

DYNAVAX TECHNOLOGIES CORP
Form 10-Q
May 07, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2015

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
(State or other jurisdiction of
incorporation or organization)

33-0728374

(IRS Employer

Identification No.)

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

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(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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of April 30, 2015, the registrant had outstanding 29,303,239 shares of common stock.

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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 and achieve regulatory approval for HEPLISAV-B™, our business and collaboration strategy, our intellectual property position, our product development efforts, our ability to commercialize our product candidates, 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, expectations and intentions. These statements appear throughout this Quarterly Report on Form 10-Q and can be identified by the use of forward-looking language such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Dynavax Technologies Corporation

Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	March 31, 2015 (unaudited)	December 31, 2014 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,713	\$49,511
Marketable securities available-for-sale	82,881	73,141
Accounts receivable	909	727
Prepaid expenses and other current assets	3,478	4,058
Total current assets	101,981	127,437
Property and equipment, net	7,528	7,924
Goodwill	2,032	2,277
Restricted cash	608	632
Other assets	20	20
Total assets	\$ 112,169	\$ 138,290
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,272	\$ 1,159
Accrued research and development	7,346	6,938
Accrued liabilities	3,593	6,317
Deferred revenues	5,694	5,865
Long-term debt, current portion	594	-
Total current liabilities	20,499	20,279
Deferred revenues, net of current portion	6,599	6,900
Long-term debt	8,913	9,559
Other long-term liabilities	1,085	1,070
Total liabilities	37,096	37,808
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock: \$0.001 par value		
Authorized: 5,000 shares; Issued and outstanding:		
Series B Convertible Preferred Stock — 17 shares at March 31, 2015 and 43 at December 31, 2014	-	-
Common stock: \$0.001 par value; 69,500 shares authorized at March 31, 2015 and December 31, 2014; 28,926 and 26,307 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively		
	29	26
Additional paid-in capital	697,149	695,058

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Accumulated other comprehensive loss	(2,955)	(1,669)
Accumulated deficit	(619,150)	(592,933)
Total stockholders' equity	75,073	100,482
Total liabilities and stockholders' equity	\$ 112,169	\$ 138,290

See accompanying notes.

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Dynavax Technologies Corporation

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenues:		
Collaboration revenue	\$471	\$2,373
Grant revenue	148	1,125
Service and license revenue	8	-
Total revenues	627	3,498
Operating expenses:		
Research and development	22,220	13,231
General and administrative	4,859	4,157
Unoccupied facility expense	-	77
Total operating expenses	27,079	17,465
Loss from operations	(26,452)	(13,967)
Other income (expense):		
Interest income	27	65
Interest expense	(247)	-
Other income, net	455	62
Net loss	\$(26,217)	\$(13,840)
Basic and diluted net loss per share	\$(0.97)	\$(0.53)
Weighted average number of shares used to compute basic and diluted net loss per share	27,065	26,283

Dynavax Technologies Corporation

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Net loss	\$(26,217)	\$(13,840)
Other comprehensive (loss) income:		
Unrealized gain on marketable securities available-for-sale	8	69

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Cumulative foreign currency translation adjustments	(1,294)	(9)
Total other comprehensive (loss) gain	(1,286)	60
Total comprehensive loss	\$(27,503)	\$(13,780)

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended	
	March 31,	2014
	2015	
Operating activities		
Net loss	\$ (26,217)	\$ (13,840)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	335	339
Gain on disposal of property and equipment	-	(20)
Accretion of discounts and amortization of premiums of marketable securities	171	264
Loss on lease	-	77
Accretion of debt discount related to debt financing	(51)	-
Accretion of end of term payment related to debt financing	57	-
Stock compensation expense	1,954	1,270
Changes in operating assets and liabilities:		
Accounts receivable	(182)	(103)
Prepaid expenses and other current assets	580	(948)
Restricted cash and other assets	-	266
Accounts payable	2,043	154
Accrued liabilities and other long term liabilities	(2,357)	(1,671)
Deferred revenues	(472)	3,036
Net cash used in operating activities	(24,139)	(11,176)

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Investing activities		
Purchases of marketable securities	(18,654)	(13,819)
Proceeds from maturities of marketable securities	8,750	28,949
Purchases of property and equipment, net	(618)	(398)
Net cash (used in) provided by investing activities	(10,522)	14,732
Financing activities		
Proceeds from exercise of stock options and restricted stock awards	10	-
Proceeds from exercise of warrants	26	-
Proceeds from Employee Stock Purchase Plan	103	69
Net cash provided by financing activities	139	69
Effect of exchange rate changes on cash and cash equivalents	(276)	3
Net (decrease) increase in cash and cash equivalents	(34,798)	3,628
Cash and cash equivalents at beginning of period	49,511	23,122
Cash and cash equivalents at end of period	\$ 14,713	\$ 26,750
Supplemental disclosure of cash flow information		
Non-cash investing and financing activities:		
Cash paid during the year for interest	\$ 184	\$ -
Disposal of fully depreciated property and equipment	\$ 4	\$ 274
Net change in unrealized gain on marketable securities	\$ 8	\$ 69

See accompanying notes.

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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 biopharmaceutical company that uses toll-like receptor (“TLR”) biology to discover and develop novel vaccines and therapeutics. Our development programs are organized under our three areas of focus: vaccine adjuvants, cancer immunotherapy, and autoimmune and inflammatory diseases. 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 can be 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, 2014, 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, 2014, 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 subsidiaries, Rhein Biotech GmbH and Dynavax International, B.V. Dynavax International, B.V. was dissolved in January 2015. All significant intercompany accounts and transactions, among consolidated entities, have been eliminated. We operate in one business segment: the discovery and development of biopharmaceutical products.

