DYNAVAX TECHNOLOGIES CORP
Form 10-Q
November 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2017

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 November 1, 2017, the registrant had outstanding 60,596,251 shares of common stock.

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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 develop, timely achieve regulatory approval for and commercialize HEPLISAV-B™, our ability to successfully develop and obtain regulatory approval of our early stage product candidates, 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 successfully commercialize our product candidates, including HEPLISAV-B, 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,” “e “predict,” “future,” or “intend,” or the negative of these 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)

| | September 30, 2017 (unaudited) | December 31, 2016 (Note 1) |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $20,096 | $24,289 |
| Marketable securities available-for-sale | 171,584 | 57,126 |
| Accounts and other receivables | 783 | 1,342 |
| Prepaid expenses and other current assets | 4,633 | 6,842 |
| Total current assets | 197,096 | 89,599 |
| Property and equipment, net | 16,622 | 17,174 |
| Goodwill | 2,213 | 1,971 |
| Restricted cash | 626 | 602 |
| Other assets | 1,270 | 334 |
| Total assets | $217,827 | $109,680 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $2,243 | $3,796 |
| Accrued research and development | 3,079 | 5,048 |
| Accrued liabilities | 7,567 | 11,192 |
| Total current liabilities | 12,889 | 20,036 |
| Other long-term liabilities | 504 | 443 |
| Total liabilities | 13,393 | 20,479 |
| Commitments and contingencies (Note 4) | | |
| Stockholders' equity: | | |
| Preferred stock: $0.001 par value; 5,000 shares authorized at September 30, 2017 and December 31, 2016; no shares issued and outstanding at September 30, 2017 and December 31, 2016 | - | - |
| Common stock: $0.001 par value; 139,000 and 69,500 shares authorized at September 30, 2017 and December 31, 2016, respectively; 60,587 and 38,599 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively | 61 | 39 |
| Additional paid-in capital | 1,085,433 | 904,957 |
| Accumulated other comprehensive loss | (1,156) | (3,624) |

| | | |
|---|---|---|
| Accumulated deficit | (879,904 ) | (812,171) |
| Total stockholders' equity | 204,434 | 89,201 |
| Total liabilities and stockholders' equity | $217,827 | $109,680 |

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Revenues: | | | | |
| Collaboration revenue | $- | $- | $- | $2,578 |
| Grant revenue | 53 | 162 | 306 | 289 |
| Service and license revenue | - | - | - | 884 |
| Total revenues | 53 | 162 | 306 | 3,751 |
| Operating expenses: | | | | |
| Research and development | 16,417 | 23,234 | 47,576 | 66,051 |
| General and administrative | 6,027 | 11,766 | 18,111 | 29,086 |
| Restructuring | - | - | 2,783 | - |
| Total operating expenses | 22,444 | 35,000 | 68,470 | 95,137 |
| Loss from operations | (22,391) | (34,838) | (68,164) | (91,386) |
| Other income (expense): | | | | |
| Interest income | 429 | 170 | 809 | 615 |
| Other (expense) income, net | (166) | (26) | (378) | 68 |
| Net loss | $(22,128) | $(34,694) | $(67,733) | $(90,703) |
| Basic and diluted net loss per share | $(0.38) | $(0.90) | $(1.36) | $(2.36) |
| Weighted average shares used to compute basic and diluted net loss per share | 57,650 | 38,512 | 49,785 | 38,493 |

Dynavax Technologies Corporation

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

| | Three Months Ended September 30, | Nine Months Ended September 30, |
|---|---|---|

| | 2017 | 2016 | 2017 | 2016 |
|---|---|---|---|---|
| Net loss | $(22,128) | $(34,694) | $(67,733) | $(90,703) |
| Other comprehensive income: | | | | |
| Unrealized gain (loss) on marketable securities available-for-sale | 14 | (61) | (31) | 7 |
| Cumulative foreign currency translation adjustments | 759 | 208 | 2,499 | 511 |
| Total other comprehensive income | 773 | 147 | 2,468 | 518 |
| Total comprehensive loss | $(21,355) | $(34,547) | $(65,265) | $(90,185) |

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2017 | 2016 |
| Operating activities | | |
| Net loss | $(67,733) | $(90,703) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 2,456 | 1,574 |
| Gain on disposal of property and equipment | (32) | - |
| Accretion of discounts and amortization of premiums on marketable securities | (104) | 155 |
| Reversal of deferred rent upon lease amendment | (209) | - |
| Cash-settled portion of stock-based compensation expense | - | 602 |
| Stock compensation expense | 10,844 | 10,030 |
| Changes in operating assets and liabilities: | | |
| Accounts and other receivables | 559 | (896) |
| Prepaid expenses and other current assets | (1,841) | 804 |
| Other assets | (936) | (99) |
| Accounts payable | (1,499) | 704 |
| Accrued liabilities and other long term liabilities | (1,274) | (286) |
| Deferred revenues | - | (2,654) |
| Net cash used in operating activities | (59,769) | (80,769) |
| Investing activities | | |
| Purchases of marketable securities | (192,684) | (122,027) |
| Proceeds from maturities of marketable securities | 78,298 | 186,670 |
| Purchases of property and equipment, net | (374) | (6,516) |
| Net cash (used in) provided by investing activities | (114,760) | 58,127 |
| Financing activities | | |
| Proceeds from issuance of common stock, net | 169,187 | - |
| Proceeds from exercise of stock options and restricted stock awards, net | 285 | 131 |
| Proceeds from Employee Stock Purchase Plan | 292 | 616 |
| Net cash provided by financing activities | 169,764 | 747 |
| Effect of exchange rate changes on cash and cash equivalents | 572 | 104 |
| Net decrease in cash and cash equivalents | (4,193) | (21,791) |
| Cash and cash equivalents at beginning of period | 24,289 | 44,812 |
| Cash and cash equivalents at end of period | $20,096 | $23,021 |
| Supplemental disclosure of cash flow information | | |
| Accrual for litigation settlement and insurance recovery (Note 4) | $- | $4,050 |
| Release of accrual for litigation settlement and insurance recovery (Note 4) | $4,050 | $- |
| Non-cash investing and financing activities: | | |
| Disposal of fully depreciated property and equipment | $- | $1,160 |
| Net change in unrealized (loss) gain on marketable securities | $(31) | $7 |
| Common stock issuance costs - cash not paid as of period end | $110 | $- |

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 clinical-stage immunotherapy company focused on leveraging the power of the body's innate and adaptive immune response through toll-like receptor ("TLR") stimulation. Our current product candidates are being investigated for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma. 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, 2016 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, 2016, 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 and development of biopharmaceutical products.

Liquidity and Financial Condition

As of September 30, 2017, we had cash, cash equivalents and marketable securities of $191.7 million. During the nine months ended September 30, 2017, we received approximately $169 million in net proceeds from our underwritten public offering in August 2017 and an At Market Issuance Sales Agreement (the "2015 ATM Agreement") and we used $59.8 million of cash in operating activities.

We have incurred significant operating losses and negative cash flows from operations since our inception. We expect spending to increase in connection with the development and manufacturing of our product candidates, particularly SD-101 and DV281, our lead investigational cancer immunotherapeutic product candidates, and to support commercialization of HEPLISAV-B, if it is approved by the U.S. Food and Drug Administration ("FDA"), as well as human clinical trials for our other product candidates and additional applications and advancement of our technology.

In order to continue these activities, we will need additional funding. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold one or more development 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 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, as well as 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

There have been no material changes in our significant accounting policies during the nine months ended September 30, 2017, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

Revenue Recognition

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may include one or more of the following elements: upfront license payments, cost reimbursement for the performance of research and development activities, milestone payments, other contingent payments, contract manufacturing service fees, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. In order to account for the multiple-element arrangements, we identify the deliverables included within the arrangement and evaluate which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

Non-refundable upfront fees received for license and collaborative agreements and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our estimated performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize revenues for costs that are reimbursed under collaborative agreements as the related research and development costs are incurred.

Contingent consideration received for the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity's performance or a specific outcome resulting from the entity's performance and (iii) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether milestones meet the criteria to be considered substantive. The conditions include: (i) work is contingent on either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of

the value of the deliverable item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we may consider our development milestones to be substantive. Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Our license and collaboration agreements with certain partners also provide for contingent payments based solely upon the performance of our partner. We expect to recognize the contingent payments as revenue upon receipt, provided that all other revenue recognition criteria have been satisfied.

Revenues from manufacturing services are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. Royalty revenue is recognized when all revenue recognition criteria have been satisfied.

Revenue from government and private agency grants is recognized as the related research expenses are incurred and to the extent that funding is approved.

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 September 30, 2017.

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.

Recent Accounting Pronouncements

Accounting Standards Update 2014-09

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Codification (“ASC”) 606, Revenue Recognition, Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods), with early application permitted. Accordingly, the updated standard is effective for the Company in the first fiscal quarter of 2018. The FASB issued supplemental adoption guidance and clarification to Accounting Standards Update (“ASU”) 2014-09 in March 2016, April 2016 and May 2016 within ASU 2016-08 "Revenue From Contracts With Customers: Principal vs. Agent Considerations," ASU 2016-10 "Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing," and ASU 2016-12 "Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients," respectively. We anticipate adoption of ASC 606 using the modified retrospective method on January 1, 2018. Based on preliminary assessment, the adoption of this guidance is not expected to materially impact the Company’s revenue recognition as there are currently no collaboration agreements where we have significant performance obligations. We will reevaluate the impact of this guidance as we enter into new revenue arrangements and will continue to review variable consideration,

potential disclosures, and the method of adoption in order to complete the evaluation of the impact on the consolidated financial statements. In addition, we will continue to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB, which may impact the current conclusions.

