

# DYNAVAX TECHNOLOGIES CORP

## **FORM 10-Q** (Quarterly Report)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**Form 10-Q**

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(Mark One)

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

For the quarterly period ended September 30, 2017

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-34207

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**Dynavax Technologies Corporation**

(Exact name of registrant as specified in its charter)

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**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**

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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

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**DYNAVAX TECHNOLOGIES CORPORATION**

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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, timely achieve regulatory approval for and commercialize HEPLISAV-B™, our ability to successfully develop and obtain regulatory approval of our early stage product candidates, SD-101 and DV281, and our other early stage compounds, our business, collaboration and regulatory strategy, our intellectual property position, our product development efforts, our ability to successfully commercialize our product candidates, including HEPLISAV-B, our ability to manufacture commercial supply and meet regulatory requirements, the timing of the introduction of our products, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds as well as our plans, objectives, strategies, expectations and intentions. These statements appear throughout this Quarterly Report on Form 10-Q and can be identified by the use of forward-looking language such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “future,” or “intend,” or the negative of these terms or other variations or comparable terminology.*

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

**Dynavax Technologies Corporation**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except per share amounts)

	September 30, 2017 <u>(unaudited)</u>	December 31, 2016 <u>(Note 1)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 20,096	\$ 24,289
Marketable securities available-for-sale	171,584	57,126
Accounts and other receivables	783	1,342
Prepaid expenses and other current assets	4,633	6,842
Total current assets	<u>197,096</u>	<u>89,599</u>
Property and equipment, net	16,622	17,174
Goodwill	2,213	1,971
Restricted cash	626	602
Other assets	1,270	334
Total assets	<u>\$ 217,827</u>	<u>\$ 109,680</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,243	\$ 3,796
Accrued research and development	3,079	5,048
Accrued liabilities	7,567	11,192
Total current liabilities	<u>12,889</u>	<u>20,036</u>
Other long-term liabilities	504	443
Total liabilities	<u>13,393</u>	<u>20,479</u>
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized at September 30, 2017 and December 31, 2016; no shares issued and outstanding at September 30, 2017 and December 31, 2016	-	-
Common stock: \$0.001 par value; 139,000 and 69,500 shares authorized at September 30, 2017 and December 31, 2016, respectively; 60,587 and 38,599 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	61	39
Additional paid-in capital	1,085,433	904,957
Accumulated other comprehensive loss	(1,156)	(3,624)
Accumulated deficit	(879,904)	(812,171)
Total stockholders' equity	<u>204,434</u>	<u>89,201</u>
Total liabilities and stockholders' equity	<u>\$ 217,827</u>	<u>\$ 109,680</u>

See accompanying notes.

**Dynavax Technologies Corporation**  
**Condensed Consolidated Statements of Operations**  
(In thousands, except per share amounts)  
(Unaudited)

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

**Dynavax Technologies Corporation**  
**Condensed Consolidated Statements of Comprehensive Loss**  
(In thousands)  
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2017	2016	2017	2016
<b>Net loss</b>	<u>\$ (22,128)</u>	<u>\$ (34,694)</u>	<u>\$ (67,733)</u>	<u>\$ (90,703)</u>
<b>Other comprehensive income:</b>				
Unrealized gain (loss) on marketable securities available-for-sale	14	(61)	(31)	7
Cumulative foreign currency translation adjustments	759	208	2,499	511
<b>Total other comprehensive income</b>	<u>773</u>	<u>147</u>	<u>2,468</u>	<u>518</u>
<b>Total comprehensive loss</b>	<u>\$ (21,355)</u>	<u>\$ (34,547)</u>	<u>\$ (65,265)</u>	<u>\$ (90,185)</u>

*See accompanying notes .*

**Dynavax Technologies Corporation**  
**Condensed Consolidated Statements of Cash Flows**  
(In thousands)  
(Unaudited)

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

*See accompanying notes.*

**Dynavax Technologies Corporation**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Organization and Summary of Significant Accounting Policies**

Dynavax Technologies Corporation (“we,” “our,” “us,” “Dynavax” or the “Company”), is a clinical-stage immunotherapy company focused on leveraging the power of the body’s innate and adaptive immune response through toll-like receptor (“TLR”) stimulation. Our current product candidates are being investigated for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

**Basis of Presentation**

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which we consider necessary to present fairly our financial position and the results of our operations and cash flows. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted. Interim-period results are not necessarily indicative of results of operations or cash flows to be expected for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2016 has been derived from audited financial statements at that date, but excludes disclosures required by GAAP for complete financial statements.

The unaudited condensed consolidated financial statements and these notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission (the “SEC”).

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

**Liquidity and Financial Condition**

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

We have incurred significant operating losses and negative cash flows from operations since our inception. We expect spending to increase in connection with the development and manufacturing of our product candidates, particularly SD-101 and DV281, our lead investigational cancer immunotherapeutic product candidates, and to support commercialization of HEPLISAV-B, if it is approved by the U.S. Food and Drug Administration (“FDA”), as well as human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue these activities, we will need additional funding. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold one or more development programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

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

## Use of Estimates

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

## Summary of Significant Accounting Policies

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

### *Revenue Recognition*

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

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

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

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether milestones meet the criteria to be considered substantive. The conditions include: (i) work is contingent on either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we may consider our development milestones to be substantive. Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement. All revenue recognized to date under our collaborative agreements has been nonrefundable.

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

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

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

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

### ***Research and Development Expenses and Accruals***

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

We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. Our accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties. We estimate our research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to us at that time. There have been no material adjustments to the prior period accrued estimates for clinical trial activities through September 30, 2017.

### ***Restructuring***

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

### **Recent Accounting Pronouncements**

#### ***Accounting Standards Update 2014-09***

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

#### ***Accounting Standards Update 2016-02***

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The ASU requires companies to recognize lease right-of-use assets and lease liabilities by lessees for all operating leases with lease terms greater than 12 months. The ASU is effective for annual periods beginning after December 15, 2018 and interim periods therein on a modified retrospective basis, and will be effective for us starting in the first quarter of fiscal 2019 with early adoption permitted. We are currently evaluating the impact this guidance will have on our consolidated financial statements and believe the adoption will modify our analyses and disclosures of lease agreements considering operating leases are a significant portion of the Company's total lease commitments.

### ***Accounting Standards Update 2016-18***

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force). This ASU requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. The ASU is effective for annual periods beginning after December 15, 2018 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

### ***Accounting Standards Update 2017-04***

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and other (Topic 350), which simplifies the test for goodwill impairment by eliminating a previous requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. We will adopt the standard effective January 1, 2020. The adoption is not expected to have a material impact on our consolidated financial statements.

### ***Accounting Standards Update 2017-09***

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

## **2. Fair Value Measurements**

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

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

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

## Recurring Fair Value Measurements

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

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>September 30, 2017</b>				
Money market funds	\$ 14,124	\$ -	\$ -	\$ 14,124
U.S. Treasuries	-	33,649	-	33,649
U.S. government agency securities	-	95,731	-	95,731
Corporate debt securities	-	45,204	-	45,204
Total	<u>\$ 14,124</u>	<u>\$ 174,584</u>	<u>\$ -</u>	<u>\$ 188,708</u>
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>December 31, 2016</b>				
Money market funds	\$ 18,981	\$ -	\$ -	\$ 18,981
U.S. Treasuries	-	3,499	-	3,499
U.S. government agency securities	-	30,437	-	30,437
Corporate debt securities	-	24,941	-	24,941
Total	<u>\$ 18,981</u>	<u>\$ 58,877</u>	<u>\$ -</u>	<u>\$ 77,858</u>

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

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

There were no transfers between Level 1 and Level 2 during the nine months ended September 30, 2017.

### 3. Cash, cash equivalents and marketable securities

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

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

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

	<b>September 30, 2017</b>	
	<u>Amortized Cost</u>	<u>Estimated Fair Value</u>
Mature in one year or less	\$ 171,612	\$ 171,584
Mature after one year through two years	-	-
	<u>\$ 171,612</u>	<u>\$ 171,584</u>

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

We have classified our entire investment portfolio as available-for-sale and available for use in current operations and accordingly have classified all investments as short-term. Available-for-sale securities are carried at fair value based on inputs that are observable, either directly or indirectly, such as quoted market prices for similar securities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the securities, with unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

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

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

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

#### 4. Commitments and Contingencies

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

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

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

<b>Years ending December 31,</b>	
2017 (remaining)	\$ 544
2018	2,349
2019	2,552
2020	2,614
2021	2,542
Thereafter	9,130
Total	<u>\$ 19,731</u>

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

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

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

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

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

## 5. Collaborative Research and Development Agreements

### AstraZeneca

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

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

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

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

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

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

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

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

## 6. Net Loss Per Share

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

## 7. Common Stock

### Common Stock Outstanding

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

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

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

## 8. Equity Plans and Stock-Based Compensation

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

	Shares Underlying Outstanding Options (in thousands)	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2016	3,975	\$ 21.38		
Options granted	329	\$ 6.99		
Options exercised	(50)	\$ 11.82		
Options cancelled:				
Options forfeited (unvested)	(351)	\$ 18.43		
Options cancelled (vested)	(217)	\$ 29.11		
Balance at September 30, 2017	<u>3,686</u>	<u>\$ 20.05</u>	<u>5.79</u>	<u>\$ 13,420</u>
Vested and expected to vest at September 30, 2017	<u>3,671</u>	<u>\$ 20.06</u>	<u>5.79</u>	<u>\$ 13,390</u>
Exercisable at September 30, 2017	<u>2,394</u>	<u>\$ 22.18</u>	<u>5.40</u>	<u>\$ 5,948</u>