Liquidity and Financial Condition

We have incurred significant operating losses and negative cash flows from operations since our inception. As of March 31, 2015, we had cash, cash equivalents and marketable securities of \$97.6 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as of March 31, 2015 and anticipated revenues and funding from existing collaboration agreements.

We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B™, human clinical trials for our product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic collaboration and licensing arrangements and/or future public or private debt

and equity financings. Sufficient additional funding may not be available on acceptable terms, or at all. 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 our other development programs while we seek strategic alternatives.

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 consolidated financial statements and accompanying notes. Actual results could differ materially from these estimates.

Reverse Stock Split

All references to numbers of shares of our common stock and per-share information in the accompanying financial statements have been adjusted retroactively to reflect the Company's ten-for-one reverse stock split effected on November 7, 2014. The par value was not adjusted as a result of the reverse stock split.

Summary of Significant Accounting Policies

There have been no significant changes in our significant accounting policies during the three months ended March 31, 2015, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

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, the Company identifies the deliverables included within the arrangement and evaluates 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 cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

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 development 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 the development milestones meet the criteria to be considered substantive. The conditions include: (i) the development 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 consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

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 and assuming all other revenue recognition criteria have been met. 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 to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt, provided that collection is reasonably assured and the 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. As a result, we recognize royalty revenue 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. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

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 such arrangements 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. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior period accrued estimates for clinical trial activities through March 31, 2015.

Recent Accounting Pronouncements

Accounting Standards Update 2014-09

In May 2014, the FASB issued guidance codified in ASC 606, Revenue Recognition — Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition. On April 1, 2015, the FASB proposed deferring the effective date by one year to December 15, 2017 for annual periods beginning after that date. The FASB also proposed permitting early adoption of the standard, but not before the original effective date of December 15, 2016. The Company is currently evaluating the impact of the provisions of ASC 606 on its financial statements.

Accounting Standards Update 2014-15

In August 2014, the FASB issued guidance codified in ASC 205, Presentation of Financial Statements — Going Concern. Accounting Standards Update 2014-15 requires an entity's management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern and if those conditions exist, to make the required disclosures. The standard is effective for annual periods ending after December 15, 2016, and interim periods therein. The Company does not expect that the adoption of this standard will have a significant impact on its financial statements.

2. Fair Value Measurements

The Company measures 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 receivable, accounts payable and accrued liabilities are considered reasonable estimates of their respective fair value because of their short-term nature. The carrying amount of our long-term debt is considered a reasonable estimate of its respective fair value as it is amortized over its life using the effective interest rate.

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 as of March 31, 2015 and December 31, 2014 (in thousands):

	Level 1	Level 2	Level 3	Total
March 31, 2015				
Money market funds	\$12,568	\$-	\$ -	\$12,568
U.S. government agency securities	-	82,881	-	82,881
Total	\$12,568	\$82,881	\$ -	\$95,449

	Level 1	Level 2	Level 3	Total
December 31, 2014				
Money market funds	\$46,989	\$-	\$ -	\$46,989
U.S. government agency securities	-	73,141	-	73,141
Total	\$46,989	\$73,141	\$ -	\$120,130

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

There were no transfers between Level 1 and Level 2 during the three months ended March 31, 2015 or December 31, 2014.

3. Cash, cash equivalents and marketable securities

The following is a summary of cash, cash equivalents and marketable securities available-for-sale as of March 31, 2015 and December 31, 2014 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
March 31, 2015				
Cash and cash equivalents:				
Cash	\$2,145	\$ -	\$ -	\$2,145

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Money market funds	12,568	-	-	12,568
Total cash and cash equivalents	14,713	-	-	14,713
Marketable securities available-for-sale:				
U.S. government agency securities	82,872	12	(3)	82,881
Total marketable securities available-for-sale	82,872	12	(3)	82,881
Total cash, cash equivalents and marketable securities	\$ 97,585	\$ 12	\$ (3)	\$ 97,594
December 31, 2014				
Cash and cash equivalents:				
Cash	\$ 2,522	\$ -	\$ -	\$ 2,522
Money market funds	46,989	-	-	46,989
Total cash and cash equivalents	49,511	-	-	49,511
Marketable securities available-for-sale:				
U.S. government agency securities	73,140	11	(10)	73,141
Total marketable securities available-for-sale	73,140	11	(10)	73,141
Total cash, cash equivalents and marketable securities	\$ 122,651	\$ 11	\$ (10)	\$ 122,652

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

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	March 31, 2015	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	\$82,872	\$ 82,881
Mature after one year through two years	-	-
	\$82,872	\$ 82,881

All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity. 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 income (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 investments 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 June 2018 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the 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. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space. The sublease income is offset against our rent expense.

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded an estimated unoccupied facility expense of \$0.9 million during 2013, representing the present value of the rent payments and other costs associated with the lease, net of estimated sublease income, for the remaining life of the operating lease. During the first three quarters of 2014, we reassessed our timing and ability to sublet a portion of our facility and recorded a total unoccupied facility expense of \$0.4 million for the year ended December 31, 2014. In December 2014, we decided to utilize the unoccupied portion of the facility and began to recognize rent expense under the terms noted in the Berkeley Lease.

Total net rent expense related to our operating leases for both three month periods ended March 31, 2015 and 2014, was \$0.5 million and \$0.4 million, respectively. Deferred rent was \$0.5 million and \$0.6 million as of March 31, 2015 and December 31, 2014, respectively.