Accounting Standards Update 2016-02

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). 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. The ASU is effective for annual periods beginning after December 15, 2018 and interim periods therein on a modified retrospective basis, and will be effective for us starting in the first quarter of fiscal 2019 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 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 ASU is effective for annual periods beginning after December 15, 2018 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2017-04

In January 2017, the FASB issued ASU 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. We will adopt the standard effective January 1, 2020. The adoption is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2017-09

In May 2017, the FASB issued ASU 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting. The ASU provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The ASU is effective for annual periods beginning after December 15, 2017 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

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.

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.

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 |
|---|---|---|---|---|
| September 30, 2017 | | | | |
| Money market funds | $14,124 | $- | $ - | $14,124 |
| U.S. Treasuries | - | 33,649 | - | 33,649 |
| U.S. government agency securities | - | 95,731 | - | 95,731 |
| Corporate debt securities | - | 45,204 | - | 45,204 |
| Total | $14,124 | $174,584 | $ - | $188,708 |

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| December 31, 2016 | | | | |
| Money market funds | $18,981 | $- | $ - | $18,981 |
| U.S. Treasuries | - | 3,499 | - | 3,499 |
| U.S. government agency securities | - | 30,437 | - | 30,437 |
| Corporate debt securities | - | 24,941 | - | 24,941 |
| Total | $18,981 | $58,877 | $ - | $77,858 |

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 nine months ended September 30, 2017.

3. Cash, cash equivalents and marketable securities

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

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| September 30, 2017 | | | | |
| Cash and cash equivalents: | | | | |
| Cash | $ 2,972 | $ - | $ - | $ 2,972 |
| Money market funds | 14,124 | - | - | 14,124 |
| Corporate debt securities | 3,000 | - | - | 3,000 |
| Total cash and cash equivalents | 20,096 | - | - | 20,096 |
| Marketable securities available-for-sale: | | | | |
| U.S. Treasuries | 33,664 | - | (15) | 33,649 |
| U.S. government agency securities | 95,748 | - | (17) | 95,731 |
| Corporate debt securities | 42,200 | 4 | - | 42,204 |
| Total marketable securities available-for-sale | 171,612 | 4 | (32) | 171,584 |
| Total cash, cash equivalents and marketable securities | $ 191,708 | $ 4 | $ (32) | $ 191,680 |
| December 31, 2016 | | | | |
| Cash and cash equivalents: | | | | |
| Cash | $ 3,557 | $ - | $ - | $ 3,557 |
| Money market funds | 18,981 | - | - | 18,981 |
| U.S. government agency securities | 1,751 | - | - | 1,751 |
| Total cash and cash equivalents | 24,289 | - | - | 24,289 |
| Marketable securities available-for-sale: | | | | |
| U.S. Treasuries | 3,499 | - | - | 3,499 |
| U.S. government agency securities | 28,685 | 3 | (2) | 28,686 |
| Corporate debt securities | 24,938 | 5 | (2) | 24,941 |
| Total marketable securities available-for-sale | 57,122 | 8 | (4) | 57,126 |
| Total cash, cash equivalents and marketable securities | $ 81,411 | $ 8 | $ (4) | $ 81,415 |

The maturities of our marketable securities available-for-sale are as follows (in thousands):

| | September 30, 2017 | |
|---|---|---|
| | Amortized Cost | Estimated Fair Value |
| Mature in one year or less | $ 171,612 | $ 171,584 |
| Mature after one year through two years | - | - |
| | $ 171,612 | $ 171,584 |

There were no realized gains or losses from the sale of marketable securities during the nine months ended September 30, 2017 and 2016.

We have classified our entire investment portfolio as available-for-sale and available for use in current operations and accordingly have classified all investments as short-term. Available-for-sale securities are carried at fair value based on inputs that are observable, either directly or indirectly, such as quoted market prices for similar securities; 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 securities, with unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

- Whether the investment has been in a continuous realized loss position for over 12 months;
- the duration to maturity of our investments;
- our intention and ability to hold the investment to maturity and if it is not more likely than not that we will be required to sell the investment before recovery of the amortized cost bases;

- the credit rating, financial condition and near-term prospects of the issuer; and
- the type of investments made.

To date, there have been no declines in fair value that have been identified as other than temporary.

4. Commitments and Contingencies

We lease our facilities in Berkeley, California ("Berkeley Lease") and Düsseldorf, Germany ("Düsseldorf Lease") under operating leases that expire in December 2025 and March 2023, respectively. In May 2017, we amended the Berkeley Lease to extend the term of the lease to expire in December 2025 and to terminate the lease of an adjacent building. The early termination of the adjacent building's lease did not result in a termination fee as the lease rate under the amended Berkeley Lease was not above market rates. In addition, as a result of the early termination, we reversed the deferred rent liability of $0.2 million against rent expense during the nine months ended September 30, 2017. The amended Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the Berkeley Lease and Dusseldorf Lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period.

Total net rent expense related to our operating leases for the three month periods ended September 30, 2017 and 2016, was $0.7 million and $0.6 million, respectively. Total net rent expense related to our operating leases for the nine month periods ended September 30, 2017 and 2016 was $1.7 million and $1.6 million, respectively. Deferred rent was $0.5 million and $0.3 million as of September 30, 2017 and December 31, 2016, respectively.

Future minimum payments under the non-cancelable portion of our operating leases at September 30, 2017, are as follows (in thousands):

| Years ending December 31, | |
|---|---|
| 2017 (remaining) | $544 |
| 2018 | 2,349 |
| 2019 | 2,552 |
| 2020 | 2,614 |
| 2021 | 2,542 |
| Thereafter | 9,130 |
| Total | $19,731 |

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events, including a $2.5 million payment due upon approval of HEPLISAV-B. In addition, in the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators as well as clinical and commercial material manufacturers. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

From time to time, we may be involved in claims, suits, and proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, commercial claims, and other matters. Such claims, suits, and proceedings are inherently uncertain and their results cannot be predicted with certainty. Regardless of the outcome, such legal proceedings can have an adverse impact on us because of legal costs, diversion of management resources, and other factors. In addition, it is possible that a resolution of one or more such proceedings could result in substantial damages, fines, penalties or orders requiring a change in our business practices, which could in the future materially and adversely affect our financial position, financial statements, results of operations, or cash flows in a particular period.

On September 7, 2016, we entered into a Stipulation of Settlement to settle the case entitled In re Dynavax Technologies Securities Litigation filed in 2013. The settlement, which was approved by the U.S. District Court for the Northern District of California on February 6, 2017, provided for a payment of $4.1 million by us and results in a dismissal and release of all claims against all defendants, including us. The settlement was paid by our insurers in February 2017. The $4.1 million accrued liability and corresponding $4.1 million prepaid expense and other current asset reflected in our consolidated balance sheet as of December 31, 2016 were released during the first quarter of 2017.

In February 2017, we tentatively agreed to a settlement for derivative complaints filed in 2013, all of which will be paid by our insurers. We recorded an accrual of $0.9 million reflected in accrued liabilities in the consolidated balance sheet as of December 31, 2016 and do not expect any significant additional charges related to this matter. In addition, we record anticipated recoveries under existing insurance contracts when recovery is assured. We recorded a current asset in the amount of $0.9 million reflected in prepaid expenses and other current assets in the consolidated balance sheet as of December 31, 2016. Amounts recorded for contingencies can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions.

5. Collaborative Research and Development Agreements

AstraZeneca

Pursuant to a research collaboration and license agreement with AstraZeneca AB (“AstraZeneca”), as amended, we discovered and performed initial clinical development of AZD1419, a TLR9 agonist product candidate for the treatment of asthma.

In June 2016, all of our remaining performance obligations under our agreement with AstraZeneca were completed. As no further performance obligations remain, we revised the estimated period of performance of development work to June 2016 from September 2016, and recognized remaining deferred payments as revenue as of June 30, 2016. The revision of the performance period led to the recognition of an additional $0.8 million in collaboration revenue during 2016.

In November 2016, AstraZeneca initiated the Phase 2a trial of AZD1419 in asthma patients. Upon AstraZeneca’s initiation of the Phase 2a trial, we earned a milestone payment of $7.2 million, which was offset against $7.4 million in unused development funding previously advanced by AstraZeneca. We recognized the $7.2 million milestone as revenue during the fourth quarter of 2016. The remaining balance of unused development funding, net of the $7.2 million milestone payment, was $0.2 million which was paid during the first quarter of 2017. No liability related to unused development funding remains on the accompanying condensed consolidated balance sheet as of September 30, 2017.