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

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

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

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

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

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

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

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

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

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

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

### Employee Stock Purchase Plan

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

### 9. Restructuring

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

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

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

	<b>Employee Severance and Other Benefits</b>	
Restructuring charges	\$	2,783
Cash payments		(2,738)
Balance at September 30, 2017	\$	<u>45</u>

#### **10. Subsequent Event**

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

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

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

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

### Overview

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

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

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

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

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

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

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

### Critical Accounting Policies and the Use of Estimates

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

### Results of Operations

#### Revenues

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

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

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

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

#### Research and Development Expense

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

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

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

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

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

### General and Administrative Expense

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

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

	Three Months Ended September 30,		Increase (Decrease) from 2016 to 2017		Nine Months Ended September 30,		Increase (Decrease) from 2016 to 2017	
	2017	2016	\$	%	2017	2016	\$	%
<b>General and Administrative:</b>								
Compensation and related personnel costs	\$ 1,771	\$ 3,446	\$ (1,675)	(49)%	\$ 5,771	\$ 9,859	\$ (4,088)	(41)%
Outside services	1,574	5,439	(3,865)	(71)%	4,336	11,164	(6,828)	(61)%
Legal costs	718	561	157	28%	2,063	1,735	328	19%
Facility costs	277	298	(21)	(7)%	804	788	16	2%
Non-cash stock-based compensation	1,687	2,022	(335)	(17)%	5,137	5,540	(403)	(7)%
Total general and administrative	<u>\$ 6,027</u>	<u>\$ 11,766</u>	<u>\$ (5,739)</u>	<u>(49)%</u>	<u>\$ 18,111</u>	<u>\$ 29,086</u>	<u>\$ (10,975)</u>	<u>(38)%</u>

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

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

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

## Restructuring

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

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

## Interest Income and Other Income (Expense), Net

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

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

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

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

## Liquidity and Capital Resources

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

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

During the six months ended June 30, 2017, we sold 15,997,202 shares of our common stock and received net cash proceeds of \$88.2 million pursuant to an At the Market Agreement that terminated in June 2017. In November 2017 we entered into an At the Market sales agreement under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of \$150 million. The November 2017 sales agreement is more fully described in Part II – Item 5 – Other Information.

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

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

During the nine months ended September 30, 2017 and 2016, net cash provided by financing activities was \$ 169.8 million and \$0. 7 million, respectively. Cash provided by financing activities in the first nine months of 2017 included net proceeds of \$ 169 .2 million from the issuance of common stock under our underwritten public offering in August 2017 and our 2015 ATM Agreement.

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

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

### ***Contractual Obligations***

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

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

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

### ***Off-balance Sheet Arrangements***

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

### **ITEM 3. Q UANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### **Quantitative and Qualitative Disclosure About Market Risk**

##### ***Interest Rate Risk***

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

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

##### ***Foreign Currency Risk***

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

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **(a) Evaluation of disclosure controls and procedures**

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

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

#### **(b) Changes in internal controls**

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

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

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

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

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

On January 18, 2017, the Company was made aware of a derivative complaint that a purported stockholder of the Company intended to file in the Superior Court of California for the County of Alameda against certain of the Company's current executive officers and directors (the "McDonald Complaint"). The McDonald Complaint was apparently filed on February 16, 2017, although the Company was not provided a copy of it until March 15, 2017. Additionally, on January 19, 2017, another purported stockholder of the Company filed a separate derivative complaint in the Superior Court of California for the County of Alameda against the same officers and directors who were named in the McDonald Complaint (the "Shumake Complaint"). Both complaints generally allege that the defendants caused or allowed the Company to issue materially misleading statements and/or omit material information regarding HEPLISAV-B and the clinical trial related thereto and otherwise mismanaged the clinical trial related to HEPLISAV-B. The complaints seek unspecified monetary damages, including restitution from defendants, corporate governance changes, attorneys' fees and costs, and other relief. Defendants were never served with the Shumake Complaint. On June 23, 2017, the plaintiff voluntarily dismissed the Shumake Complaint without prejudice. Defendants filed a demurrer in the McDonald case seeking to dismiss the lawsuit on June 19, 2017. On July 26, 2017, pursuant to a stipulation between the parties, the state court stayed the McDonald case pending the final resolution of the 2016 securities class action, *In re Dynavax Technologies Securities Litigation*.

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

## ITEM 1A. RISK FACTORS

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

### Risks Related to our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

We are currently undertaking clinical trials of SD-101 and DV281, including combination studies with other oncology agents, and expect to commence clinical trials for other product candidates in our immuno-oncology pipeline in the future. Our strategy with respect to development of SD-101 and DV281 involves combination studies with other oncology agents. While we believe that this combination agent approach increases the potential for success, these clinical trials are dependent on continuing access to the other oncology agents, and for combination studies that are pursuant to a collaboration they are contingent on agreement with our combination agent study partners regarding the use of the other agents, concurrence on a protocol and supply of clinical materials. Most of our combination agent study partners, such as Merck, are significantly larger than we are and are conducting various other combination studies with other immuno-oncology agents and collaborators. We are not certain these clinical trials will be successful, or that even if successful we would be able to reach agreement to conduct larger, more extensive clinical trials required to achieve regulatory approval for a combination product candidate regimen. In addition, results from smaller, earlier stage clinical studies may not be representative of larger, controlled clinical trials that would be required in order to obtain regulatory approval of a product candidate or a combination of product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **Risks Related to our Finances and Capital Requirements**

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

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

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

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

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

To continue development of our product candidates and, if it is approved, to launch HEPLISAV-B, we will need significant additional funds. Addressing this need may occur through strategic alliance and licensing arrangements and/or future public or private financings. We expect to continue to spend substantial funds in connection with:

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

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

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

### **Risks Related to our Intellectual Property**

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

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

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

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

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

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

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

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

Our success depends on our ability to:

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

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

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

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

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

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

### **Risks Related to an Investment in our Common Stock**

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

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

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

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

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

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

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

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

Our share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by our Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at \$0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of our common stock or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

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

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

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

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

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

## **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

## **ITEM 5. OTHER INFORMATION**

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

Cowen may sell the common stock by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act of 1933, as amended (the “Act”), including without limitation sales made by means of ordinary brokers’ transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. Cowen will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the Agreement. We have also provided Cowen with customary indemnification rights under the Agreement.

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

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

## Incorporated by Reference

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

**Incorporated by Reference**

Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>					X
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>					X
32.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X
32.2*	<a href="#">Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X

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

+       Indicates management contract, compensatory plan or arrangement

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

**SIGNATURES**

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: November 3, 2017

By: /s/ EDDIE GRAY  
Eddie Gray  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 3, 2017

By: /s/ MICHAEL OSTRACH  
Michael Ostrach  
Chief Financial Officer  
(Principal Financial Officer)

Date: November 3, 2017

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

Glen Y. Sato  
+1 650 843 5502  
gsato@cooley.com

Via Email

November 3, 2017

Dynavax Technologies Corporation  
2929 Seventh Street, Suite 100  
Berkeley, California 94710-2753

**RE: Dynavax Technologies Corporation**

Ladies and Gentlemen:

We have acted as counsel to Dynavax Technologies Corporation, a Delaware corporation (the “**Company**”), with respect to certain matters in connection with the offering by the Company of \$150,000,000 million of shares of the Company’s common stock, par value \$0.001 per share (the “**Shares**”) (and the preferred stock purchase rights (the “**Rights**”) associated with the Common Stock to be issued pursuant to that certain Rights Agreement (the “**Rights Agreement**”), dated November 5, 2008, between the Company and Mellon Investor Services LLC, as Rights Agent (the “**Rights Agent**”), pursuant to a Registration Statement on Form S-3 (No. 333-219781) (the “**Registration Statement**”), filed with the Securities and Exchange Commission (the “**Commission**”) under the Securities Act of 1933, as amended (the “**Act**”), the prospectus included within the Registration Statement (the “**Base Prospectus**”), and the prospectus supplement dated November 3, 2017, filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations of the Act (together with the Base Prospectus, the “**Prospectus**”). The Shares are to be sold by the Company in accordance with that certain Sales Agreement, dated November 3, 2017, between the Company and Cowen and Company, LLC (as amended, the “**Agreement**”), as described in the Prospectus.

In connection with this opinion, we have examined the Registration Statement, the Prospectus, the Agreement, the Company’s Restated Certificate of Incorporation, as amended and Amended and Restated Bylaws, the Rights Agreement, each as currently in effect, and such other documents, records, certificates, memoranda and other instruments as in our judgement are necessary or appropriate to render the opinion expressed below. In rendering this opinion, we have assumed the genuineness and authenticity of all signatures on original documents; the genuineness and authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies; and the accuracy, completeness and authenticity of certificates of public officials. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not sought independently to verify such matters.

We have assumed (i) that each sale of the Shares will be duly authorized by the Board of Directors of the Company, a duly authorized committee thereof or a person or body pursuant to an authorization granted in accordance with Section 152 of the General Corporation Law of the State of Delaware (the “**DGCL**”) and (ii) that no more than 7,142,857 Shares will be sold at a price of not less than \$21.00 per share, representing the last reported sale price of the Common Stock on the NASDAQ Global Select Market on November 1, 2017. We express no opinion to the extent that future issuances of securities of the Company and/or anti-dilution adjustments to outstanding securities of the Company cause the number of shares of Common Stock outstanding or issuable upon conversion or exercise of outstanding securities of the Company to exceed the number of Shares then issuable under the Agreement.