Future minimum payments under the non-cancelable portion of our operating leases at March 31, 2015, excluding payments from sublease agreements, are as follows (in thousands):

Years ending December 31,	
2015 (remaining)	\$1,623
2016	2,209
2017	2,258
2018	1,226
2019	463
Thereafter	1,506
Total	\$9,285

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 research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of March 31, 2015, under the terms of our agreements, including certain agreements relating to the ongoing Phase 3 trial of HEPLISAV-B, we are obligated to make future payments as services are provided of approximately \$16.4 million through 2016. 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 are 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 monetary damage awards, fines and penalties or orders requiring a change in our business practices, which could in the future materially and adversely affect our financial position, results of operations, or cash flows in a particular period.

5. Collaborative Research and Development Agreements

AstraZeneca

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease.

In October 2011, we amended our agreement with AstraZeneca to provide that we will conduct initial clinical development of AZD1419 and AstraZeneca agreed to fund all program expenses to cover the cost of development activities through Phase 2a. Under the terms of the amended agreement, we received an initial payment of \$3 million in 2011 to begin the clinical development program. We and AstraZeneca agreed to advance AZD1419 towards a Phase 1 clinical trial, which resulted in a development funding payment of \$6 million received in the fourth quarter of 2012.

In January 2014, we amended our agreement with AstraZeneca for the clinical development of AZD1419 whereby responsibility for conducting clinical trials was transferred from Dynavax to AstraZeneca upon completion of the Phase 1 trial. In the first quarter of 2014, we received a \$5.4 million payment that was due upon execution of this amendment.

The agreement with AstraZeneca has been amended several times, including most recently, in December 2014. Under the terms of this amendment, AstraZeneca will fully fund and Dynavax will conduct a Phase 2a safety and efficacy trial of AZD1419 in patients with asthma. In the fourth quarter of 2014, we received an \$8.0 million payment due upon execution of this amendment, to be applied towards research and development expenses incurred in conducting the Phase 2a study.

Under the terms of this agreement, as amended, we are eligible to receive up to \$100 million in additional milestone payments, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization, 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.

Revenue from the \$8.0 million payment received in the fourth quarter of 2014 was deferred and is being recognized as development work is performed, through December 2017. The \$5.4 million payment received in the first quarter of 2014 and the \$3.0 million initial payment received in 2011 were also deferred and are being recognized over the estimated remaining period of performance of development work, which is approximately 33 months.

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

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	Three Months Ended March 31, 2015 2014	
Initial payment	\$63	\$180
Subsequent payment	237	675
Performance of research activities	171	887
Total	\$471	\$1,742

As of March 31, 2015 and December 31, 2014, total deferred revenue from the initial payment, subsequent payment and development funding payments was \$12.3 million and \$12.8 million, respectively.

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.

National Institutes of Health ("NIH") and Other Funding

We have been awarded various grants from the NIH and the NIH's National Institute of Allergy and Infectious Disease ("NIAID") in order to fund research. The awards are related to specific research objectives and we earn revenue as the related research expenses are incurred. We have earned revenue during the periods ended March 31, 2015 and 2014 from the following awards:

- August 2014, NIH awarded us \$0.2 million to fund research in developing a transgenic mouse model to study human TLR9 role in disease.
- September 2013, NIH awarded us \$0.2 million to fund research in developing TLR antagonists for therapy of hepatic fibrosis and cirrhosis.
- June 2012, NIH awarded us \$0.6 million to fund research in screening for inhibitors of TLR8 for treatment of autoimmune diseases.
- May 2012, NIH awarded us \$0.4 million to fund development of TLR8 inhibitors for treatment of rheumatoid arthritis.
- August 2010, NIAID awarded us a grant to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against the hepatitis B virus. This study will be one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program. We have been awarded a total of \$1.4 million under this grant.

The following table summarizes the revenues recognized under the various arrangements with the NIH and NIAID (in thousands):

	Three Months Ended March 31, 2015 2014	
NIAID contracts	\$-	\$874
All other NIH contracts	148	251
Total grant revenue	\$148	\$1,125

6. Long-Term Debt

In December 2014, we entered into a Loan and Security Agreement (“Loan Agreement”) with Hercules Technology Growth Capital, Inc. (“Hercules”) under which we may borrow up to \$40.0 million in two tranches.

We drew down the first tranche of \$10.0 million upon closing of the transaction on December 23, 2014. The second tranche, of \$30.0 million, can be drawn at our option any time prior to September 30, 2015, but only if we have achieved certain milestones relating to the ongoing HEPLISAV-B Phase 3 study (“Milestone A”). We plan to use the proceeds received under the Loan Agreement to provide additional funding for HEPLISAV-B development and pre-commercialization activities, as a potential source of funding for clinical trials for our cancer immunotherapeutic product candidate, SD-101, and for general corporate purposes.

The interest rate for each tranche in the Loan Agreement is calculated at a rate equal to the greater of either: (i) 9.75% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.25%, and (ii) 9.75%. Payments under the Loan Agreement

are interest only until February 1, 2016 (which will be extended until August 1, 2016, if we achieve Milestone A on or before September 30, 2015, and which will be extended until February 1, 2017, if we meet certain additional HEPLISAV-B Phase 3 related milestones (“Milestone B”) on or before August 1, 2016). The interest only period will be followed by equal monthly payments of principal and interest amortized over a 30 month schedule through the scheduled maturity date on July 1, 2018 (which would be extended through January 1, 2019 if we achieve Milestone A on or before September 30, 2015 or Milestone B on or before August 1, 2016) (the “Loan Maturity Date”). The entire principal balance, including a balloon payment of principal, as applicable, will be due and payable on the Loan Maturity Date, which we recorded as a liability and debt discount at the origination of the loan.