Under the terms of the agreement, as amended, we are eligible to receive up to approximately $100 million in additional milestone payments, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization of AZD1419, we are eligible to receive tiered royalties ranging from the mid to high single-digits based on product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

The following table summarizes the revenues earned under our agreement with AstraZeneca, included as collaboration revenue in our consolidated statements of operations (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Initial payment | $ - | $ - | $ - | $ 521 |
| Subsequent payment | - | - | - | 1,953 |
| Performance of research activities | - | - | - | 104 |
| Total | $ - | $ - | $ - | $ 2,578 |

As of September 30, 2017 and December 31, 2016, no deferred revenue from the initial payment, subsequent payment or development funding payments remained.

Absent early termination, the agreement will expire when all of AstraZeneca's payment obligations expire. AstraZeneca has the right to terminate the agreement at any time upon prior written notice and either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement.

6. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and giving effect to all potentially dilutive common shares using the treasury-stock method. For purposes of this calculation, outstanding options and stock awards are considered to be potentially dilutive common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Stock options and stock awards totaling approximately 6,120,000 and 4,680,000 shares of common stock as of September 30, 2017 and 2016, respectively, were excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2017 and 2016, because the effect of their inclusion would have been anti-dilutive. For periods in which we have a net loss and no instruments are determined to be dilutive, such as the three and nine months ended September 30, 2017 and 2016, basic and diluted net loss per share are the same.

7. Common Stock

Common Stock Outstanding

As of September 30, 2017, there were 60,587,000 shares of our common stock outstanding.

In August 2017, we completed an underwritten public offering of 5,750,000 shares of our common stock and received net proceeds of approximately $80.8 million.

During 2017, we sold 15,997,202 shares of our common stock and received net cash proceeds of $88.2 million pursuant to an At the Market Agreement that terminated in June 2017. See Note 10.

8. Equity Plans and Stock-Based Compensation

Option activity under our stock-based compensation plans during the nine months ended September 30, 2017 was as follows (in thousands except per share amounts):

| | Shares Underlying Outstanding Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Term (years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| | (in thousands) | | | |
| Balance at December 31, 2016 | 3,975 | $ 21.38 | | |
| Options granted | 329 | $ 6.99 | | |
| Options exercised | (50) | $ 11.82 | | |
| Options cancelled: | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Options forfeited (unvested) | (351 | ) | $ 18.43 | | |
| Options cancelled (vested) | (217 | ) | $ 29.11 | | |
| Balance at September 30, 2017 | 3,686 | | $ 20.05 | 5.79 | $ 13,420 |
| Vested and expected to vest at September 30, 2017 | 3,671 | | $ 20.06 | 5.79 | $ 13,390 |
| Exercisable at September 30, 2017 | 2,394 | | $ 22.18 | 5.40 | $ 5,948 |

In June 2017, stockholders of the Company approved a proposal to increase the aggregate number of shares of common stock authorized for issuance under the 2011 Equity Incentive Plan, as amended, by 1,600,000 shares.

Restricted stock unit activity under our stock-based compensation plans during the nine months ended September 30, 2017 was as follows (in thousands except per share amounts):

| | Number of Shares (In thousands) | | Weighted-Average Grant-Date Fair Value |
|---|---|---|---|
| Non-vested as of December 31, 2016 | 699 | | $ 12.12 |
| Granted | 2,136 | | 4.83 |
| Vested | (171 | ) | 18.62 |
| Forfeited or expired | (221 | ) | 8.44 |
| Non-vested as of September 30, 2017 | 2,443 | | $ 5.62 |

The aggregate intrinsic value of the restricted stock units outstanding as of September 30, 2017, based on our stock price on that date, was $52.5 million. Fair value of restricted stock units is determined at the date of grant using our closing stock price.

As of September 30, 2017, approximately 21,000 shares underlying stock options and approximately 63,000 restricted stock unit awards with performance-based vesting criteria were outstanding. Vesting criteria for these restricted stock units awards with performance-based awards were not probable as of September 30, 2017.

Under our stock-based compensation plans, option awards generally vest over a three or four-year period contingent upon continuous service, and expire seven to ten years from the date of grant (or earlier upon termination of continuous service). The fair value-based measurement of each option is estimated on the date of grant using the Black-Scholes option valuation model.

The fair value-based measurements and weighted-average assumptions used in the calculations of these measurements are as follows:

| | Stock Options Three Months Ended September 30, | | Stock Options Nine Months Ended September 30, | | Employee Stock Purchase Plan Nine Months Ended September 30, | |
|---|---|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 | 2017 | 2016 |
| Weighted-average fair value | $8.11 | $8.90 | $4.73 | $9.67 | $3.05 | $7.86 |
| Risk-free interest rate | 1.9 % | 1.1 % | 1.9 % | 1.4 % | 1.0 % | 0.6 % |
| Expected life (in years) | 4.5 | 4.5 | 4.5 | 4.9 | 1.2 | 1.2 |
| Volatility | 0.9 | 0.7 | 0.9 | 0.7 | 1.0 | 0.6 |

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. The components of stock-based compensation expense were (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Research and development | $1,973 | $1,639 | $5,707 | $4,490 |
| General and administrative | 1,687 | 2,022 | 5,137 | 5,540 |
| Total | $3,660 | $3,661 | $10,844 | $10,030 |

As of September 30, 2017, the total unrecognized compensation cost related to non-vested equity awards including all awards with time-based vesting amounted to $22.0 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years. Additionally, as of September 30, 2017, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria not deemed probable of vesting amounted to $0.4 million.

Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan, as amended, (the “Purchase Plan”) provides for the purchase of common stock by eligible employees and became effective on May 28, 2014. The purchase price per share is the lesser of (i) 85% of the fair market value of the common stock on the commencement of the offer period (generally, the sixteenth day in February or August) or (ii) 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period (generally, the fifteenth day in February or August). For the nine months ended September 30, 2017, employees have acquired 84,247 shares of our common stock under the Purchase Plan and 98,227 shares of our common stock remained available for future purchases under the Purchase Plan.

9. Restructuring

In January 2017, we implemented organizational restructuring and cost reduction plans to align around our immuno-oncology business while allowing us to advance HEPLISAV-B through the FDA review and approval process. To achieve these cost reductions, we suspended manufacturing activities, commercial preparations and other long term investment related to HEPLISAV-B and reduced our global workforce by approximately 40 percent.

In the first quarter of 2017 we recorded charges of $2.8 million related to severance, other termination benefits and outplacement services. There were no additional charges during the three months ended June 30, 2017 and September 30, 2017. Of that amount, we paid $2.7 million during the nine month period ended September 30, 2017 and expect to pay the remaining amount in the fourth quarter of 2017.

The outstanding restructuring liabilities are included in accrued liabilities on the condensed consolidated balance sheets. As of September 30, 2017, the components of the liabilities were as follows (in thousands):

| | Employee Severance and Other Benefits |
|---|---|
| Restructuring charges | $ 2,783 |
| Cash payments | (2,738) |
| Balance at September 30, 2017 | $ 45 |

10. Subsequent Event

In November 2017, we entered into an At the Market sales agreement under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to, the period for which we estimate our cash resources are sufficient, the availability of additional funds, as well as those set forth under "Risk Factors" and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.

The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. This discussion should be read in conjunction with the unaudited Condensed Consolidated Financial Statements and related Notes included in Item 1 of this Quarterly Report on Form 10-Q and the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2016.

Overview

We are a clinical-stage immunotherapy company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation. Our current product candidates are being investigated for use as a vaccine for the prevention of hepatitis B and in multiple cancer indications.

HEPLISAV-B is our investigational adult hepatitis B vaccine. We resubmitted our application to market HEPLISAV-B to the FDA in February 2017 and on July 28, 2017 the FDA's Vaccines and Related Biological Products Advisory Committee ("VRBPAC") voted 12 to 1 (with 3 abstentions) that the safety data for HEPLISAV-B support licensure for immunization against hepatitis B infection in adults 18 years of age and older and provided commentary on the design of our proposed post-marketing safety study for HEPLISAV-B. A prior VRBPAC panel voted 13 to 1 that the immunogenicity data for HEPLISAV-B support approval and thus the July 2017 VRBPAC was only asked to vote on safety. The FDA is not bound by VRBPAC's recommendations regarding safety and efficacy, but takes its advice into consideration when reviewing marketing applications. Since the July VRBPAC meeting, we have worked with FDA on completing the details of the post-marketing study and other steps required for an approval decision. We have reinitiated preparations for the launch of HEPLISAV-B, including resumption of operations at our manufacturing plant in Dusseldorf, Germany, and hiring of personnel and retention of consultants and vendors for commercialization related infrastructure. HEPLISAV-B has a Prescription Drug User Fee Act ("PDUFA") date of November 9, 2017. If approved by the PDUFA date, costs related to these activities will increase in the fourth quarter of 2017 and into 2018 as we prepare for commercial launch in the first quarter of 2018.

Our lead cancer immunotherapy candidate is SD-101, a C Class CpG TLR9 agonist that was selected for characteristics optimal for treatment of cancer, including high interferon induction. Directly injecting SD-101 into a tumor site optimizes its effect by ensuring proximity to tumor-specific antigens. In animal models, SD-101 demonstrated significant anti-tumor effects at both the injected site and at distant sites. We are conducting a research and clinical program intended to assess potential efficacy of SD-101 in a range of tumors and in combination with a range of treatments, including checkpoint inhibitors and other therapies. In June 2017, we presented updated data at the American Society of Clinical Oncology Annual Meeting in patients with metastatic melanoma from the dose-escalation phase of an ongoing Phase 1/2 study of SD-101 in combination with Keytruda® (pembrolizumab), an anti-PD-1 therapy developed by Merck, known as MSD outside the United States and Canada. Results in patients naïve to anti-PD-1 or anti-PDL-1 treatment showed an overall response rate of 100 percent (seven of seven evaluable patients) and a complete response rate of 29 percent. The combination of the two drugs was generally well tolerated with no dose-limiting toxicities.