**November 3, 2017**

Page Two

We have also assumed that the Rights Agreement has been duly authorized, executed and delivered by the Rights Agent and that the members of the Board of Directors of the Company have acted in a manner consistent with their fiduciary duties as required under applicable law in adopting the Rights Agreement. This opinion does not address whether the Board of Directors of the Company may be required to redeem or terminate, or take other action with respect to, the Rights in the future based on the facts and circumstances then existing. Moreover, this opinion addresses corporate procedures in connection with the issuance of the Rights associated with the Shares, and not any particular provision of the Rights or the Rights Agreement. It should be understood that it is not settled whether the invalidity of any particular provision of a rights agreement or purchase rights issued thereunder would invalidate such rights in their entirety.

Our opinion herein is expressed solely with respect to the DGCL. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares and the associated Rights, when sold and issued against payment therefor in accordance with the Agreement, the Registration Statement and the Prospectus, will be validly issued, and the Shares will be fully paid and nonassessable.

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to a Quarterly Report on Form 10-Q to be filed with the Commission for incorporation by reference into the Registration Statement.

Very truly yours,

**COOLEY LLP**

By: /s/ Glen Y. Sato  
Glen Y. Sato

152964531 v3

Cooley LLP 3175 Hanover Street Palo Alto, CA 94304-1130  
t: (650) 843-5000 f: (650) 849-7400 cooley.com

## DYNAVAX TECHNOLOGIES CORPORATION

Common Stock  
(par value \$0.001 per share)

**SALES AGREEMENT**

November 3, 2017

Cowen and Company, LLC  
599 Lexington Avenue  
New York, NY 10022

Ladies and Gentlemen:

Dynavax Technologies Corporation, a Delaware corporation (the “**Company**”), confirms its agreement (this “**Agreement**”) with Cowen and Company, LLC (“**Cowen**”), as follows:

1. **Issuance and Sale of Shares**. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through Cowen, acting as agent and/or principal, shares (the “**Placement Shares**”) of the Company’s common stock, par value \$0.001 per share (the “**Common Stock**”), having an aggregate offering price of up to \$150,000,000.00, *provided, however*, that in no event shall the Company issue or sell through Cowen such number of Placement Shares that (a) would cause the Company not to satisfy the eligibility requirements for use of Form S-3, (b) exceeds the number of shares of Common Stock registered on the effective Registration Statement (as defined below) pursuant to which the offering is being made, or (c) exceeds the number of authorized but unissued shares of Common Stock (the lesser of (a), (b) and (c), the “**Maximum Amount**”). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this **Section 1** on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and Cowen shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through Cowen will be effected pursuant to the Registration Statement (as defined below) filed by the Company and declared effective by the Securities and Exchange Commission (the “**Commission**”), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Common Stock.

The Company has filed in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the “**Securities Act**”), with the Commission a registration statement on Form S-3, including a base prospectus, relating to certain securities, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the “**Exchange Act**”).

The Company has prepared a prospectus supplement to the base prospectus included as part of such registration statement specifically relating to the Placement Shares (the “**Prospectus Supplement**”). The Company will furnish to Cowen, for use by Cowen, copies of the base prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, , including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule

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424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act, is herein called the “**Registration Statement**.” The base prospectus, including all documents incorporated or deemed incorporated therein by reference to the extent such information has not been superseded or modified in accordance with Rule 412 under the Securities Act (as qualified by Rule 430(g) under the Securities Act), included in the Registration Statement, as supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any “issuer free writing prospectus,” as defined in Rule 433 of the Securities Act (“**Rule 433**”), relating to the Common Stock that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g), is herein called the “**Prospectus**.” Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated or deemed incorporated by reference therein, and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein (the “**Incorporated Documents**”). For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to either the Electronic Data Gathering Analysis and Retrieval System or Interactive Data Electronic Applications (collectively “**IDEA**”).

2. **Placements.** Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a “**Placement**”), it will notify Cowen by email notice (or other method mutually agreed to in writing by the parties) of the number of Placement Shares, the time period during which such sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one day and any minimum price below which sales must not be made (a “**Placement Notice**”), the form of which is attached hereto as **Schedule 1**. The Placement Notice shall originate from any of the individuals from the Company set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from Cowen set forth on **Schedule 2**, as such **Schedule 2** may be amended from time to time. The Placement Notice shall be immediately effective upon receipt by Cowen unless and until (i) in accordance with the notice requirements set forth in Section 4, Cowen declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) in accordance with the notice requirements set forth in Section 4, the Company suspends or terminates the Placement Notice, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) the Agreement has been terminated under the provisions of **Section 11**. The amount of any discount, commission or other compensation to be paid by the Company to Cowen in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in **Schedule 3**. It is expressly acknowledged and agreed that neither the Company nor Cowen will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to Cowen and Cowen does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of Sections 2 or 3 of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. **Sale of Placement Shares by Cowen.** Subject to the terms and conditions herein set forth, for the period specified in the Placement Notice, Cowen will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Stock Market, Inc. (“**Nasdaq**”) to sell such Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. Cowen

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will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to Cowen pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by Cowen (as set forth in Section 5(a)) from the gross proceeds that it receives from such sales. Subject to the terms of a Placement Notice, Cowen may sell Placement Shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act, including without limitation sales made through Nasdaq, on any other existing trading market for the Common Stock or to or through a market maker. If expressly authorized by the Company in a Placement Notice, Cowen may also sell Placement Shares by any other method permitted by law, including but not limited to negotiated transactions. The Company acknowledges and agrees that (i) there can be no assurance that Cowen will be successful in selling Placement Shares, and (ii) Cowen will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by Cowen to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares as required under this Section 3. For the purposes hereof, “**Trading Day**” means any day on which the Company’s Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

#### 4. Suspension of Sales.

(a) The Company or Cowen may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 2), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or impair either party’s obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the Parties agrees that no such notice under this Section 4 shall be effective against the other unless it is made to one of the individuals named on Schedule 2 hereto, as such schedule may be amended from time to time.

(b) Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and Cowen agree that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares, and (iii) Cowen shall not be obligated to sell or offer to sell any Placement Shares.

(c) If either Cowen or the Company has reason to believe that the exemptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are not satisfied with respect to the Common Stock, it shall promptly notify the other party, and Cowen may, at its sole discretion, suspend sales of the Placement Shares under this Agreement. Cowen shall calculate on a weekly basis the average daily trading volume (as defined by Rule 100 of Regulation M under the Exchange Act) of the Common Stock.

#### 5. Settlement.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2<sup>nd</sup>) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a “**Settlement Date**” and the first such settlement date, the “**First Delivery Date**”). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement

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Shares sold (the “**Net Proceeds**”) will be equal to the aggregate sales price received by Cowen , after deduction for (i) Cowen ’s commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to Cowen hereunder pursuant to Section 7(g) (Expenses) hereof, less any reimbursements payable by Cowen to the Company herewith, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares . On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting Cowen’s or its designee’s account (provided Cowen shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form. On each Settlement Date, Cowen will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. Cowen will be responsible for providing DWAC instructions or instructions for delivery by other means with regard to the transfer of Placement Shares being sold. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date (other than as a result of a failure by Cowen to provide instructions for delivery), the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 10(a) (Indemnification and Contribution) hereto, it will (i) hold Cowen harmless against any loss, claim, damage, or reasonable, documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent and (ii) pay to Cowen (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(c) Limitations on Offering Size . Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Placement Shares under this Agreement, the Maximum Amount, (B) the amount available for offer and sale under the currently effective registration statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Company’s board of directors, a duly authorized committee thereof or a duly authorized officer, and notified to Cowen in writing. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Company’s board of directors, a duly authorized committee thereof or a duly authorized officer, and notified to Cowen in writing.

6. Representations and Warranties of the Company . Except as disclosed in the Registration Statement, the Prospectus or any prospectus supplement (including the Incorporated Documents), the Company represents and warrants to, and agrees with Cowen that, unless such representation, warranty or agreement specifies otherwise, as of the date of this Agreement and as of each Applicable Time (as defined in Section 22(a)):

(a) Compliance with Registration Requirements . The Registration Statement has been filed and will be declared effective by the Commission under the Securities Act prior to the issuance of any Placement Notices by the Company. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the Company’s knowledge, are contemplated or threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act. As of the date hereof, the sale of the Placement Shares hereunder meets the requirements or General Instruction I.B.1 of Form S-3.

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(b) No Misstatement or Omission. The Registration Statement, when it became or becomes effective, and the Prospectus, and any amendment or supplement thereto, on the date of such Prospectus or amendment or supplement, conformed and will conform to the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became effective, complied and, as of each of the Settlement Dates, if any, will comply in all material respects with the Securities Act and did not and, as of each of the Settlement Dates, if any, will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of each Applicable Time, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to Cowen furnished to the Company in writing by Cowen expressly for use therein. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Company is not an “ineligible issuer” in connection with the offering of the Placement Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Each free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Except for the Issuer Free Writing Prospectuses (as defined below), if any, and electronic road shows, if any, furnished to Cowen before first use, the Company has not prepared, used or referred to, and will not, without Cowen’s prior consent, prepare, use or refer to, any Issuer Free Writing Prospectus.