A final payment equal to \$840,000 (if an aggregate of \$10.0 million is advanced under the Loan Agreement) or \$2,400,000 (if an aggregate of \$40.0 million is advanced under the Loan Agreement) will be due on the Loan Maturity Date, or such earlier date specified in the Loan Agreement. Our obligations under the Loan Agreement are secured by a security interest in substantially all of our assets, other than our intellectual property. Additionally, we paid a \$400,000 facility charge to Hercules. The debt issuance costs and final payment fee are being amortized and accreted, respectively, to interest expense over the term of the term loan using the effective interest method.

In addition, Hercules was granted the right, at its discretion, to participate in any Subsequent Financing in an aggregate amount of up to \$1,500,000 (that is, a maximum amount of \$1,500,000 with respect to all subsequent financings collectively) on the same terms, conditions and pricing afforded to others participating in any such Subsequent Financing.

The Loan Agreement includes customary affirmative and restrictive covenants, but does not include any financial maintenance covenants, and also includes standard events of default. At March 31, 2015, we were in compliance with all loan covenants. Upon an event of default, including a change of control, Hercules has the option to accelerate repayment of the loan, including payment of any applicable prepayment charges, which is 1.50% of the outstanding loan balance and accrued but unpaid interest.

As of March 31, 2015 and December 31, 2014, we had outstanding borrowings under the Loan Agreement of \$10.0 million, with a carrying value of \$9.5 million and \$9.6 million, respectively, net of the debt discounts. The following table summarizes our outstanding future minimum payments associated with our long-term debt as of March 31, 2015 (in thousands):

Obligations:	Total	2015	2016-2017	2018-2019	2020 and Thereafter
Principal payments on long-term debt	\$10,000	\$-	\$ 7,425	\$ 2,575	\$ -
Interest payments on long-term debt	2,159	745	1,328	86	-
Total	\$12,159	\$745	\$ 8,753	\$ 2,661	\$ -

7. 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, common stock subject to repurchase by us, outstanding options, stock awards, Series B Convertible Preferred Stock, and warrants 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, Series B Convertible Preferred Stock, warrants and stock awards totaling approximately 5,310,000 and 7,780,000 shares of common stock as of March 31, 2015 and 2014, respectively, were excluded from the calculation of diluted net loss per share for the three months ended March 31, 2015 and 2014, because the effect of their inclusion would have been anti-dilutive. For periods in which the Company has a net loss and no instruments are determined to be dilutive, such as the three months ended March 31, 2015 and 2014, basic and diluted loss per share are the same.

8. Stockholders' Equity

Option activity under our stock-based compensation plans during the three months ended March 31, 2015 was as follows (in thousands except per share amounts):

	Shares Underlying Options (in thousands)	Outstanding Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2014	1,820	\$ 27.48		
Options granted	619	16.30		
Options exercised	(2)	10.22		
Options cancelled:				
Options forfeited (unvested)	(54)	17.88		
Options cancelled (vested)	(70)	48.75		
Balance at March 31, 2015	2,313	24.06	6.94	\$ 8,276
Vested and expected to vest at March 31, 2015	2,313	24.06	6.94	\$ 8,276
Exercisable at March 31, 2015	1,126	30.20	4.55	\$ 2,298

Restricted stock unit activity under our stock-based compensation plans during the three months ended March 31, 2015 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, 2014	179	\$ 17.13
Granted	24	\$ 16.16
Vested	(3)	\$ 16.90
Forfeited or expired	(5)	\$ 18.80
Non-vested as of March 31, 2015	195	\$ 16.97

The aggregate intrinsic value of the restricted stock units outstanding as of March 31, 2015, based on our stock price on that date, was \$4.4 million.

As of March 31, 2015, approximately 75,000 shares underlying stock options and restricted stock units awards with performance-based vesting criteria were outstanding.

Under our stock-based compensation plans, option awards generally vest over a four-year period contingent upon continuous service and expire 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 March 31,		Employee Stock Purchase Plan Three Months Ended March 31,	
	2015	2014	2015	2014
Weighted-average fair value	\$ 10.85	\$ 15.70	\$ 17.32	\$ 9.20
Risk-free interest rate	1.6 %	1.8 %	0.4 %	0.2 %
Expected life (in years)	5.8	5.9	1.2	1.1
Volatility	0.8	1.4	2.4	0.9

We recognized stock-based compensation expense of \$2.0 million and \$1.3 million for the three months ended March 31, 2015 and 2014, respectively. The components of stock-based compensation expense were (in thousands):

	Three Months Ended March 31,	
	2015	2014
Research and development	\$885	\$692
General and administrative	1,069	578
Total	\$1,954	\$1,270

As of March 31, 2015, the total unrecognized compensation cost related to non-vested equity awards including all awards with time-based vesting amounted to \$19.8 million, which is expected to be recognized over the remaining weighted-average vesting period of 3.08 years. Additionally, as of March 31, 2015, 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

As of March 31, 2015, 99,600 shares were approved for issuance under the 2004 Employee Stock Purchase Plan, subject to adjustment for a stock split, or any future stock dividend or other similar change in our common stock or capital structure. As of March 31, 2015, employees have acquired 94,410 shares of our common stock under the 2004 Employee Stock Purchase Plan. As of March 31, 2015, 5,190 shares of our common stock remained available for future purchases.

In May 2014, stockholders of the Company approved the 2014 Employee Stock Purchase Plan (the "Purchase Plan"), pursuant to which the Company may issue up to 50,000 shares of its common stock to its employees. 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 fifteenth 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 fourteenth day in February or August). As of March 31, 2015, employees have acquired 7,959 shares of our common stock under the Purchase Plan and 42,041 shares of our common stock remained available for future purchases.