We are developing DV281, a novel investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases. In October 2017 we announced initiation of dosing in a Phase 1b study of inhaled DV281, in combination with anti-PD-1 therapy, in patients with non small cell lung cancer.

In addition to the research programs we are conducting and product candidates we are developing, we discovered and licensed to AstraZeneca AB ("AstraZeneca") an inhaled TLR agonist, AZD1419, which is being developed by AstraZeneca for the treatment of asthma pursuant to a collaboration and license agreement. AstraZeneca initiated a Phase 2a trial in 2016.

Our revenues have historically consisted of amounts earned from collaborations, grants and fees from services and licenses. Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our drug candidates. We have yet to generate any revenues from product sales and have recorded an accumulated deficit of $879.9 million as of September 30, 2017. These losses have resulted principally from costs incurred in connection with research and development activities, compensation and other related personnel costs and general corporate expenses. Research and development activities include costs of outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees. General corporate expenses include outside services such as accounting, consulting, business development, commercial, investor relations, insurance services and legal costs. Our operating results may fluctuate substantially from period to period principally as a result of the timing of preclinical activities and other activities related to clinical trials for our drug candidates.

Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, government grants and revenues from collaboration agreements to fund our operations. We expect spending to increase in connection with the development and manufacturing of our product candidates, particularly SD-101 and DV281, our lead investigational cancer immunotherapeutic product candidates, and to support commercialization of HEPLISAV-B if it is approved, as well as human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue these activities, we will need additional funding. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold one or more development programs while we seek strategic alternatives.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, assumptions and judgments described below that have the greatest potential impact on our condensed consolidated financial statements, including those related to revenue recognition, research and development activities and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Accounting assumptions and estimates are inherently uncertain and actual results may differ materially from these estimates under different assumptions or conditions. We believe that there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2017, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, grants and services and license fees. Service and license fees include revenues related to license fees and royalty payments.

The following is a summary of our revenues (in thousands, except for percentages):

| | Three Months Ended September 30, | | Increase (Decrease) from 2016 to 2017 | | Nine Months Ended September 30, | | Increase (Decrease) from 2016 to 2017 | |
|---|---|---|---|---|---|---|---|---|
| Revenues: | 2017 | 2016 | $ | % | 2017 | 2016 | $ | % |
| Collaboration revenue | $ - | $ - | $ - | - | $ - | $ 2,578 | $ (2,578) | (100)% |
| Grant revenue | 53 | 162 | (109) | (67)% | 306 | 289 | 17 | 6 % |
| Service and license revenue | - | - | - | - | - | 884 | (884) | (100)% |
| Total revenues | $ 53 | $ 162 | $ (109) | (67)% | $ 306 | $ 3,751 | $ (3,445) | (92)% |

Collaboration revenue decreased in the 2017 periods as all performance obligations under the AstraZeneca agreement were completed in 2016. Service and license revenue decreased in the 2017 periods as no manufacturing services were performed on behalf of third parties in 2017.

Research and Development Expense

Research and development expense consists of compensation and related personnel costs (which include benefits, recruitment, travel and supply costs), outside services, allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings and manufacturing of our product candidates. For the nine months ended September 30, 2017 and 2016, approximately 35% and 69%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our investigational adult hepatitis B vaccine, HEPLISAV-B. The following is a summary of our research and development expense (in thousands, except for percentages):

| Research and Development: | Three Months Ended September 30, 2017 | 2016 | Increase (Decrease) from 2016 to 2017 $ | % | Nine Months Ended September 30, 2017 | 2016 | Increase (Decrease) from 2016 to 2017 $ | % |
|---|---|---|---|---|---|---|---|---|
| Compensation and related personnel costs | $6,587 | $9,313 | $(2,726) | (29)% | $21,305 | $27,675 | $(6,370) | (23)% |
| Outside services | 5,705 | 9,653 | (3,948) | (41)% | 14,331 | 26,334 | (12,003) | (46)% |
| Facility costs | 2,152 | 2,629 | (477) | (18)% | 6,233 | 7,552 | (1,319) | (17)% |
| Non-cash stock-based compensation | 1,973 | 1,639 | 334 | 20 % | 5,707 | 4,490 | 1,217 | 27 % |
| Total research and development | $16,417 | $23,234 | $(6,817) | (29)% | $47,576 | $66,051 | $(18,475) | (28)% |

For both the three and nine months ended September 30, 2017 compared to 2016:

Compensation and related personnel costs decreased due to implementation of organizational restructuring and cost reduction plans in January 2017. Outside services expense decreased primarily due to a reduction of costs related to HEPLISAV-B clinical and manufacturing activities partially offset by increased costs relating to seeking regulatory approval for HEPLISAV-B and the ongoing development of SD-101 and earlier stage oncology programs. Non-cash stock-based compensation increased due to recognition of expense related to share-based awards granted to employees in 2016 and 2017. Facility costs, which includes an overhead allocation primarily comprised of occupancy and related expenses, decreased due to overall lower facility and related costs and a decrease in headcount.

We expect research and development spending to increase in connection with the development and manufacturing of our product candidates, particularly SD-101 and DV281, and to support a post-marketing study of HEPLISAV-B, if it is approved by the FDA.

General and Administrative Expense

General and administrative expense consists of compensation and related personnel costs; costs for outside services such as accounting, commercial development, consulting, business development and investor relations and for insurance; legal costs that include corporate and patent-related expenses; allocated facility costs and non-cash stock-based compensation.

The following is a summary of our general and administrative expense (in thousands, except for percentages):

| General and Administrative: | Three Months Ended September 30, 2017 | 2016 | Increase (Decrease) from 2016 to 2017 $ | % | Nine Months Ended September 30, 2017 | 2016 | Increase (Decrease) from 2016 to 2017 $ | % |
|---|---|---|---|---|---|---|---|---|
| Compensation and related personnel costs | $1,771 | $3,446 | $(1,675) | (49)% | $5,771 | $9,859 | $(4,088) | (41)% |
| Outside services | 1,574 | 5,439 | (3,865) | (71)% | 4,336 | 11,164 | (6,828) | (61)% |
| Legal costs | 718 | 561 | 157 | 28 % | 2,063 | 1,735 | 328 | 19 % |
| Facility costs | 277 | 298 | (21) | (7)% | 804 | 788 | 16 | 2 % |
| Non-cash stock-based compensation | 1,687 | 2,022 | (335) | (17)% | 5,137 | 5,540 | (403) | (7)% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Total general and administrative | $6,027 | $11,766 | $(5,739) | (49)% | $18,111 | $29,086 | $(10,975) | (38)% |

For both the three and nine months ended September 30, 2017 compared to 2016:

Compensation and related personnel costs and non-cash stock-based compensation decreased due to implementation of organizational restructuring and cost reduction plans in January 2017. Outside services decreased as the first nine months of 2016 included costs related to hiring of consultants for administrative and commercial development services for the anticipated commercial launch of HEPLISAV-B.

We expect general and administrative spending to increase in connection with the commercialization of HEPLISAV-B, if it is approved by the FDA.

Restructuring

In January 2017, we implemented organizational restructuring and cost reduction plans to align around our immuno-oncology business while allowing us to advance HEPLISAV-B through the FDA review and approval process. To achieve these cost reductions, we suspended manufacturing activities, commercial preparations and other longer term investment related to HEPLISAV-B and reduced our global workforce by approximately 40 percent. If HEPLISAV-B is approved, we plan to use existing stockpiled inventory to support initial commercial demand.

During the nine months ended September 30, 2017 we recorded charges of $2.8 million related to severance, other termination benefits and outplacement services. Of that amount, we paid $2.7 million during the first nine month period ended September 30, 2017 and expect to pay the remaining balance in the fourth quarter of 2017.

Interest Income and Other Income (Expense), Net

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Other (expense) income, net includes gains and losses on foreign currency transactions and disposal of property and equipment.

The following is a summary of our interest income and other (expense) income, net (in thousands, except for percentages):

| | Three Months Ended September 30, | | Increase (Decrease) from 2016 to 2017 | | | Nine Months Ended September 30, | | Increase (Decrease) from 2016 to 2017 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 2017 | 2016 | $ | % | | 2017 | 2016 | $ | % | |
| Interest income | $429 | $170 | $ 259 | 152 | % | $809 | $615 | $ 194 | 32 | % |
| Other (expense) income, net | $(166) | $(26 ) | $ 140 | 538 | % | $(378) | $68 | $ (446 ) | (656 | )% |

For both the three and nine months ended September 30, 2017 compared to 2016, interest income increased due to a higher average rate of return on our investments and a higher average investment balance. The change in other (expense) income, net is primarily due to foreign currency transactions resulting from fluctuations in the value of the Euro compared to the U.S. dollar.

