Restricted cash	605	602
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$22,077	$24,891

Restricted cash balances relate to certificates of deposit issued as collateral to certain letters of credit issued as security to our lease arrangements. See Note 6.

Cash, cash equivalents and marketable securities consist of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
March 31, 2018				
Cash and cash equivalents:				
Cash	$ 1,908	$ -	$ -	$ 1,908
Money market funds	25,923	-	-	25,923
U.S. treasuries	4,000	-	-	4,000
Corporate debt securities	4,236	-	-	4,236
Total cash and cash equivalents	36,067	-	-	36,067
Marketable securities available-for-sale:				