Warrants

As of March 31, 2015, warrants to purchase an aggregate of approximately 1,060,000 shares of our common stock were outstanding. The warrants are exercisable at a weighted average price of \$15 per share and have an expiration date of April 16, 2015. During the three months ended March 31, 2015, approximately 19,900 warrants were exercised resulting in the issuance of approximately 7,500 shares of our common stock.

Between April 1, 2015 and April 16, 2015 approximately 1,060,000 warrants were exercised resulting in the issuance of 375,000 shares of our common stock. No warrants remained outstanding as of April 16, 2015.

Preferred Stock Outstanding

As of March 31, 2015, there were 5,000,000 shares of preferred stock authorized and 17,430 shares of \$0.001 par value Series B Convertible Preferred Stock outstanding. On February 26, 2015, 26,000 shares of our Series B Convertible Preferred Stock were converted into 2,600,000 shares of common stock.

Each share of Series B Convertible Preferred Stock is convertible into 100 shares of common stock at any time at the holder's option. However, the holder is prohibited from converting the Series B Convertible Preferred Stock into shares of common stock if, as a result of such conversion, the holder and its affiliates would own more than 9.98% of

the total number of shares of common stock then issued and outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of Series B Convertible Preferred Stock will receive a payment equal to \$0.001 per share before any proceeds are distributed to the common stockholders. Shares of Series B Convertible Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Convertible Preferred Stock is required to amend the terms of the Series B Convertible Preferred Stock. Holders of Series B Convertible Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Company's board of directors. The Series B Convertible Preferred Stock ranks senior to the Company's common stock as to distributions of assets upon the Company's liquidation, dissolution or winding up, whether voluntarily or involuntarily. The Series B Convertible Preferred Stock may rank senior to, on parity with or junior to any class or series of the Company's capital stock created in the future depending upon the specific terms of such future stock issuance.

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, clinical development timing and progress, and ability to enter into strategic and licensing arrangements, 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 (“SEC”).

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, 2014.

Overview

We are a clinical-stage biopharmaceutical company that uses toll-like receptor (“TLR”) biology to discover and develop novel vaccines and therapeutics. Our development programs are organized under our three areas of focus: vaccine adjuvants, cancer immunotherapy, and autoimmune and inflammatory diseases.

Our vaccine research has focused on the use of TLR9 agonists as novel adjuvants. Our lead vaccine product candidate is HEPLISAV-B™, an investigational adult hepatitis B vaccine in Phase 3 clinical development. HEPLISAV-B combines our proprietary TLR9 agonist adjuvant and recombinant hepatitis B surface antigen (“rHBsAg”) to elicit a response after two doses. In Phase 3 trials, HEPLISAV-B demonstrated earlier protection with fewer doses than currently-licensed vaccines and an adverse event profile similar to a licensed hepatitis B vaccine. Based on those data, we submitted a Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) in 2012. In 2013, the FDA issued a Complete Response Letter (“CRL”) indicating that it would not approve the BLA because hypothetical risks of the novel adjuvant warranted a larger safety database to assess the possibility of rare autoimmune side effects. In April 2014, we initiated HBV-23, a Phase 3 study of HEPLISAV-B, in order to provide a sufficiently-sized database for the FDA to complete its review of our BLA. HBV-23 was fully enrolled in September 2014. We expect follow-up for the last patients to be complete in October 2015. In the first quarter of 2016, we intend to submit to FDA our revised BLA with answers to all questions raised and that submission is expected to be assigned a 6-month Prescription Drug User Fee Act (“PDUFA”) review period. If approved, we expect under current plans to launch HEPLISAV-B in the fourth quarter of 2016.

Through our expertise in TLR biology we have designed compounds that stimulate multiple innate mechanisms of tumor killing along with developing immune memory associated with antigens found in tumors. 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. In animal models, SD-101 demonstrated significant anti-tumor effects at both the injected site and at distant sites. We have begun a clinical program intended to assess the preliminary efficacy of SD-101 in a range of tumors and in combination with a range of treatments.

We have several clinical and preclinical programs focused on therapeutics for autoimmune and inflammatory diseases. Our most advanced inflammatory disease candidate is AZD1419, which is partnered with AstraZeneca AB (“AstraZeneca”). AZD1419 is designed to change the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms by converting the response from one primarily mediated by type-2 helper T cells (“Th2”) to type-1 helper T cells (“Th1”). A Phase 1a study of AZD1419 demonstrated its safety and tolerability in healthy subjects. We are currently working with AstraZeneca to design a Phase 2 study,

fully funded by AstraZeneca, which we expect to conduct beginning in the second half of 2015.

There is also a strong rationale for the use of TLR inhibitors to treat autoimmune diseases. These conditions arise from dysfunction in the innate immune system resulting in the body seeing its own cells and tissues as pathogens and attacking them. Various autoimmune diseases are characterized by over-stimulation of endosomal TLRs. Our lead inhibitor product candidate is DV1179, our TLR7/9 inhibitor for autoimmune or inflammatory conditions. We are assessing potential clinical applications for DV1179, including autoimmune pancreatitis, nonalcoholic steatohepatitis (“NASH”) and autoimmune skin diseases such as scleroderma and dermatomyositis.

Our revenues consist 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 \$619.2 million at March 31, 2015. 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, 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.

As of March 31, 2015, we had \$97.6 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 and revenues from collaboration agreements to fund our operations. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. 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 the HEPLISAV-B program or other 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 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 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 three months ended March 31, 2015, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, grants and service and license fees. Collaboration revenue includes amounts recognized under our collaboration agreements. Grant revenue includes amounts earned under government and private agency grants. Service and license fees include revenues related to research and development and contract manufacturing services, license fees and royalty payments.