Liquidity and Capital Resources

As of September 30, 2017, we had $191.7 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, government grants and revenues from collaboration agreements to fund our operations. Our funds are currently invested in short-term money market funds, U.S. Treasuries, U.S. Government agency securities and corporate debt securities.

In August 2017, we completed an underwritten public offering of 5,750,000 shares of our common stock and received net proceeds of approximately $80.8 million.

During the six months ended June 30, 2017, we sold 15,997,202 shares of our common stock and received net cash proceeds of $88.2 million pursuant to an At the Market Agreement that terminated in June 2017. In November 2017

we entered into an At the Market sales agreement under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million. The November 2017 sales agreement is more fully described in Part II – Item 5 – Other Information.

During the nine months ended September 30, 2017, we used $59.8 million of cash for our operations primarily due to our net loss of $67.7 million, of which $13.0 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, reversal of deferred rent upon lease amendment and accretion and amortization on marketable securities. We also recorded charges of $2.8 million primarily related to severance, resulting from implementation of organizational restructuring and cost reduction plans in January 2017. By comparison, during the nine months ended September 30, 2016, we used $80.8 million of cash for our operations primarily due to a net loss of $90.7 million, of which $12.4 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization and accretion and amortization on marketable securities. Cash used in our operations during the first nine months of 2017 decreased by $21.0 million. Net cash used in operating activities is impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the nine months ended September 30, 2017, net cash used in investing activities was $114.8 million compared to $58.1 million in net cash provided by investing activities for the nine months ended September 30, 2016. Cash used in investing activities during the first nine months of 2017 included $114.4 million of net purchases of marketable securities compared with $64.6 million of net proceeds of marketable securities during the first nine months of 2016. Cash used in net purchases of property and equipment decreased by $6.1 million during the first nine months of 2017 compared to the same period in 2016 primarily due to the purchase of manufacturing equipment in 2016 for HEPLISAV-B.

During the nine months ended September 30, 2017 and 2016, net cash provided by financing activities was $169.8 million and $0.7 million, respectively. Cash provided by financing activities in the first nine months of 2017 included net proceeds of $169.2 million from the issuance of common stock under our underwritten public offering in August 2017 and our 2015 ATM Agreement.

We have incurred significant operating losses and negative cash flows from operations since our inception. As of September 30, 2017, we had cash, cash equivalents and marketable securities of $191.7 million and we used $59.8 million of cash in operating activities during the first nine months of 2017. We believe that our available cash, cash equivalents and marketable securities will be sufficient to meet our projected operating requirements for at least the next 12 months from the date of this filing. We expect spending to increase in connection with the development and manufacturing of our product candidates, particularly SD-101 and DV281, our lead investigational cancer immunotherapeutic product candidates, human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue our development activities and if HEPLISAV-B is approved, we will need additional funding or a partnership to enable commercialization. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold one or more development 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, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

Contractual Obligations

We lease our facilities in Berkeley, California (“Berkeley Lease”) and Düsseldorf, Germany (“Düsseldorf Lease”) under operating leases that expire in December 2025 and March 2023, respectively. In May 2017, we amended the Berkeley Lease to extend the term of the Berkeley Lease to expire in December 2025 and to terminate the lease of an adjacent building. As a result of the amendment to the Berkeley Lease, our total future minimum lease payments at September 30, 2017 are $19.7 million.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In addition, in the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators as well as clinical and commercial material manufacturers. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by rules enacted by the Securities and Exchange Commission and, accordingly, no such arrangements are likely to have a current or future effect on our financial position.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK
Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The primary objective of our investment activities is to preserve principal and, secondarily, to maximize income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in short-term money market funds, U.S. government agency securities, U.S. Treasuries and corporate debt securities. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt or home equity loans. We do not have derivative financial instruments in our investment portfolio. To assess our risk, we calculate that if interest rates were to rise or fall from current levels by 100 basis points or by 125 basis points, the pro forma change in fair value of our net unrealized loss on investments would be $1.1 million or $1.4 million, respectively.

Due to the short duration and nature of our cash equivalents and marketable securities, as well as our intention to hold the investments to maturity, we do not expect any material loss with respect to our investment portfolio.

Foreign Currency Risk

We have certain investments outside the U.S. for the operations of Dynavax GmbH with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the condensed consolidated balance sheet as of September 30, 2017 was $1.2 million primarily related to translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of September 30, 2017, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

ITEM 4. CONTROLS AND PROCEDURES
(a) Evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”)) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance of achieving the desired control objectives.

Based on their evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report, our management, with participation of our Chief Executive Officer and our Chief Financial Officer, concluded that our disclosure controls and procedures are effective and were operating at the reasonable assurance level to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

(b) Changes in internal controls

There has been no change in our internal controls over financial reporting as defined in Rule 13a – 15(f) under the Exchange Act during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time in the ordinary course of business, Dynavax receives claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations.

On July 3, 2013, a purported stockholder derivative complaint was filed in the Superior Court of California for the County of Alameda against certain of our current and former executive officers and directors. On August 9, 2013, a substantially similar purported stockholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The derivative complaints allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that certain of our current and former executive officers and directors caused or allowed for the dissemination of materially false and misleading statements regarding our product, HEPLISAV-B. Plaintiffs are seeking unspecified monetary damages, including restitution from defendants, attorneys' fees and costs, and other relief.

On August 21, 2013, pursuant to a stipulation between the parties, the state court stayed the state derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation. On October 17, 2013, pursuant to a stipulation between the parties, the federal court stayed the federal derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation. On May 8, 2015, the parties filed a stipulation to keep the state derivative case stayed until a final resolution in the In re Dynavax Technologies Securities Litigation. On May 15, 2015, the parties also stipulated to keep the federal derivative case stayed until a final resolution in the In re Dynavax Technologies Securities Litigation. The parties entered into a stipulation of settlement which provides that the Company will enter into certain corporate governance reforms, that the Company shall cause to be paid an attorneys' fee of $925,000 to plaintiffs' counsel, and for dismissal of all claims against defendants in both the state and federal derivative actions. On August 21, 2017, the state court entered an order preliminarily approving the settlement and setting a final approval hearing date of October 17, 2017. On October 17, 2017, the state court entered the final approval order and dismissed the state court action. On October 20, 2017, the parties to the federal derivative action submitted a stipulation to the federal court to dismiss with prejudice the federal derivative action in light of the settlement. On October 24, 2017, the federal court granted the stipulation and dismissed the federal derivative action with prejudice.

On November 18, 2016, two substantially similar securities class action complaints were filed in the U.S. District Court for the Northern District of California against the Company and two of its executive officers, in Soontjens v. Dynavax Technologies Corporation et. al., ("Soontjens") and Shumake v. Dynavax Technologies Corporation et al., ("Shumake"). The Soontjens complaint alleges that between March 10, 2014 and November 11, 2016, the Company and certain of its executive officers violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, in connection with statements related to HEPLISAV-B. The Shumake complaint alleges violations of the same statutes related to the same subject, but between January 7, 2016 and November 11, 2016. The plaintiffs in both actions are seeking an unspecified amount of damages and attorneys' fees and costs. On January 17, 2017, these two actions and all related actions that subsequently may be filed in, or transferred to, the District Court were consolidated into a single case entitled In re Dynavax Technologies Securities Litigation. On January 31, 2017, the court appointed lead plaintiff and lead counsel. Lead plaintiff filed a consolidated amended complaint on March 17, 2017. Defendants' filed a motion to dismiss the consolidated amended complaint on May 1, 2017. On September 12, 2017, the District Court granted Defendants' motion to dismiss, but gave lead plaintiff an opportunity to amend his complaint. On October 3, 2017, plaintiff filed a Second Amended Complaint. Defendants' motion to dismiss is due on November 3, 2017.

On January 18, 2017, the Company was made aware of a derivative complaint that a purported stockholder of the Company intended to file in the Superior Court of California for the County of Alameda against certain of the

Company's current executive officers and directors (the "McDonald Complaint"). The McDonald Complaint was apparently filed on February 16, 2017, although the Company was not provided a copy of it until March 15, 2017. Additionally, on January 19, 2017, another purported stockholder of the Company filed a separate derivative complaint in the Superior Court of California for the County of Alameda against the same officers and directors who were named in the McDonald Complaint (the "Shumake Complaint"). Both complaints generally allege that the defendants caused or allowed the Company to issue materially misleading statements and/or omit material information regarding HEPLISAV-B and the clinical trial related thereto and otherwise mismanaged the clinical trial related to HEPLISAV-B. The complaints seek unspecified monetary damages, including restitution from defendants, corporate governance changes, attorneys' fees and costs, and other relief. Defendants were never served with the Shumake Complaint. On June 23, 2017, the plaintiff voluntarily dismissed the Shumake Complaint without prejudice. Defendants filed a demurrer in the McDonald case seeking to dismiss the lawsuit on June 19, 2017. On July 26, 2017, pursuant to a stipulation between the parties, the state court stayed the McDonald case pending the final resolution of the 2016 securities class action, In re Dynavax Technologies Securities Litigation.

The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously. However, the lawsuits are subject to inherent uncertainties, the actual costs may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies with respect to these lawsuits, but coverage could be denied or prove to be insufficient.