(c) Offering Materials Furnished to Cowen. If so requested by Cowen, the Company will deliver to Cowen one manually signed copy of the Registration Statement (including exhibits thereto), each amendment thereto and each consent and certificate of experts filed as a part thereof.

(d) Distribution of Offering Material By the Company. The Company has not distributed and will not distribute, prior to the completion of Cowen’s distribution of the Placement Shares pursuant to this Agreement, any offering material in connection with the offering and sale of the Placement Shares other than the Registration Statement, Prospectus and any Issuer Free-Writing Prospectus reviewed and consented to by Cowen.

(e) The Sales Agreement. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable against the Company in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(f) Authorization of the Common Stock. The Placement Shares, when issued and delivered, will be duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be duly authorized, validly issued, fully paid and nonassessable, and the issuance and sale of the Placement Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Placement Shares.

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(g) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(h) No Material Adverse Change. Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement and Prospectus: (i) there has been no material adverse change, or any development that could reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, operations or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change is called a “**Material Adverse Change**”); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, not in the ordinary course of business nor entered into any material transaction or agreement not in the ordinary course of business; and (iii) there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for regular quarterly dividends publicly announced by the Company or dividends paid to the Company or other subsidiaries, by any of its subsidiaries on any class of capital stock or repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(i) Independent Accountants. Ernst & Young LLP, who have expressed their opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) and supporting schedules filed with the Commission or incorporated by reference as a part of the Registration Statement and included in the Prospectus, are (i) an independent registered public accounting firm as required by the Securities Act and the Exchange Act, (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the Public Company Accounting Oversight Board (“**PCAOB**”) whose registration has not been suspended or revoked and, to the Company’s knowledge, who has not requested such registration to be withdrawn.

(j) Preparation of the Financial Statements. The financial statements filed with the Commission as a part of or incorporated within the Registration Statement and included in the Prospectus present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of and at the dates indicated and the results of their operations and cash flows for the periods specified. The supporting schedules included in or incorporated in the Registration Statement present fairly, in all material respects, the information required to be stated therein. Such financial statements and supporting schedules have been prepared in conformity with generally accepted accounting principles as applied in the United States applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in or incorporated in the Registration Statement or Prospectus. The financial data set forth or incorporated in the Registration Statement and Prospectus under the caption “Ratio of Earnings to Fixed Charges” fairly present, in all material respects, the information set forth therein on a basis consistent with that of the audited financial statements contained, incorporated or deemed to be incorporated in the Registration Statement.

(k) XBRL. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the each Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission’s rules and guidelines applicable thereto.

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(l) Company's Accounting System. The Company maintains a system of internal accounting controls designed to provide sufficient assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles as applied in the United States and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as has previously been disclosed to Cowen, the Company is unaware of any significant deficiencies or material weakness in the Company's internal control over financial reporting (whether or not remediated) as of December 31, 2016 or at any time since such date; since December 31, 2016, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(m) Incorporation and Good Standing of the Company and its Subsidiaries. The Company and each of its subsidiaries (as the term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation or other entity, as applicable, in good standing under the laws of the jurisdiction of its incorporation or organization and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Prospectus and, in the case of the Company, to enter into and perform its obligations under this Agreement, except where the failure to be in good standing would not reasonably be expected to result in a Material Adverse Change. The Company and each of its subsidiaries is duly qualified as a foreign corporation or other entity, as applicable, to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except for such jurisdictions where the failure to so qualify or to be in good standing would not, individually or in the aggregate, result in a Material Adverse Change. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company (directly or through the Company's other subsidiaries) free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed on **Schedule 4** hereto.

(n) Capital Stock Matters. The authorized, issued and outstanding capital stock of the Company is as set forth in the Prospectus (other than for subsequent issuances, if any, pursuant to employee benefit plans or upon the exercise of outstanding options or warrants described in the Prospectus). The Common Stock (including the Placement Shares) conforms in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with federal and state securities laws. None of the outstanding shares of Common Stock were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those accurately described in all material respects in the Prospectus. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

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(o) Exchange Listing. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is listed on Nasdaq, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the common Stock from Nasdaq, nor has the Company received any notification that the commission or Nasdaq is contemplating terminating such registration or listing.

(p) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter or by-laws, or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) (“**Default**”) under any indenture, mortgage, loan or credit agreement, note, contract, franchise, lease or other instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound (including, without limitation, any credit agreement, indenture, pledge agreement, security agreement or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness of the Company or any of its subsidiaries), or to which any of the property or assets of the Company or any of its subsidiaries is subject (each, an “**Existing Instrument**”), except for such Defaults as would not, individually or in the aggregate, result in a Material Adverse Change. The Company’s execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus and the issuance and sale of the Placement Shares (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, or similar organizational documents, as applicable, of the Company or any of its subsidiaries, (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument, and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries, except in the case of clauses (ii) and (iii), for such breaches, defaults, results or violations as would not, individually or in the aggregate, result in a Material Adverse Change. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company’s execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus, except such as have been obtained or made or will be made by the Company under the Securities Act or that may be required under applicable state securities or blue sky laws and from the Financial Industry Regulatory Authority (“**FINRA**”). As used herein, a “**Debt Repayment Triggering Event**” means any event or condition that gives, or with the giving of notice or lapse of time, would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder’s behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(q) No Material Actions or Proceedings. Except as disclosed in the Prospectus, there are no legal or governmental actions, suits or proceedings pending or, to the Company’s knowledge, threatened (i) against or affecting the Company or any of its subsidiaries, (ii) which have as the subject thereof any officer or director of, or property owned or leased by, the Company or any of its subsidiaries or (iii) relating to environmental or discrimination matters, where in any such case (A) there is (in the case of pending actions, suits or proceedings, to the Company’s knowledge) a reasonable possibility that such action, suit or proceeding will be determined adversely to the Company, any of its subsidiaries or such officer or director, (B) any such action, suit or proceeding, if so determined adversely, would reasonably be expected to result in a Material Adverse Change or adversely affect the consummation of the transactions contemplated by this Agreement or (C) any such action, suit or proceeding is or would be material in the context of the sale of shares of Common Stock. No material labor dispute with the employees of the Company or any of its subsidiaries, or, to the Company’s knowledge, with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or (in the case of labor disputes with the employees of the Company or any of its subsidiaries, to the Company’s knowledge), is threatened or imminent.

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(r) Intellectual Property Rights. The Company and each of its subsidiaries own or possess (or can acquire on reasonable terms) sufficient trademarks, trade names, patent rights, copyrights, domain names, licenses, approvals, trade secrets and other similar rights (collectively, “**Intellectual Property Rights**”) reasonably necessary to conduct their businesses as now conducted, except to the extent the failure to own, possess or acquire on reasonable terms would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. Except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change, (i) there are no third parties who have or, to the Company’s knowledge, will be able to establish rights to any Intellectual Property Rights; (ii) to the Company’s knowledge, there is no infringement by third parties of any Intellectual Property Rights; (iii) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the Company’s rights in or to any Intellectual Property Rights, and the Company is unaware of any facts that would form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any Intellectual Property Rights, and the Company is unaware of any facts that would form a reasonable basis for any such action, suit, proceeding or claim; and (v) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of products or services described in the Registration Statement and Prospectus as under development and as currently configured, infringe or violate, any currently issued patent, trademark, tradename, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts that would form a reasonable basis for any such action, suit, proceeding or claim. None of the technology employed by the Company or any of its subsidiaries has been obtained or is being used by the Company or any of its subsidiaries in violation of any contractual obligation binding on the Company or any of its subsidiaries or, to the Company’s knowledge, any of its or its subsidiaries’ officers, directors or employees or otherwise in violation of the rights of any persons, except in each case for such violations as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

(s) Clinical Trials. The clinical and pre-clinical trials conducted by or on behalf of or sponsored by the Company or its subsidiaries, or in which the Company or its subsidiaries have participated, that are described in the Registration Statement and Prospectus, as applicable, and are intended to be submitted to Regulatory Authorities as a basis for product approval, were and, if still pending, are being conducted by the Company or, to the knowledge of the Company on behalf of the Company, in all material respects in accordance with the medical and scientific research procedures described in the applicable trial protocols and all applicable statutes, rules and regulations of the United States Food and Drug Administration and comparable drug regulatory agencies outside of the United States to which they are subject (collectively, the “**Regulatory Authorities**”), including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, and 312. The descriptions in the Prospectus of the results of such studies and tests are accurate and complete in all material respects and present fairly the data derived from such trials. The Company has no knowledge of any other clinical trials the results of which reasonably call into question the results described or referred to in the Registration Statement and Prospectus. The Company and its subsidiaries have operated and are currently in compliance with all applicable statutes, rules and regulations of the Regulatory Authorities, except as would not reasonably be expected to have a Material Adverse Change. In the last two years, neither the Company nor any of its subsidiaries has received any written notices, correspondence or other written communication from the Regulatory Authorities or any other governmental agency requiring or threatening the premature termination or suspension of any clinical or pre-clinical trials that are described in the Registration Statement and Prospectus or the results of which are referred to in the Registration Statement and Prospectus, and, to the Company’s knowledge, there are no reasonable grounds for same.