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

Increase
(Decrease) from

Revenues:	Three Months Ended			
	March 31, 2015	2014	2014 to 2015	
			\$	%
Collaboration revenue	\$71	\$ 2,373	\$ (1,902)	(80)%
Grant revenue	148	1,125	(977)	(87)%
Service and license revenue	8	-	8	100%
Total revenues	\$27	\$ 3,498	\$ (2,871)	(82)%

Total revenues for the three months ended March 31, 2015 decreased by \$2.9 million, or 82%, as compared to the same quarter of 2014. Collaboration revenue decreased by \$1.9 million due to winding down of work performed for the Phase 1 clinical trial for AZD1419, extension of the estimated performance period for the \$5.4 million payment received from AstraZeneca in March 2014, and expiration of our collaboration agreement with GlaxoSmithKline (“GSK”) in 2014. Grant revenue decreased by \$1.0 million primarily due to a decrease in revenue recognized from our National Institute of Health’s National Institute of Allergy and Infectious Diseases contracts for adjuvant development that expired in 2014 and other programs funded by grants.

Research and Development Expense

Research and development expense consists primarily 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 as well as our regulatory filings and manufacturing of our product candidates. For the three months ended March 31, 2015 and 2014, approximately 86% and 51%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our lead product candidate, HEPLISAV-B. The remainder of our research and development expense results primarily from earlier-stage programs.

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

	Three Months Ended March 31,		Increase (Decrease) from 2014 to 2015	
Research and Development:	2015	2014	\$	%
Compensation and related personnel costs	\$7,145	\$5,654	\$1,491	26 %
Outside services	12,490	5,295	7,195	136 %
Facility costs	1,700	1,590	110	7 %
Non-cash stock-based compensation	885	692	193	28 %
Total research and development	\$22,220	\$13,231	\$8,989	68 %

Total research and development expense for the three months ended March 31, 2015, increased by \$9.0 million, or 68%, as compared to the same quarter in 2014. Outside services expense increased by \$7.2 million primarily due to the initiation of our HEPLISAV-B clinical trial in April 2014. Compensation and related personnel costs increased by \$1.5 million and non-cash stock-based compensation increased by \$0.2 million due to an overall increase in employee headcount. Facility costs increased by \$0.1 million due to repair and maintenance of our manufacturing facility.

General and Administrative Expense

General and administrative expense consists primarily of compensation and related personnel costs; outside services such as accounting, consulting, business development, investor relations and insurance services; 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):

	Three Months Ended March 31,		Increase (Decrease) from 2014 to 2015	
General and Administrative:	2015	2014	\$	%
Compensation and related personnel costs	\$1,958	\$1,483	\$475	32 %
Outside services	1,129	1,177	(48)	(4)%
Legal costs	520	756	(236)	(31)%
Facility costs	183	163	20	12 %
Non-cash stock-based compensation	1,069	578	491	85 %
Total general and administrative	\$4,859	\$4,157	\$702	17 %

General and administrative expense for the three months ended March 31, 2015, increased by \$0.7 million, or 17%, as compared to the same period in 2014. Non-cash stock-based compensation increased by \$0.5 million due to increased annual stock option grants in 2015 and a full quarter of expense related to 2014 annual option grants in the first

quarter of 2015. Compensation and related personnel costs increased by \$0.5 million due to an overall increase in employee headcount. Legal costs decreased by \$0.2 million as certain ongoing litigation expenses incurred in the first quarter of 2015 were covered under the Company's insurance.

Interest Income, Interest Expense, and Other Income

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Interest expense includes interest expense incurred on debt. Other income includes gains and losses on foreign currency transactions as well as gains and losses on disposals of property and equipment. The following is a summary of our interest income and expense and other income (in thousands, except for percentages):

	Three Months Ended March 31,		Increase (Decrease) from 2014 to 2015	
	2015	2014	\$	%
Interest income	\$27	\$ 65	\$ (38)	(58)%
Interest expense	\$(247)	\$ -	\$ (247)	(100)%
Other income	\$455	\$ 62	\$ 393	634 %

Interest income remained flat for the three months ended March 31, 2015, as compared to the same period in 2014. Interest expense for the three months ended March 31, 2015, increased by \$0.2 million compared to the same period in 2014, due to interest expense related to the loan from Hercules Technology Growth Capital, Inc. (“Hercules”) entered into in December 2014. Other income for the three months ended March 31, 2015 increased by \$0.4 million due to gains on foreign currency transactions resulting from fluctuations in the value of the Euro compared to the U.S. dollar and withholding taxes paid in Europe.

Liquidity and Capital Resources

As of March 31, 2015, we had \$97.6 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 and revenues from collaboration agreements to fund our operations. Our funds are currently invested in short-term money market funds and U.S. government agency securities.

During the three months ended March 31, 2015, we used \$24.1 million of cash for our operations primarily due to our net loss of \$26.2 million, of which \$2.5 million consisted of non-cash charges such as stock-based compensation, interest expense, depreciation and amortization and accretion and amortization on marketable securities. By comparison, during the three months ended March 31, 2014, we used \$11.2 million of cash for our operations primarily due to a net loss of \$13.8 million, of which \$1.9 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 three months of 2015 increased by \$13.0 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 three months ended March 31, 2015, cash used in investing activities was \$10.5 million compared to \$14.7 million of cash provided by investing activities for the three months ended March 31, 2014. Cash used in investing activities during the first three months of 2015 included \$9.9 million of net purchases of marketable securities versus \$15.1 million of net proceeds from maturities of marketable securities during the first three months of 2014.