ITEM 1A. RISK FACTORS

Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future efforts to obtain regulatory approval, timing of development activities, commercialize approved products, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors. We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described under Part 1, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2016 that was filed with the Securities and Exchange Commission on March 13, 2017.

Risks Related to our Business

We are dependent on the success of our product candidates, especially HEPLISAV-B and SD-101, which depend on regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy, consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. Failure to obtain regulatory approvals or the delay and additional costs that would be required to obtain regulatory approvals could require us to discontinue operations.*

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA, and foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approvals for our most advanced product candidates. Approval processes in the U.S. and in other countries are uncertain, can take many years and require the expenditure of substantial resources, and we are unable to predict the timing of when regulatory approval may be received, if ever, in any jurisdiction.

For our most advanced product, HEPLISAV-B, on July 28, 2017 the FDA's Vaccines and Related Biological Products Advisory Committee ("VRBPAC") voted 12 to 1 (with 3 abstentions) that the safety data for HEPLISAV-B support licensure for immunization against hepatitis B infection in adults 18 years of age and older. A prior VRBPAC panel voted 13 to 1 that the immunogenicity data for HEPLISAV-B support approval and thus the July 2017 VRBPAC was only asked to vote on safety. The FDA is not bound by VRBPAC's recommendations regarding safety and efficacy, but takes its advice into consideration when reviewing marketing applications. HEPLISAV-B has a Prescription Drug User Fee Act ("PDUFA") date of November 9, 2017. There can be no assurance that the FDA will complete its review by that date and the review period could be further extended. In addition, unless we reach an agreement on the post-marketing study our BLA may not be approved or the study may result in a cost that restricts our ability to justify further investment in the product. Finally, despite the favorable VRBPAC vote, there can be no assurance that the FDA will not issue a Complete Response Letter ("CRL") in reconsidering our submission or otherwise further delay the review period.

In the U.S., our BLA must be approved by the FDA and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining approval of a BLA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials, including the Phase 3 results, or the development program are satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or proposed post-marketing study, or a conclusion that the data fails to meet statistical or clinical significance or safety requirements; acceptability of data generated at our clinical trial sites that are monitored by third party contract research organizations ("CROs"); or a decision by the FDA not to approve our BLA despite an advisory committee recommendation of approval; and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, we received two CRLs from the FDA previously in 2013 and 2016, respectively. We have responded to each CRL, but there can be no assurance that we have addressed the

outstanding FDA questions in a manner sufficient for approval in the U.S.

In February 2014, we announced our withdrawal of our Marketing Authorization Application ("MAA") for approval of HEPLISAV-B to the EMA, in part because the required time frame for response under the MAA procedure was not long enough to permit the collection of the necessary clinical data.

In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by the authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after completion of the trial. The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval.

Failure to receive approval or significant additional delay in obtaining an FDA approval decision by the anticipated new November 9, 2017 PDUFA date for HEPLISAV-B would have a material adverse effect on our business and results of operations, including possible termination of HEPLISAV-B development and focusing our business on our earlier stage clinical and research immuno-oncology programs. During the pendency of an FDA decision on approval, we expect to increase expenditures relating to HEPLISAV-B in anticipation of potential approval. Even if HEPLISAV-B is approved, the labeling approved by the relevant regulatory authority may negatively impact the potential commercial opportunity for this product, including restricting how and to whom we and our potential partners, if any, may market the product or the manner in which our HEPLISAV-B product may be administered and sold, which could limit the potential for entering into a partnership and commercial opportunity for such product.

Before granting product approval, the FDA must determine that our or our third party contractors' manufacturing facilities meet GMP requirements before we can use them in the commercial manufacture of our products. We and all of our contract manufacturers are required to comply with the applicable GMP regulations. Manufacturers of biological products must also comply with the FDA's general biological product standards. In addition, GMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation sufficient to ensure the quality of the approved product. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product.

The FDA may require more clinical trials for our product candidates than we currently expect or are conducting before granting regulatory approval, if regulatory approval is granted at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

Our registration and commercial timelines depend on further discussions with the FDA and corresponding foreign regulatory agencies and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- potentially limit the markets for those products;
- adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;
- cause us to abandon the development of the affected product candidate; or
- limit our ability to obtain additional financing on acceptable terms, if at all.

Clinical trials for our product candidates are expensive and time consuming, may involve combinations with other agents, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.*

Clinical trials, including post-marketing studies, to generate sufficient data to meet FDA requirements can be expensive and time consuming. With respect to HEPLISAV-B, the FDA has requested additional information regarding our proposed post-marketing study. Unless we reach an agreement on the post-marketing study, our BLA may not be approved or the study may result in a cost that restricts our ability to justify further investment in the product.

We are currently undertaking clinical trials of SD-101 and DV281, including combination studies with other oncology agents, and expect to commence clinical trials for other product candidates in our immuno-oncology pipeline in the future. Our strategy with respect to development of SD-101 and DV281 involves combination studies with other oncology agents. While we believe that this combination agent approach increases the potential for success, these clinical trials are dependent on continuing access to the other oncology agents, and for combination studies that are pursuant to a collaboration they are contingent on agreement with our combination agent study partners regarding the

use of the other agents, concurrence on a protocol and supply of clinical materials. Most of our combination agent study partners, such as Merck, are significantly larger than we are and are conducting various other combination studies with other immuno-oncology agents and collaborators. We are not certain these clinical trials will be successful, or that even if successful we would be able to reach agreement to conduct larger, more extensive clinical trials required to achieve regulatory approval for a combination product candidate regimen. In addition, results from smaller, earlier stage clinical studies may not be representative of larger, controlled clinical trials that would be required in order to obtain regulatory approval of a product candidate or a combination of product candidates.

Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain Institutional Review Board ("IRB") or regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments.

Failure by us or our CROs to conduct a clinical study in accordance with GCP standards and other applicable regulatory requirements could result in disqualification of the clinical trial from consideration in support of approval of a potential product.

We are responsible for conducting our clinical trials consistent with GCP standards and for oversight of our vendors to ensure that they comply with such standards. We depend on medical institutions and CROs to conduct our clinical trials in compliance with GCP. To the extent that they fail to comply with GCP standards, fail to enroll participants for our clinical trials, or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under GMP and other requirements in foreign countries, and may require large numbers of participants.

The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including with respect to our product candidates and those of our partners in combination agent studies:

- deficiencies in the trial design;
- deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- a product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether a product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- a product candidate or combination study may appear to be no more effective than current therapies;
- the quality or stability of a product candidate may fail to conform to acceptable standards;
- the inability to produce or obtain sufficient quantities of a product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- the inability to obtain regulatory approval to conduct a clinical trial;
- lack of adequate funding to continue a clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- the inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- the inability to retain participants who have initiated a clinical trial but may withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

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In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger populations, which often occur in later-stage clinical trials, or less favorable clinical outcomes. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management's time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by a Data Safety Monitoring Board ("DSMB"), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Any such delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

HEPLISAV-B, SD-101 and most of our earlier stage programs rely on oligonucleotide TLR agonists. Serious adverse event data relating to TLR agonists may require us to reduce the scope of or discontinue our operations.

Most of our programs, including our most advanced such as HEPLISAV-B and SD-101, incorporate TLR9 agonist CpG oligonucleotides. If any of our product candidates in clinical trials or similar products from competitors produce serious adverse event data, we may be required to delay, discontinue or modify many of our clinical trials or our clinical trial strategy. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

We have no commercialization experience, and the time and resources to reinstitute manufacturing and develop sales, marketing and distribution capabilities for HEPLISAV-B are significant. If we fail to achieve and sustain commercial success for HEPLISAV-B, either independently or with a partner, our business would be harmed.*

If our most advanced product candidate, HEPLISAV-B, is approved by the FDA, we will need to establish sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services. These efforts will require resources and time and we may not be able to achieve these capabilities or enter into these arrangements on acceptable terms and in a timely manner. In particular, significant resources may be necessary to successfully market, sell and distribute HEPLISAV-B to patients with diabetes, a group recommended by the Centers for Disease Control ("CDC") and Advisory Committee on Immunization Practices ("ACIP") to receive hepatitis B vaccination.

Factors that may inhibit our efforts to commercialize HEPLISAV-B include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market HEPLISAV-B, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues would likely be lower than if we marketed and sold our products directly.

Moreover, our pricing and reimbursement strategies with respect to our initial approval plans for HEPLISAV-B may significantly impact our ability to achieve commercial success in this potential patient population. Our ability to successfully obtain any market share and obtain profitability will be significantly dependent on our ability to invest appropriate resources in the marketing and launch of our product as well as the market's acceptance of a sufficient price for HEPLSIAV-B to achieve profitability.

In addition, although we currently believe that we have sufficient inventory of HEPLISAV-B to launch the product, since we previously reduced our manufacturing efforts with respect to HEPLISAV-B following the 2016 CRL, we will have to restart production for the manufacture HEPLISAV-B in order to continue to supply product for use following launch. There can be no assurances that our estimates regarding product necessary to launch HEPLISAV-B will be sufficient or that we can successfully manufacture sufficient quantities in compliance with GMP in order to meet market demand.