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(t) All Necessary Permits, etc. The Company and each of its subsidiaries possess such valid and current certificates, authorizations or permits issued by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their respective businesses as currently conducted by them and described in the Registration Statement and Prospectus; and neither the Company nor any of its subsidiaries has received, or has any reason to believe that it will receive, any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit which, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Change.

(u) Title to Properties. The Company and each of its subsidiaries have good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in Section 6(j) above (or elsewhere in the Prospectus), in each case that are material to the business of the Company and its subsidiaries taken as a whole and in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except such as do not materially and adversely affect the value of such property and assets and do not materially interfere with the use made or proposed to be made of such property and assets by the Company or any of its subsidiaries. To the Company's knowledge, the real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or any of its subsidiaries.

(v) Tax Law Compliance. The Company and its consolidated subsidiaries have filed all necessary federal, state and foreign income and franchise tax returns (or have properly requested extensions thereof) and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 6(j) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or its consolidated subsidiaries has not been finally determined.

(w) Company Not an "Investment Company". The Company is not, and will not, either after receipt of payment for the Placement Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Prospectus, be, required to register as an "investment company" or an entity "controlled" by an "investment company" under the Investment Company Act of 1940, as amended (the "**Investment Company Act**").

(x) Insurance. The Company and each of its subsidiaries is insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are reasonably adequate and customary for their businesses as currently conducted and described in the Registration Statement and Prospectus, including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction and acts of vandalism and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Change. During the past three years, neither of the Company nor any of its subsidiaries has been denied any insurance coverage material to the Company or such subsidiary, respectively, which it has sought or for which it has applied.

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(y) No Price Stabilization or Manipulation ; Compliance with Regulation M. The Company has not taken, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Common Stock or any other “reference security” (as defined in Rule 100 of Regulation M under the Exchange Act (“**Regulation M**”)) whether to facilitate the sale or resale of the Placement Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(z) Related Party Transactions. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Prospectus which have not been described as required.

(aa) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto became effective and at each Applicable Time, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(bb) FINRA Matters. All of the information provided to Cowen or to counsel for Cowen by the Company, its officers and directors and, to the Company’s knowledge, the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rule 5110 or Conduct Rule 2720 of the National Association of Securities Dealers, Inc. (the “**NASD**”), is true, complete and correct. In accordance with FINRA Conduct Rule 5110(b)(7)(C)(i), the Placement Shares have been or will be registered with the Commission on Form S-3 under the Securities Act pursuant to the standards for such Form S-3 in effect prior to October 21, 1992.

(cc) Statistical and Market-Related Data. The statistical, demographic and market-related data included in the Registration Statement and Prospectus are based on or derived from sources that the Company believes to be reliable and accurate or represent the Company’s good faith estimates that are made on the basis of data derived from such sources.

(dd) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting. The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), which (i) are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company’s principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company’s most recent fiscal quarter; and (iii) the Company’s principal executive officer and principal financial officer have concluded to be effective at the reasonable assurance level. Based on the most recent evaluation of its disclosure controls and procedures (in accordance with Rule 13a-15(b)), the Company is not aware of (x) any material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information or (y) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

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(ee) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any director, officer, employee, agent, affiliate or other person acting on behalf of the Company or any subsidiary has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government officials or employees, political parties or campaigns, political party officials, or candidates for political office from corporate funds; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or any applicable anti-corruption laws, rules, or regulations of any other jurisdiction in which the Company or any subsidiary conducts business; or (iv) made any other unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any person.

(ff) Compliance with Environmental Laws. Except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change, (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "Environmental Laws"), (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (iii) there are no pending or threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (iv) there are, to the Company's knowledge, no events or circumstances that might reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(gg) Brokers. Except as contemplated by this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(hh) No Outstanding Loans or Other Indebtedness. Since the adoption of Section 13(k) of the Exchange Act, neither the Company nor any of its subsidiaries has extended or maintained credit, arranged for the extension of credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company or any of its subsidiaries except for such extensions of credit as are expressly permitted by Section 13(k) of the Exchange Act.

(ii) Dividend Restrictions. None of the subsidiaries of the Company is currently prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or any other subsidiary.

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(jj) Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the U.S. Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “**Anti-Money Laundering Laws**”), and no action, suit or proceeding by or before any court or governmental agency, authority, body or any arbitrator involving the Company or any of its subsidiaries with respect to Anti-Money Laundering Laws is pending, or to the knowledge of the Company, threatened.

(kk) Compliance with OFAC.

- (i) Neither the Company nor any of its subsidiaries, nor any director, officer or employee thereof, nor to the Company’s knowledge, any agent, affiliate, representative, or other person acting on behalf of the Company or any of its subsidiaries, is an individual or entity (“**Person**”) that is, or is owned or controlled by a Person that is: (i) the subject of any sanctions administered or enforced by the U.S. Department of Treasury’s Office of Foreign Assets Control (“**OFAC**”), the United Nations Security Council, the European Union, Her Majesty’s Treasury, or other relevant sanctions authority (collectively, “**Sanctions**”), nor (ii) located, organized, or resident in a country or territory that is the subject of a U.S. government embargo (including, without limitation, Cuba, Iran, North Kora, Sudan, Syria and the Crimea).
- (ii) The Company will not, directly or indirectly, use the Net Proceeds, or lend, contribute or otherwise make available such Net Proceeds to any subsidiary, joint venture partner or other Person: (i) to fund or facilitate any activities or business of or with any Person that, at the time of such funding or facilitation, is the subject of Sanctions, or in any country or territory that, at the time of such funding or facilitation, is the subject of a U.S. government embargo; or (ii) in any other manner that will result in a violation of Sanctions by any Person (including Cowen).
- (iii) For the past five (5) years, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any direct or indirect dealings or transactions with any Person that at the time of the dealing or transaction is or was the subject of Sanctions or any country or territory that, at the time of the dealing or transaction is or was the subject of a U.S. government embargo.

(ll) No Reliance. The Company has not relied upon Cowen or legal counsel for Cowen for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(mm) Cowen Purchases. The Company acknowledges and agrees that Cowen has informed the Company that Cowen may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell shares of Common Stock for its own account while this Agreement is in effect, *provided, that* (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent Cowen may engage in sales of Placement Shares purchased or deemed purchased from the Company as a “riskless principal” or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by Cowen.

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(nn) Compliance with Laws. The Company has not been advised, and has no reason to believe, that it and each of its subsidiaries are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not result in a Material Adverse Change.

Any certificate signed by an officer of the Company and delivered to Cowen or to counsel for Cowen in connection with this Agreement shall be deemed to be a representation and warranty by the Company, as applicable, to Cowen as to the matters set forth therein.

The Company acknowledges that Cowen and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to Cowen, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with Cowen that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a prospectus relating to any Placement Shares is required to be delivered by Cowen under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act) (the “**Prospectus Delivery Period**”) (i) the Company will notify Cowen promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference or amendments not related to any Placement, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus related to the Placement or for additional information related to the Placement; (ii) the Company will prepare and file with the Commission, promptly upon Cowen’s request, any amendments or supplements to the Registration Statement or Prospectus that, in Cowen’s reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by Cowen (*provided, however*, that the failure of Cowen to make such request shall not relieve the Company of any obligation or liability hereunder, or affect Cowen’s right to rely on the representations and warranties made by the Company in this Agreement; (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to Cowen within a reasonable period of time before the filing and Cowen has not reasonably objected thereto (*provided, however*, that (A) the failure of Cowen to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect Cowen’s right to rely on the representations and warranties made by the Company in this Agreement, (B) the Company has no obligation to provide Cowen any advance copy of such filing or to provide Cowen an opportunity to object to such filing if the filing does not name Cowen or does not relate to the transaction herein provided, and (C) the only remedy Cowen shall have with respect to the failure by the Company to provide Cowen with such copy or the filing of such amendment or supplement despite Cowen’s objection shall be to cease making sales under this Agreement); (iv) the Company will furnish to Cowen at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via IDEA; and (v) the Company will cause each amendment or supplement to the Prospectus to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company’s reasonable opinion or reasonable objections, shall be made exclusively by the Company).

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(b) Notice of Commission Stop Orders. The Company will advise Cowen , promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise Cowen promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or any Issuer Free Writing Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus .

(c) Delivery of Prospectus; Subsequent Changes . During the Prospectus Delivery Period, the Company will use commercially reasonable efforts to comply in all material respects with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430A under the Securities Act, it will use its commercially reasonable efforts to comply in all material respects with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430A and to notify Cowen promptly of all such filings. If during the Prospectus Delivery Period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such Prospectus Delivery Period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify Cowen to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; *provided, however* , that the Company may delay the filing of any amendment or supplement, if in the judgment of the Company, it is in the best interest of the Company.

(d) Listing of Placement Shares . During the Prospectus Delivery Period, the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as Cowen reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however*, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus . The Company will furnish to Cowen and its counsel (at the reasonable expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during the Prospectus Delivery Period (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as Cowen may from time to time reasonably request and, at Cowen's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to furnish any document (other than the Prospectus) to Cowen to the extent such document is available on IDEA.

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(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Expenses. The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, filing, including any fees required by the Commission, and printing of the Registration Statement (including financial statements and exhibits) as originally filed and of each amendment and supplement thereto and each Free Writing Prospectus, in such number as Cowen shall deem reasonably necessary, (ii) the printing and delivery to Cowen of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the certificates, if any, for the Placement Shares to Cowen, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to Cowen, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the fees and expenses of the transfer agent and registrar for the Common Stock, (vi) the filing fees incident to any review by FINRA of the terms of the sale of the Placement Shares, and (vii) the fees and expenses incurred in connection with the listing of the Placement Shares on the NASDAQ.