During the three months ended March 31, 2015 and 2014, cash provided by financing activities was \$0.1 million. During the three months ended March 31, 2015, we received proceeds of \$0.1 million from employee purchases of our common stock under the 2014 Employee Stock Purchase Plan.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand as of March 31, 2015 and

anticipated revenues and funding from existing agreements. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private debt or 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 the HEPLISAV-B program or other development programs while we seek strategic alternatives.

Contractual Obligations

We lease our facilities in Berkeley, California (the “Berkeley Lease”), and Düsseldorf, Germany (the “Düsseldorf Lease”) under operating leases that expire in June 2018 and March 2023, respectively.

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded an estimated unoccupied facility expense of \$0.9 million during 2013, representing the present value of the rent payments and other costs

associated with the lease, net of estimated sublease income, for the remaining life of the operating lease. During the first three quarters of 2014, we reassessed our timing and ability to sublet a portion of our facility and recorded a total unoccupied facility expense of \$0.4 million for the year ended December 31, 2014. In December 2014, we decided to utilize the unoccupied portion of the facility and began to recognize rent expense under the terms noted in the operating lease agreement.

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. Also, 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 upfront fees, milestones, royalties on net sales of products originating from the licensed technologies or other payments contingent upon the occurrence of an event that cannot reasonably be estimated.

In December 2014, we entered into a Loan and Security Agreement with Hercules under which we may borrow up to \$40.0 million in two tranches. We drew down the first tranche of \$10.0 million upon closing of the transaction on December 23, 2014. The second tranche, of \$30.0 million, can be drawn at our option any time prior to September 30, 2015, but only if we have achieved certain milestones relating to the ongoing HEPLISAV-B Phase 3 study. The term loan accrues interest at equal to the greater of either (i) 9.75% plus the prime rate as reported from time to time in The Wall Street Journal minus 5.25%, and (ii) 9.75% per annum, and is secured by substantially all of our existing and after-acquired assets, excluding our intellectual property assets.

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of March 31, 2015, under the terms of our agreements, including certain agreements relating to the Phase 3 trial of HEPLISAV-B, we are obligated to make future payments as services are provided of approximately \$16.4 million through 2016. 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 SEC and, accordingly, no such arrangements are likely to have a current or future effect on our financial position.

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 and U.S. government agency 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 \$1.0 million or \$1.2 million, respectively.

Due to the short duration and conservative 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 our wholly-owned subsidiary Rhein Biotech GmbH (“Dynavax Europe”) with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of March 31, 2015 was \$3.0 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. As of March 31, 2015, 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 currently 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 SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief 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, including 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 SEC rules and forms.

(b) Changes in internal controls

There has been no change in our internal controls over financial reporting 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, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations.

On June 18, 2013, the first of two substantially similar securities class action complaints was filed in the U.S. District Court for the Northern District of California against the Company and certain of its former executive officers. The second was filed on June 26, 2013. On August 22, 2013, these two complaints 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 September 27, 2013, the Court appointed a lead plaintiff and lead counsel. On November 12, 2013, lead plaintiff filed his consolidated class action complaint (the “consolidated complaint”), which named a former director of the Company as a defendant in addition to the Company and the former executive officers identified in the two prior complaints (collectively, the “defendants”). The consolidated complaint alleged that between April 26, 2012 and June 10, 2013, the Company and certain of its executive officers and directors violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with statements related to the Company’s product, HEPLISAV-B, an investigational adult hepatitis B vaccine. The consolidated complaint sought unspecified damages, interest, attorneys’ fees, and other costs. On January 10, 2014, defendants filed a motion to dismiss the consolidated complaint.

On March 10, 2014, plaintiffs filed an opposition to the motion to dismiss the consolidated complaint. The opposition introduced a new theory of the case, so defendants permitted plaintiffs to amend their complaint. On April 7, 2014, plaintiffs filed an amended consolidated complaint (“ACC”). The ACC added a new plaintiff and several new defendants, and alleged that, between April 26, 2012 and June 10, 2013, the Company, certain of its executive officers and directors, and entities related to certain of its directors, violated Sections 10(b), 20A, and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with statements related to our product candidate, HEPLISAV-B. Specifically, the ACC alleged that the Company made fraudulent misrepresentations or omissions regarding the manufacture of HEPLISAV-B and that certain insiders unlawfully profited from such misrepresentations or omissions. The ACC sought unspecified damages, interest, attorneys’ fees, and other costs. On June 6, 2014, defendants filed a motion to dismiss the ACC. On August 8, 2014, plaintiffs filed their Opposition to that motion.

On September 10, 2014, plaintiffs filed the second amended complaint (“SAC”) to remove or correct erroneous statements attributed to confidential witnesses. The SAC retains all allegations asserted in the ACC. On October 10, 2014, defendants filed a motion to dismiss the SAC. On November 10, 2014, plaintiffs filed an opposition to the Company’s motion to dismiss the SAC. The Company filed its reply in support of the motion on December 1, 2014.

A hearing on the motion to dismiss the SAC occurred on February 20, 2015. The Court granted the motion with respect to some of the alleged misrepresentations and omissions made by the Company or certain named defendants as well as some of the insider trading claims against certain insiders and denied the motion to dismiss with respect to other alleged misrepresentations and omissions and insider trading claims. The Company filed an answer to the SAC on April 6, 2015.

Additionally, 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 former and current 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 complaint alleges 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. Plaintiff is seeking unspecified monetary damages, including restitution from defendants and 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. Both cases remain stayed.

The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously.

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, 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. There have been no 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, 2014 that was filed with the SEC on March 5, 2015.