If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategy, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing HEPLISAV-B, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market HEPLISAV-B, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, certain revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture our product candidates. We rely on a limited number of suppliers to produce the oligonucleotides we require for development and commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities.*

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including 1018 and SD-101, certain antigens, the combination of the oligonucleotide and the antigens, and the formulation, fill and finish. In connection with our restructuring in January 2017, we elected to retain, but furlough, the majority of the workforce in Düsseldorf supporting the manufacture of HEPLISAV-B and utilize the existing stockpiled inventory of HEPLISAV-B to meet expected initial demand if the product is approved. If HEPLISAV-B is approved, we will need to re-activate and qualify our facility in Düsseldorf. If expected initial demand exceeds our estimates, this may result in a shortage until we can begin manufacturing. Regulatory or other limitations on our ability to re-activate our manufacturing facility, or the termination or interruption of relationships with key suppliers may result in higher cost or delays in our product development or commercialization efforts.

We have also relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our 1018 for HEPLISAV-B. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing suppliers for 1018 and SD-101, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV-B. We or other third parties may not be able to produce product at a cost, quantity and quality that are available from our current third-party suppliers or at all.

We utilize our facility in Düsseldorf to manufacture rHBsAg for HEPLISAV-B. The commercial manufacturing of biological products is a time-consuming and complex process, which must be performed in compliance with GMP regulations. There can be no assurance that the FDA will find our manufacturing controls and facilities to be acceptable to support the approval of HEPLISAV-B.

In addition, we may not be able to comply with ongoing and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit, delay or disrupt the commercialization of HEPLISAV-B or our other product candidates and could result in significant expense.

If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.

We and our third party manufacturers and suppliers are required to comply with applicable GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Manufacturers and suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, third party manufacturers and suppliers and any manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

If, as a result of the FDA's inspections, it determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after approval and commercialization.

We face uncertainty regarding coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our product candidates on commercially reasonable terms.*

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV-B, where existing products are already marketed. While in the U.S., pricing for hepatitis B vaccines is currently stable and reimbursement is favorable as private and public payors recognize the value of prophylaxis in this setting given the high costs of potential morbidity and mortality, there can be no assurance that HEPLISAV-B would launch with stable pricing and favorable reimbursement.

Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is uncertain. We will have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

We may develop, seek regulatory approval for and market our product candidates outside the U.S., requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.

We may seek to introduce certain of our product candidates, including HEPLISAV-B, in various markets outside the U.S. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial burdens on our resources and divert management's attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;

- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
    - legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

We have withdrawn our MAA for HEPLISAV-B in Europe and we may not be able to provide sufficient data or respond to other comments to our previously filed MAA sufficient to obtain regulatory approvals in Europe in a reasonable time period or at all.

Any failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications, require labeling content that diminishes market uptake of our products or limits our marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- sufficient third-party reimbursement.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.*

We may need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV-B, if approved. Failure to obtain a collaborative relationship for HEPLISAV-B, particularly in markets requiring extensive sales efforts, may significantly impair the potential for this product and we may be required to raise additional capital. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact the willingness of companies to collaborate with us;
- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and successfully manufacture and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially

invalidate our proprietary information or expose us to potential liability;

- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors as a result of these disadvantages we may be unable to generate revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat cancer and infectious and inflammatory diseases. For example, if it is approved in the future, HEPLISAV-B will compete in the U.S. with established hepatitis B vaccines marketed by Merck and GSK and outside the U.S. with vaccines from those companies and several additional established pharmaceutical companies. The field of oncology therapeutics is extremely competitive, with numerous biotechnology and pharmaceutical companies developing therapies for all of the targets we are pursuing. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates.

Existing and potential competitors may also compete with us for qualified scientific and management personnel, as well as for technology that would be advantageous to our business. Although certain of our employees have commercialization experience, as a company we currently have limited sales, marketing and distribution capabilities. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

We rely on CROs and Clinical Sites and Investigators for our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.

We rely on CROs, Clinical Sites and Investigators for our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we maintain oversight over our clinical trials and conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that clinical trials are conducted properly and that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

As we evolve from a company primarily involved in research and development to a company potentially involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.*

If we are successful in advancing HEPLISAV-B through approval and commercialization, we will need to expand our organization, including adding marketing and sales capabilities or contracting with third parties to provide these

capabilities for us. As our operations expand, we expect that we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we may not be able to manage our growth efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

If we fail to comply with the extensive requirements applicable to biopharmaceutical manufacturers and marketers under the healthcare fraud and abuse, anticorruption, privacy, transparency and other laws of the jurisdictions in which we conduct our business, we may be subject to significant liability.

Our activities, and the activities of our agents, including some contracted third parties, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. If we obtain approval for and commercialize a vaccine or other product, our interactions with physicians and others in a position to prescribe or purchase our products will be subject to a legal

regime designed to prevent healthcare fraud and abuse and off-label promotion. We also are subject to laws pertaining to transparency of transfers of value to healthcare providers; privacy and data protection; compliance with industry voluntary compliance guidelines; and prohibiting the payment of bribes. Relevant U.S. laws include:

- the Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;
- the federal, Food, Drug and Cosmetic Act and governing regulations which, among other things, prohibit off-label promotion of prescription drugs;
- laws that require transparency regarding financial arrangements with health care professionals, such as the reporting and disclosure requirements imposed by the Patient Protection and Affordable Care Act ("PPACA") and state laws;
- the federal Health Insurance Portability and Accountability Act of 1997 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Criminal Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the Foreign Corrupt Practices Act, which prohibits the payment of bribes to foreign government officials and requires that a company's books and records accurately reflect the company's transactions; and
- foreign and state law equivalents of each of the federal laws described above, such as anti-kickback and false claims laws which may apply to items or services reimbursed by state health insurance programs or any third party payor, including commercial insurers; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government.

The Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states' Attorneys General and other governmental authorities actively enforce the laws and regulations discussed above. These entities also coordinate extensively with the FDA, using legal theories that connect violations of the Federal Food, Drug and Cosmetic Act (such as off-label promotion) to the eventual submission of false claims to government healthcare programs. Prosecution of such promotion cases under the healthcare fraud and abuse laws provides the potential for private parties (qui tam relators, or "whistleblowers") to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction.

In the U.S., pharmaceutical and biotechnology companies have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, or submission of incorrect pricing information.

Violations of any of the laws described above or any other applicable governmental regulations and other similar foreign laws may subject us, our employees or our agents to criminal and/or civil sanctions, including fines, civil monetary penalties, exclusion from participation in government health care programs (including Medicare and Medicaid), and the restriction or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Additionally, whether or not we have complied with the law, an investigation into alleged unlawful conduct may cause us to incur significant expense, cause reputational damage, divert management time and attention, and otherwise adversely affect our business. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants, contractors, or other agents are or will be in compliance with all applicable U.S. or foreign laws.

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws and/or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives. In addition, our continued growth in anticipation of commercialization may result in difficulties in managing our growth and expanding our operations successfully.*

We depend on our senior executive officers, as well as key scientific and other personnel. Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, including our Chief Executive Officer. We currently have no key person insurance on any of our employees.

As we advance HEPLISAV-B to commercialization, we will need to expand our regulatory, manufacturing, administrative, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various vendors, partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to effectively manage our commercialization efforts, research efforts and clinical trials and hire, train and integrate additional regulatory, manufacturing, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company and achieving profitability.

We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited clinical trial liability and umbrella insurance coverage for our clinical trials. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.

We are involved in legal actions that are expensive and time consuming, and, if resolved adversely, could harm our business, financial condition, or results of operations.

Securities class action lawsuits against us are pending and purported stockholder derivative complaints have been brought against us. Any negative outcome from such lawsuits could result in payments of monetary damages or fines, or adversely affect our products, and accordingly our business, financial condition, or results of operations could be materially and adversely affected.

There can be no assurance that a favorable final outcome will be obtained in these cases, and defending any lawsuit is costly and can impose a significant burden on management and employees. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of monetary damages or fines not covered by insurance, or we may decide to settle lawsuits on unfavorable terms, which could adversely affect our business, financial conditions, or results of operations.

We use hazardous materials and controlled substances in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials and substances could be time consuming and costly to resolve.

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste, and controlled substances. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials, substances, and certain waste products. We believe we are currently in compliance with all government permits that are required for the storage, use and disposal of these materials and controlled substances. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials, or that controlled substances will be accidentally stored or used in violation of relevant federal, state and local requirements. In the event of an accident related to hazardous materials or a violation of requirements pertaining to controlled substances, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations, and laws and regulations pertaining to the storage and use of controlled substances.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet based systems, to support business processes as well as internal and external communications. The size and complexity of our

computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events.

Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to our Finances and Capital Requirements

We have incurred substantial losses since inception and do not have any commercial products that generate revenue.

We have experienced significant net losses in each year since our inception. Our accumulated deficit was $879.9 million as of September 30, 2017. To date, our revenue has resulted from collaboration agreements, government and private agency grants and services and license fees from our customers, including the customers of our wholly-owned subsidiary Dynavax GmbH. We anticipate that we will incur substantial additional net losses in future years as a result of our continuing investment in research and development activities and to commercialize HEPLISAV-B if it is approved by the FDA.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV-B or any of our other product candidates can be successfully developed, financed or commercialized in a timely manner based on our current plans. We will not be able to achieve approval or generate meaningful sales without significant additional resources. Our ability to generate revenue depends upon obtaining regulatory approvals for our product candidates, generating product sales and entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations, enter into a transaction that constitutes a change in control of the company or raise additional capital on less than favorable terms.