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for 5 trading days following the termination of any Placement Notice given hereunder, the Company shall provide Cowen notice as promptly as reasonably possible before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with the (i) issuance, grant or sale of Common Stock, options to purchase shares of Common Stock or Common Stock issuable upon the exercise of options or other equity awards pursuant to the any stock option, stock bonus or other stock plan or arrangement described in the Prospectus; (ii) the issuance of securities in connection with an acquisition, merger or sale or purchase of assets; (iii) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to Cowen in advance; (iv) any shares of common stock issuable upon the exchange, conversion or redemption of securities or the exercise of warrants, options or other rights in effect or outstanding; or (v) any shares of common stock, or securities convertible into or exercisable for common stock, offered and sold in a privately negotiated transaction to vendors, customers, investors, strategic partners or potential strategic partners and otherwise conducted in a manner so as not to be integrated with the offering of common stock hereby.

(j) Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice, advise Cowen promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to Cowen pursuant to this Agreement.

(k) Due Diligence Cooperation. During the term of the Agreement, the Company will cooperate with any reasonable due diligence review conducted by Cowen or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices or such other location mutually agreeable by the parties, as Cowen may reasonably request.

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(l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing under Rule 424(b), a “**Filing Date**”), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through Cowen, the Net Proceeds to the Company and the compensation payable by the Company to Cowen with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(m) Representation Dates; Certificate. On or prior to the First Delivery Date and each time during the term of this Agreement the Company (i) post-effectively amends the Registration Statement or supplements the Prospectus, but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares (as set forth in (ii)-(iv) below); (ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing restated financial statements or a material amendment to the previously filed Form 10-K); (iii) files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) files a report on Form 8-K containing amended audited financial information (other than information “furnished” pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a “**Representation Date**”); the Company shall furnish Cowen (but in the case of clause (iv) above only if (1) a Placement Notice is pending, (2) Cowen reasonably determines that the information contained in such Form 8-K is material to a holder of Common Stock and (3) Cowen requests such certificate within three (3) days after the filing of such Form 8-K with the Commission) with a certificate, in the form attached hereto as Exhibit 7(m). The requirement to provide a certificate under this Section 7(m) shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, (i) upon the delivery of the first Placement Notice hereunder and (ii) if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide Cowen with a certificate under this Section 7(m), then before Cowen sells any Placement Shares, the Company shall provide Cowen with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

(n) Legal Opinion.

(i) On or prior to the date of the first Placement Notice given hereunder, and thereafter within two (2) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause to be furnished to Cowen written opinions and statements of Cooley LLP (“**Company Counsel**”), or other counsel reasonably satisfactory to Cowen; *provided, however*, the Company shall not be required to furnish any such letter if the Company does not intend to deliver a Placement Notice in such calendar quarter until such time as the Company delivers its next Placement Notice; *provided, further*, that the Company’s obligation to have Company Counsel furnish a negative assurance statement is conditioned upon counsel to Cowen furnishing a negative assurance statement dated as of the same such date; *provided, further*, that in lieu of such letters for subsequent periodic filings under the Exchange Act, Company Counsel may furnish Cowen with a letter (a “**Reliance Letter**”) to the effect that Cowen may rely on a prior letter delivered under this Section 7(n) to the same extent as if it were dated the date of such letter (except that statements in such prior letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

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(ii) On or prior to the date of the first Placement Notice given hereunder and at each subsequently occurring Representation Date requiring the delivery of written opinions and statements by Company Counsel, Cowen shall cause to be furnished to it written negative assurances of Goodwin Procter LLP, or other counsel reasonably satisfactory to Cowen (“**Cowen Counsel**”).

(o) **Comfort Letter**. On or prior to the date of the first Placement Notice given hereunder and within two (2) Trading Days after each subsequent Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as **Exhibit 7(m)** for which no waiver is applicable, the Company shall cause its independent accountants to furnish Cowen letters (the “**Comfort Letters**”), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(o). The Comfort Letter from the Company’s independent accountants shall be in a form and substance satisfactory to Cowen, (i) confirming that they are an independent public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants’ “comfort letters” to underwriters in connection with registered public offerings (the first such letter, the “**Initial Comfort Letter**”) and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) **Market Activities**. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of Common Stock or (ii) sell, bid for, or purchase Common Stock in violation of Regulation M, or pay anyone any compensation for soliciting purchases of the Placement Shares other than Cowen.

(q) **Investment Company Act**. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an “investment company,” as such term is defined in the Investment Company Act.

(r) **No Offer to Sell**. Other than an Issuer Free Writing Prospectus approved in advance by the Company and Cowen in its capacity as agent hereunder pursuant to Section 20, neither Cowen nor the Company (including its agents and representatives, other than Cowen in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(s) **Sarbanes-Oxley Act**. The Company will maintain and keep accurate books and records reflecting its assets and maintain internal accounting controls in a manner designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company’s consolidated financial statements in accordance with GAAP, (iii) that receipts and expenditures of the Company are being made only in accordance with management’s and the Company’s directors’ authorization, and (iv) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company’s assets that could have a material effect on its financial statements. The Company will maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that

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information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure and to ensure that material information relating to the Company or its subsidiaries is made known to them by others within those entities, particularly during the period in which such periodic reports are being prepared .

8. Conditions to Cowen's Obligations . The obligations of Cowen hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by Cowen of a due diligence review satisfactory to it in its reasonable judgment, and to the continuing satisfaction (or waiver by Cowen in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective . The Registration Statement shall have become effective and shall be available for the sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices . None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification from the Commission or any other federal or state governmental authority with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission . Cowen shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in Cowen's reasonable opinion is material, or omits to state a fact that in Cowen's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes . Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any Material Adverse Change, or any development that could reasonably be expected to cause a Material Adverse Change.

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(e) Legal Opinion. Cowen shall have received the opinion of Company Counsel and negative assurances of Company Counsel and Cowen Counsel required to be delivered pursuant Section 7( n ) on or before the date on which such delivery of such opinions are required pursuant to Section 7( n ).

(f) Comfort Letter. Cowen shall have received the Comfort Letter required to be delivered pursuant Section 7(o) on or before the date on which such delivery of such letter is required pursuant to Section 7(o).

(g) Representation Certificate. Cowen shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

(h) Secretary's Certificate. On or prior to the First Delivery Date, Cowen shall have received a certificate, signed on behalf of the Company by its corporate Secretary, in form and substance satisfactory to Cowen and its counsel.

(i) No Suspension. Trading in the Common Stock shall not have been suspended on Nasdaq and the Common Stock shall not have been delisted from the Nasdaq.

(j) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to Cowen such appropriate further information, certificates and documents as Cowen may reasonably request. All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof. The Company will furnish Cowen with such conformed copies of such opinions, certificates, letters and other documents as Cowen shall reasonably request.

(k) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(l) Approval for Listing. The Placement Shares shall either have been approved for listing on the Nasdaq, subject only to notice of issuance, or the Company shall have filed an application for listing of the Placement Shares on the Nasdaq at, or prior to, the issuance of any Placement Notice.

(m) No Termination Event. There shall not have occurred any event that would permit Cowen to terminate this Agreement pursuant to Section 11(a).

#### 9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless Cowen, the directors, officers, partners, employees and agents of Cowen and each person, if any, who (i) controls Cowen within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with Cowen from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable investigative, legal and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which Cowen, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of

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a material fact contained in the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on information furnished in writing by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission or (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading; *provided, however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission made in reliance upon and in conformity with information relating to Cowen and furnished in writing to the Company by Cowen expressly for use therein. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) Cowen Indemnification. Cowen agrees to indemnify and hold harmless the Company and its directors and each officer of the Company who signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with information relating to Cowen and furnished to the Company in writing by Cowen expressly for use therein.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each

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of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly after the indemnifying party receives a written invoice relating to fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or Cowen, the Company and Cowen will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than Cowen, such as persons who control the Company within the meaning of the Securities Act or the Exchange Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and Cowen may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and Cowen on the other hand. The relative benefits received by the Company on the one hand and Cowen on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by Cowen (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and Cowen, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Cowen, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and Cowen agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), Cowen shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of

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this Section 9 (d), any person who controls a party to this Agreement within the meaning of the Securities Act or the Exchange Act, and any officers, directors, partners, employees or agents of Cowen , will have the same rights to contribution as that party, and each officer and director of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9 (d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9 (d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9 (c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9 (c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of Cowen, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

#### 11. Termination.

(a) Cowen shall have the right by giving notice as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Change, or any development that could reasonably be expected to result in a Material Adverse Change has occurred that, in the reasonable judgment of Cowen, may materially impair the ability of Cowen to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder; *provided, however*, in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion, or letter required under Sections 7(m), 7(n), or 7(o), Cowen's right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than thirty (30) days from the date such delivery was required; or (iii) any other condition of Cowen's obligations hereunder is not fulfilled, or (iv), any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If Cowen elects to terminate this Agreement as provided in this Section 11(a), Cowen shall provide the required notice as specified in Section 12 (Notices).

(b) The Company shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Payment of Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Governing Law and Time; Waiver of Jury Trial) and Section 17 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination.