Risks Related to our Business

The success of our product candidates, in particular HEPLISAV-B, depends 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 Good Manufacturing Practices (“GMP”) regulations are insufficient for regulatory approval. Failure 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 lead product, HEPLISAV-B, 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 is satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or a conclusion that the data fails to meet statistical or clinical significance; acceptability of data generated at our clinical trial sites that are monitored by third party contract research organizations (“CROs”); the results of an FDA or other advisory committee that may recommend against approval of our BLA or may recommend that the FDA or other agencies require, as a condition for approval, additional preclinical studies or clinical trials; and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, in our 2013 CRL, HEPLISAV-B was not approvable for the proposed indication based on insufficient patient safety data for an indication in adults 18-70 years of age without further evaluation of safety. While we are undertaking a study intended to obtain additional safety data information that we can submit to the FDA, there can be no assurance that this additional clinical study will support approval, or that the data will provide acceptable immunogenicity data for patients with diabetes. The FDA also requested additional data from our manufacturing process validation program as well as clarifying information on the manufacturing controls and facilities in our Düsseldorf manufacturing facility with respect to quality assurance of commercial product. There can be no assurance that we can successfully produce the requisite data in a timely manner or that the data will be sufficient for approval in the U.S.

In February 2014, we announced our withdrawal of our Marketing Authorization Application (“MAA”) for approval to the European Medicines Agency (“EMA”). The Day 180 List of Outstanding Issues (“LOI”) provided by the EMA indicated that, based primarily on the Good Clinical Practices (“GCP”) inspection findings, Study HBV-17 was not acceptable without additional assurances regarding the study results and because some of the findings were related to our overall GCP compliance systems, the other pivotal HEPLISAV-B studies (HBV-10 and HBV-16) were questioned by the EMA. The LOI also noted that the HEPLISAV-B safety database was considered to be too small to rule out a risk of less common serious adverse events, particularly in light of the GCP concerns. We withdrew the application, 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 delay in being able to provide the safety and manufacturing information required for approval of our BLA for HEPLISAV-B would have a material adverse effect on our business and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product may restrict to whom we and our potential partners, if any, may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

Before granting product approval, the FDA must determine that our or our third party contractor's 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 take longer than we expect or may not be completed at all, and their outcomes are uncertain.

We are currently undertaking clinical trials of HEPLISAV-B and SD-101 and expect to commence clinical trials for our other product candidates in the future. 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:

- deficiencies in the trial design;

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- 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;
- the 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 the 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;
- the product candidate may appear to be no more effective than current therapies;
- the quality or stability of the product candidate may fail to conform to acceptable standards;
- our inability to produce or obtain sufficient quantities of the 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;
- our inability to obtain regulatory approval to conduct a clinical trial;
- lack of adequate funding to continue the 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;
- our 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
- our inability to retain participants who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

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. 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 an independent Data and 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 and most of our earlier stage programs rely on oligonucleotide TLR agonists. Serious adverse event data relating to either 1018 or other TLR agonists may require us to reduce the scope of or discontinue our operations.

HEPLISAV-B incorporates 1018, a TLR9 agonist CPG oligonucleotide, and most of our research and development programs use similar oligonucleotides. If any of our product candidates in clinical trials produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. Most of our clinical product candidates contain oligonucleotides, and if a common safety risk across therapeutic areas were identified, it may hinder our ability to enter into potential collaboration arrangements or commercialize our product candidates. 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 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.

Our lead product candidate, HEPLISAV-B, if approved, would require us 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

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may not be able to enter into these arrangements on acceptable terms. In particular, significant resources may be necessary to successfully market, sell and distribute HEPLISAV-B to patients with diabetes, a group recently recommended by the CDC and ACIP to receive hepatitis B vaccination. 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.

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 oligonucleotide we will require for 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, certain antigens, the combination of the oligonucleotide and the antigens, and the formulation, fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development or commercialization efforts.

We have 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 supplier for 1018, 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 1018 at a cost, quantity and quality that are available from our current third-party supplier.

We currently 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. As part of the review of our BLA filing for HEPLISAV-B, the FDA requested additional data regarding our manufacturing process validation program as well as clarifying information on the manufacturing controls and facilities and there can be no assurance that our responses will be sufficient to meet the FDA requirements for GMP manufacturing.

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 and could result in significant expense. Moreover, depending on the level of market acceptance of HEPLISAV-B, if approved, we may not have the capacity in our existing facility to meet all of our future commercial supply needs. Our current manufacturing capacity could supply up to approximately 2 million doses of rHBsAg annually, and our ability to expand Düsseldorf manufacturing capacity by improving utilization in our existing facility, improving upon our current production yields or using a new facility will take time to implement and could result in substantial cost. In the event that demand exceeds our current capacity plans, we may experience a shortage in supply of HEPLISAV-B, which could have a material adverse effect on the success of HEPLISAV-B. Likewise, in the event that HEPLISAV-B is not approved, we would have to consider other alternatives for the facility in

Düsseldorf, including its sale or closure, and any such efforts would be complex, expensive, and time-consuming.

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 suppliers are required to comply with applicable GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. 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, these third parties and our 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.

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 commercialization.

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.

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 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 or 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;

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- 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.

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 are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. The uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to forecast changes that may affect our business. In Europe, the success of our products, in particular HEPLISAV-B, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments. Many countries in Europe have adopted legislation and increased efforts to control prices of healthcare products. We are unable to predict the impact these actions will have on our business or future prospects.

We rely on CROs to conduct 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 third parties to conduct 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 conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure 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.

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.

Notwithstanding our initial plans to launch HEPLISAV-B in the U.S., we may 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 the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this product, and our recent withdrawal of our MAA increases the risk that we may be unable to enter into a collaborative relationship prior to regulatory approval. 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 despite these disadvantages we may be unable to generate revenues and our business will be harmed.