If we are unable to generate significant revenues or achieve profitability, we will require substantial additional capital to continue development of our product candidates and if our most advanced candidate, HEPLISAV-B, is approved, to commence manufacturing, sales and marketing activities.

To continue development of our product candidates and, if it is approved, to launch HEPLISAV-B, we will need significant additional funds. Addressing this need may occur through strategic alliance and licensing arrangements

and/or future public or private financings. We expect to continue to spend substantial funds in connection with:

- development, manufacturing and, if approved, commercialization of our product candidates, particularly HEPLISAV-B;
- various human clinical trials for our product candidates, including significant costs for post-marketing study obligations to maintain approval; and
- protection of our intellectual property.

The cash requirements of our current operations will be significantly impacted by the FDA decision regarding potential approval for HEPLISAV-B. Although we believe we have current funds for at least the next twelve months based on our current operational plans, cash, cash equivalents and marketable securities on hand, we expect that if HEPLISAV-B is approved by the FDA, we will require additional capital following approval, in particular if we fail to enter into a third party collaboration following approval.

Sufficient additional financing through future public or private financings, strategic alliance and licensing arrangements or other financing sources may not be available on acceptable terms or at all. Our ability to raise additional capital in the equity and debt markets 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, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. Equity or other financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

Risks Related to our Intellectual Property

We rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to maintain them would severely harm our business.

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party’s patents, which may not be possible or could require substantial funds and time.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming and delay or prevent development or commercialization of our product candidates.

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party’s proprietary rights, including a challenge as to the validity of our issued and pending claims. From time to time we are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering methods of production of rHBsAg, a component of HEPLISAV-B. In addition, the Institut Pasteur also owns or has exclusive licenses to patents relating to aspects of production of rHBsAg in the U.S. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S. To the extent we are able to commercialize HEPLISAV-B in the U.S. while these patents remain in force, Merck, GSK or their respective licensors or the Institut Pasteur may bring claims against us.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in connection with the commercialization of HEPLISAV-B or any similar product candidate, we or our collaborator could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third party. A license may require the payment of substantial fees or royalties, require a grant of a cross-license to our technology or may not be available on acceptable terms, if at all. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

One of our potential competitors, Pfizer, has issued patent claims, as well as patent claims pending with the PTO and foreign patent offices, that may be asserted against our TLR agonist products and our TLR inhibitor products. We may need to obtain a license to one or more of these patent claims held by Pfizer by paying fees or royalties or offering rights to our own proprietary technologies to commercialize one or more of our formulations other than with respect to HEPLISAV-B, for which we have a license. A license for other uses may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the U.S., legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights, we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

Risks Related to an Investment in our Common Stock

Our stock price is subject to volatility, and your investment may suffer a decline in value.

The market prices for securities of biopharmaceutical companies have in the past been, and are likely to continue in the future, to be, very volatile. The market price of our common stock is subject to substantial volatility depending upon many factors, many of which are beyond our control, including:

- progress or results of any of our clinical trials or regulatory or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and BLA filing and communications, from the FDA or other regulatory agencies, including a decision by the FDA regarding our response to its 2016 CRL for HEPLISAV-B;

- our ability to receive timely regulatory approval for our product candidates;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- our ability to raise additional capital to fund our operations;
- the success or failure of clinical trials involving our immuno-oncology product candidates and the product candidates of third party collaborators in combination studies;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;
- our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;
- our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;
- changes in government regulations, general economic conditions or industry announcements;
- issuance of new or changed securities analysts' reports or recommendations;
- actual or anticipated fluctuations in our quarterly financial and operating results; and
- the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action and shareholder derivative litigation has often been brought against a company following a decline in the market price of its securities. We are currently the target of such litigation, resulting from the decline in our common stock following the disclosure in November 2016 of the FDA's 2016 CRL related to HEPLISAV-B. We may in the future be the target of additional such litigation. Securities and shareholder derivative litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

The anti-takeover provisions of our certificate of incorporation, our bylaws, Delaware law and our share purchase rights plan may prevent or frustrate a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Provisions of our certificate of incorporation and bylaws may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting or other rights of the holders of our common stock. These provisions include:

- authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;
- limiting the persons who can call special meetings of stockholders;
- prohibiting stockholder actions by written consent;
- creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;
- providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and
- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Our share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by our Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at $0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of our common stock or (ii) the final expiration date of the rights, the effect of the rights

plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the Securities and Exchange Commission and the NASDAQ Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

Future sales of our common stock or the perception that such sales may occur in the public market could cause our stock price to fall.*

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of September 30, 2017 we had 60,587,000 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

Under our universal shelf registration statement filed by us in August 2017, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, including pursuant to our 2017 At the Market Agreement with Cowen under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150,000,000. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
None.

ITEM 5. OTHER INFORMATION
On November 3, 2017, we entered into an At the Market issuance (“ATM”) Sales Agreement (the “Agreement”) with Cowen and Company, LLC (“Cowen”) under which we may offer and sell from time to time at our sole discretion shares of our common stock having an aggregate offering price of up to $150,000,000 through Cowen as our sales agent.

Cowen may sell the common stock by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act of 1933, as amended (the “Act”), including without limitation sales made by means of ordinary brokers’ transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. Cowen will use commercially reasonable efforts to sell the

common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the Agreement. We have also provided Cowen with customary indemnification rights under the Agreement.

We are not obligated to make any sales of common stock under the Agreement. The offering of shares of our common stock pursuant to the Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Agreement, or (ii) termination of the Agreement in accordance with its terms.

The foregoing description of the Agreement is not complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which is filed herewith as Exhibit 10.1 to this report and is incorporated herein by reference. A copy of the opinion of Cooley LLP relating to the legality of the issuance and sale of the securities under the Agreement is filed as Exhibit 5.1 to this report.

ITEM 6. EXHIBITS

| Exhibit Number | Document | Incorporated by Reference Exhibit Number | Filing | Filing Date | File No. | Filed Herewith |
|---|---|---|---|---|---|---|
| 3.1 | Sixth Amended and Restated Certificate of Incorporation | 3.1 | S-1/A | February 5, 2004 | 333-109965 | |
| 3.2 | Certificate of Amendment of Amended and Restated Certificate of Incorporation | 3.1 | 8-K | January 4, 2010 | 001-34207 | |
| 3.3 | Certificate of Amendment of Amended and Restated Certificate of Incorporation | 3.1 | 8-K | January 5, 2011 | 001-34207 | |
| 3.4 | Certificate of Amendment of Amended and Restated Certificate of Incorporation | 3.6 | 8-K | May 30, 2013 | 001-34207 | |
| 3.5 | Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation | 3.1 | 8-K | November 10, 2014 | 001-34207 | |
| 3.6 | Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation | 3.1 | 8-K | June 2, 2017 | 001-34207 | |
| 3.7 | Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation | 3.1 | 8-K | July 31, 2017 | 001-34207 | |
| 3.8 | Amended and Restated Bylaws | 3.2 | S-1/A | February 5, 2004 | 333-109965 | |
| 3.9 | Form of Certificate of Designation of Series A Junior Participating Preferred Stock | 3.3 | 8-K | November 6, 2008 | 000-50577 | |
| 4.1 | Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8 and 3.9 above | | | | | |
| 4.2 | Form of Specimen Common Stock Certificate | 4.2 | S-1/A | January 16, 2004 | 333-109965 | |
| 4.3 | Rights Agreement, dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC | 4.4 | 8-K | November 6, 2008 | 000-50577 | |
| 4.4 | Form of Right Certificate | 4.5 | 8-K | November 6, 2008 | 000-50577 | |
| 4.5 | Form of Restricted Stock Unit Award Agreement under the 2004 Stock Incentive Plan | 4.6 | 10-K | March 6, 2009 | 001-34207 | |
| 5.1 | Opinion of Cooley LLP | | | | | X |
| 10.1 | Sales Agreement, dated November 3, 2017, by and between the Company and Cowen and Company, LLC | | | | | X |
| 10.2 | License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and the Company | | | | | X |

| Exhibit Number | Document | Incorporated by Reference Exhibit Number | Filing | Filing Date | File No. | Filed Herewith |
|---|---|---|---|---|---|---|
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 31.2 | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.1* | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.2* | Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |

| | |
|---|---|
| EX—101.INS | XBRL Instance Document |
| EX—101.SCH | XBRL Taxonomy Extension Schema Document |
| EX—101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| EX—101.DEF | XBRL Taxonomy Extension Definition Linkbase |
| EX—101.LAB | XBRL Taxonomy Extension Labels Linkbase Document |
| EX—101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

+ Indicates management contract, compensatory plan or arrangement

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Berkeley, State of California.

DYNAVAX TECHNOLOGIES CORPORATION

Date: November 3, 2017 By: /s/ EDDIE GRAY
Eddie Gray
Chief Executive Officer
(Principal Executive Officer)

Date: November 3, 2017 By: /s/ MICHAEL OSTRACH
Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

Date: November 3, 2017 By: /s/ DAVID JOHNSON
David Johnson
Vice President, Chief Accounting Officer
(Principal Accounting Officer)