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(c) Cowen shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Payment of Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Governing Law and Time; Waiver of Jury Trial) and Section 17 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through Cowen on the terms and subject to the conditions set forth herein except that the provisions of Section 7(g) (Payment of Expenses), Section 9 (Indemnification and Contribution), Section 11 (Representations and Agreements to Survive Delivery), Section 16 (Governing Law and Time; Waiver of Jury Trial) and Section 17 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g) (Payment of Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Governing Law and Time; Waiver of Jury Trial) and Section 17 (Consent to Jurisdiction) shall remain in full force and effect. Upon termination of this Agreement, the Company shall not have any liability to Cowen for any discount, commission or other compensation with respect to any Placement Shares not otherwise sold by Cowen under this Agreement.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by Cowen or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified, and if sent to Cowen, shall be delivered to:

Cowen & Company, LLC  
599 Lexington Avenue  
New York, New York 10022  
Attention: General Counsel  
Telephone: (646) 562-1923  
Email: Bradley.friedman@cowen.com

with a copy to:

Goodwin Procter LLP  
620 Eighth Avenue  
New York, NY 10018  
Attention: Michael D. Maline  
Telephone: (212) 813-8966  
Email: mmaline@goodwinlaw.com

and if to the Company, shall be delivered to:

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Dynavax Technologies Corporation  
2929 Seventh Street, Suite 100  
Berkeley, CA 94710

Attention:  
Telephone:  
Email:

General Counsel  
(510) 665-7257  
mostrach@dynavax.com

with a copy to:

Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304-1130

Attention:  
Telephone:  
Email:

Glen Y. Sato  
(650) 843-5502  
gsato@cooley.com

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally, by email, or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, “ **Business Day** ” shall mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

An electronic communication (“ **Electronic Notice** ”) shall be deemed written notice for purposes of this Section 12 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives confirmation of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form (“ **Nonelectronic Notice** ”) which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and Cowen and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided, however* , that Cowen may assign its rights and obligations hereunder to an affiliate of Cowen without obtaining the Company’s consent .

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share consolidation, stock split, stock dividend, corporate domestication or similar event effected with respect to the Placement Shares.

15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire

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agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and Cowen. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

17. Waiver of Jury Trial. The Company and Cowen each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

18. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile transmission.

19. Effect of Headings. The section and Exhibit headings herein are for convenience only and shall not affect the construction hereof.

20. Permitted Free Writing Prospectuses. The Company represents, warrants and agrees that, unless it obtains the prior consent of Cowen (such consent not to be unreasonably withheld, conditioned or delayed), and Cowen represents, warrants and agrees that, unless it obtains the prior consent of the Company (such consent not to be unreasonably withheld, conditioned or delayed), it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by Cowen or by the Company, as the case may be, is hereinafter referred to as a “**Permitted Free Writing Prospectus**.” The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an “issuer free writing prospectus,” as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping.

21. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

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(a) Cowen has been retained solely to act as sales agent in connection with the sale of the Common Stock and that no fiduciary, advisory or agency relationship between the Company and Cowen has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether Cowen has advised or is advising the Company on other matters;

(b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Company has been advised that Cowen and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that Cowen has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) the Company waives, to the fullest extent permitted by law, any claims it may have against Cowen, for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that Cowen shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.

22. Definitions. As used in this Agreement, the following term has the meaning set forth below:

“Applicable Time” means (i) each Representation Date and (ii) the time of each sale of any Placement Shares pursuant to this Agreement.

“Issuer Free Writing Prospectus” means any “issuer free writing prospectus,” as defined in Rule 433, relating to the Placement Shares that (i) is required to be filed with the Commission by the Company, (ii) is a “road show” that is a “written communication” within the meaning of Rule 433(d)(8)(i) whether or not required to be filed with the Commission, or (iii) is exempt from filing pursuant to Rule 433(d)(5) (i) because it contains a description of the Placement Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g) under the Securities Act Regulations.

“Rule 172,” “Rule 405,” “Rule 415,” “Rule 424,” “Rule 424(b),” “Rule 430B,” and “Rule 433” refer to such rules under the Securities Act Regulations.

All references in this Agreement to financial statements and schedules and other information that is “contained,” “included” or “stated” in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be.

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All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR; all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR; and all references in this Agreement to “supplements” to the Prospectus shall include, without limitation, any supplements, “wrappers” or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by Cowen outside of the United States.

**[Remainder of Page Intentionally Blank]**

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If the foregoing correctly sets forth the understanding between the Company and Cowen , please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and Cowen .

Very truly yours,

**COWEN AND COMPANY, LLC**

By: /s/ GEORGE MILSTEIN

Name: George Milstein

Title: Managing Director

**ACCEPTED as of the date**

**first-above written:**

**DYNAVAX TECHNOLOGIES CORPORATION**

By: /s/ MICHAEL OSTRACH

Name: Michael Ostrach

Title: Senior Vice President

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Signature Page

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**FORM OF PLACEMENT NOTICE**

From: [ ]  
Cc: [ ]  
To: [ ]  
Subject: Cowen at the Market Offering—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Dynavax Technologies Corporation (the “**Company**”), and Cowen and Company, LLC (“**Cowen**”) dated November 3, 2017 (the “**Agreement**”), I hereby request on behalf of the Company that Cowen sell up to [ ] shares of the Company’s common stock, par value \$0.001 per share, at a minimum market price of \$\_\_\_\_\_ per share. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold] [the aggregate sales price of the shares reaches \$\_\_\_\_\_].

[The Company may include such other sales parameters as it deems appropriate.]

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**Notice Parties**

**Dynavax Technologies Corporation**

Michael Ostrach Chief Financial Officer and Principal Financial Officer

David Johnson Vice President and Chief Accounting Officer

**Cowen and Company, LLC**

Robert Sine            Director

William Follis        Director

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**Compensation**

Cowen shall be paid compensation up to 3.0% of the gross proceeds from the sales of Common Stock pursuant to the terms of this Agreement.

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**Schedule Of Subsidiaries**

Dynavax GmbH

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**OFFICER CERTIFICATE**

The undersigned, the duly qualified and elected \_\_\_\_\_, of Dynavax Technologies Corporation (“ **Company** ”), a Delaware corporation, does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated November 3, 2017 (the “ **Sales Agreement** ”) between the Company and Cowen and Company, LLC, that to the best of the knowledge of the undersigned.

- (i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Change, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and
- (ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

By: \_\_\_\_\_  
Name:  
Title:

Date: \_\_\_\_\_

**COLEY PHARMACEUTICAL GROUP, INC.**

**And**

**DYNAVAX TECHNOLOGIES CORPORATION**

**LICENSE AGREEMENT**

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**Dated June 26, 2007**

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## LICENSE AGREEMENT

This LICENSE AGREEMENT (this “Agreement”), effective as of June 26, 2007 (the “Effective Date”), is between Coley Pharmaceutical Group, Inc., a Delaware corporation located at 93 Worcester Street, Suite 101, Wellesley, Massachusetts 02481 USA, and its Affiliates (collectively, “Coley”), and Dynavax Technologies Corporation, a Delaware corporation having a principal place of business at 2929 Seventh Street, Suite 100, Berkeley, California 94710 USA and its Affiliates (“Licensee”) (each, a “Party” and collectively, the “Parties”).

### RECITALS

WHEREAS, Coley is the owner or licensee of certain rights, title, and interests in proprietary technologies involving immunomodulatory oligonucleotides; and

WHEREAS, Licensee has developed and/or is developing or evaluating a vaccine containing an HBsAg Antigen (as hereinafter defined) for the prevention of infection by Hepatitis B Virus in humans; and

WHEREAS, Licensee desires to obtain a license under the Patents (as hereinafter defined) in the Field (as hereinafter defined) and in the Territory (as hereinafter defined), and Coley desires to grant Licensee such rights and license; and

NOW, THEREFORE, in consideration of the premises and covenants contained herein and other good and valuable consideration, the adequacy of which is hereby acknowledged, and intending to be legally bound, the Parties hereby agree as follows:

#### **1. DEFINITIONS.**

##### **1.1 General.**

Unless otherwise specified, references in this Agreement to any section are references to such section of this Agreement and, unless otherwise specified, references in any section or definition to any clause are references to such clause of such section or definition. Terms which are defined in this Agreement shall apply equally to the singular and plural forms of the terms defined. Whenever the context may permit or require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The term “including” means including, without limiting the generality of any description proceeding such term. Each reference herein to any Person shall include a reference to such Person’s permitted successors and assigns. Unless otherwise specified, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto. References to “dollars” or “\$” are to United States dollars.

## 1.2 Defined Terms.

As used in this Agreement, the following terms shall have the following respective meanings:

(a) “Affiliate” shall mean any individual or entity directly or indirectly controlling, controlled by or under common control with a Party to this Agreement. For purposes of this definition, the term “control” means (i) direct or indirect ownership of more than fifty percent (50%) of the voting interest in the entity in question, or more than fifty percent (50%) interest in the income of the entity in question; provided, however, that if local law requires a minimum percentage of local ownership, in addition to the foregoing clause, control will also be established by direct or indirect beneficial ownership of one hundred percent (100%) of the maximum ownership percentage that may, under such local law, be owned by foreign interests; or (ii) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise).

(b) “Agreement” shall have the meaning set forth in the first paragraph of this Agreement.

(c) “Antigen” shall mean the recombinant Hepatitis B surface antigen.

(d) “Business Day” shall mean a day other than a Saturday or Sunday on which banking institutions in New York, New York are open for business.

(e) “Claim” shall mean any claim, demand, action or other proceedings (including for personal injury, death or disability) by a Third Party.

(f) “Coley” shall have the meaning set forth in the first paragraph of this Agreement.

(g) “Coley Indemnified Party” shall have the meaning set forth in Section 10.1.

(h) “Commercially Reasonable Efforts” shall have the meaning set forth in Section 4.1.

(i) “Compound” shall mean an immunomodulatory oligonucleotide identified by Licensee as ISS 1018, having a phosphorothioate backbone and the nucleotide base sequence 5’TGACTGTGAACGTTTCGAGATGA3’.

(j) “Confidential Information” shall mean any confidential and proprietary scientific, technical, commercial, marketing or other business information or Data furnished, directly or indirectly (including in connection with

meetings with Regulatory Authorities or Third Parties), and whether in writing, orally or otherwise, by one Party or one of its Affiliates (the “ Disclosing Party ”) to the other Party or one of its Affiliates (the “ Receiving Party ”) pursuant to or in connection with this Agreement (including the negotiation of this Agreement) or the activities or transactions contemplated hereby or thereby.

(k) “ Data ” shall mean all data and other information included or referenced in a Submission.

(l) “ Delivery Method ” for the Licensed Product shall mean intramuscular or subcutaneous delivery.

(m) “ Develop ” shall mean to engage in Development.

(n) “ Development ” shall mean all activities related to research, preclinical and other non-clinical testing, test method development, process development, Manufacturing scale-up, qualification and validation, quality assurance/quality control and clinical trials, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of any application for Regulatory Approval, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval.

(o) “ Disclosing Party ” shall have the meaning set forth in Section 1.2(j).

(p) “ Effective Date ” shall have the meaning set forth in the first paragraph of this Agreement.

(q) “ EU Major Market Country ” shall mean France, Germany, Italy, Spain and the United Kingdom .

(r) “ Exploit ” and cognates thereof shall mean to make, have made, import, use, sell, or offer for sale, including to Develop, register, modify, enhance, improve, Manufacture, have Manufactured, store, formulate, export, transport, distribute, promote, market, or otherwise dispose of.

(s) “ FDA ” shall mean the United States Food and Drug Administration or any successor entity.

(t) “ Field ” shall mean the use of the Licensed Product for the prevention of infection by Hepatitis B Virus in humans. The Field specifically excludes any product for the prevention of disease, indications or disorders other than Hepatitis B Virus in humans and any product for the treatment of any disease, indications or disorders .

(u) “First Commercial Sale” shall mean, with respect to the Licensed Product and a particular country in the Territory, the first transaction by Licensee or a Sublicensee that transfers to an arm’s-length Third Party purchaser, for value, title and right of physical possession of the Licensed Product for use in the Field in the country (other than named patient sales) . Notwithstanding the provisions of the preceding sentence, transfer of possession and title to an Affiliate shall not constitute a First Commercial Sale unless the Affiliate is an end user of the Licensed Product.

(v) “Indemnitee” shall have the meaning set forth in Section 10.3.

(w) “Indemnitor” shall have the meaning set forth in Section 10.3.

(x) “Iowa Agreement” shall mean that certain License Agreement by and between CpG ImmunoPharmaceuticals, Inc. (the predecessor corporation to Coley) and UIRF, dated March 31, 1997, as amended March 7, 2001, as it exists on the Effective Date. A redacted copy of the Iowa Agreement is attached hereto as Exhibit B.

(y) “Large Pharmaceutical Company” shall mean any pharmaceutical or biotechnology company that has at least two billion dollars (\$2,000,000,000) in aggregate annual pharmaceutical net sales for its most recently-completed fiscal year (consisting of 12 consecutive months) based on data provided by IMS International, or if such data is not available, such other reliable data as determined by Licensee and agreed to in writing by Coley, such agreement not to be unreasonably withheld.

(z) “Liability” shall have the meaning set forth in Section 10.1.

(aa) “Licensed Product” shall mean a prophylactic vaccine containing the Compound co-formulated with the Antigen for delivery by the Delivery Method. No Licensed Product(s) may be developed for the prevention, treatment or control of any cancer nor may any clinical trial be conducted with clinical endpoints of prevention, treatment or control of any cancer.

(bb) “Licensee” shall have the meaning set forth in the first paragraph of this Agreement.

(cc) “Licensee Indemnified Party” shall have the meaning set forth in Section 10.2.

(dd) “Manufacture” and “Manufacturing” shall mean, with respect to a product or compound, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such product or compound.

(ee) “ Net Sales ” shall mean the gross amount invoiced by Licensee and its Affiliates and its Sublicensees for sales of the Licensed Product for end use or consumption to Third Parties that are not Affiliates or Sublicensees of the selling party (unless such purchasing Affiliate or Sublicensee is the end user of the Licensed Product, in which case the amount billed therefore shall be deemed to be the same amount that would be billed to a Third Party end user in an arms-length transaction) in the Territory, less the total of the following deductions to the extent they are included in the gross invoiced sale price of the Licensed Product or otherwise directly paid or incurred by Licensee or its Affiliates or its Sublicensees with respect to the sale of the Licensed Product:

- (i) trade, cash, and/or quantity discounts not already reflected in the amount invoiced;
- (ii) excise, sales and other consumption taxes and customs duties to the extent included in the invoice price;
- (iii) freight, insurance and other transportation charges to the extent included in the invoice price;
- (iv) amounts repaid or credited by reason of rejections and defects;
- (v) returns or retroactive price reductions;
- (vi) payments and rebates directly related to the sale of the Licensed Product, and

any other specifically identifiable amounts included in gross amounts invoiced for the Licensed Product, to the extent such amounts are customary exclusions from net sales calculations in the vaccines industry for reasons substantially equivalent to those listed above and are reasonable in amount relative to similar deductions taken by Licensee or its Affiliates or Sublicensees in calculating net sales of its other products. Any such exclusions shall be negotiated in good faith between the Parties and, if they are unable to agree, resolved in accordance with the dispute resolution mechanism in Section 11.3, as determined in accordance with Licensee’s accounting methods (which are in accordance with its or its Sublicensee’s accounting standards as generally and consistently applied).

In the case of any sale or other disposal for value, such as barter or counter-trade, of the Licensed Product or part thereof, other than in an arm’s length transaction exclusively for money, Net Sales shall be calculated as above on the fair market value of the consideration received by Licensee or its Affiliates or Sublicensees .

(ff) “ OHRI Agreement ” shall mean the License Agreement, effective as of September 1, 1998 between The Ottawa Health Research Institute at the Ottawa Hospital (successor in interest to The Loeb Health Research Institute at Ottawa Hospital) (“ OHRI ”) and Coley Pharmaceutical Group, Inc. (formerly known as CpG ImmunoPharmaceuticals, Inc.), as amended on September 25, 2001. A redacted copy of the OHRI Agreement is attached hereto as Exhibit C.

(gg) “ Party ” and “ Parties ” shall have the meaning set forth in the first paragraph of this Agreement.

(hh) “ Patents ” shall mean the patents and patent applications listed on Exhibit A including (a) utility models, petty patents, design patents and certificates of invention, (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patent or patent application, and (c) any unissued or ungranted foreign or international equivalent of any of the foregoing.

(ii) “ Permitted Assignment ” shall have the meaning set forth in Section 11.1;

(jj) “ Person ” shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, or similar entity or organization, including a government or political subdivision, department or agency of a government, or an academic or research institution.

(kk) “ Receiving Party ” shall have the meaning set forth in Section 1.2(j) .

(ll) “ Regulatory Approval ” shall mean the marketing authorization (including pricing approval or reimbursement approval, if applicable to the sale ) of the Licensed Product in a country in the Territory, in each case by the appropriate Regulatory Authority.

(mm) “ Regulatory Authority ” shall mean, with respect to each country in the Territory, the government agency or health authority that regulates and is responsible for granting approvals for the Manufacture, marketing and/or sale of pharmaceutical products in such country.

(nn) “ Regulatory Milestone ” shall have the meaning set forth in Section 3.2.

(oo) “ Regulatory Milestone Payment ” shall have the meaning set forth in Section 3.2.

(pp) “ Royalty Payments ” has the meaning set forth in Section 3.3(a) .

(qq) “ Royalty Period ” shall mean the initial partial Royalty Quarter commencing on the date of the First Commercial Sale in any country in the Territory and every complete or partial Royalty Quarter thereafter with respect to which Licensee has the obligation to make Royalty Payments under Section 3 .

(rr) “ Royalty Report ” shall have the meaning set forth in Section 3.3(b) .

(ss) “ Royalty Quarter ” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

(tt) “ Royalty Year ” shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

(uu) “Submission” shall mean an application to obtain Regulatory Approval by a Regulatory Authority.

(vv) “ Sublicensee ” shall mean a Third Party who has been granted the right by Licensee strictly for the purpose of commercializing the Licensed Product.

(ww) “ Term ” shall have the meaning set forth in Section 6.1.

(xx) “ Territory ” shall mean all the countries of the world.

(yy) “ Third Party ” shall mean any Person other than Coley or Licensee.

(zz) “ Third Party Claim ” shall mean all claims of any Third Party that are subject to indemnification as provided for in Sections 10.1 or 10.2.

(aaa) “ UIRF ” shall mean the University of Iowa Research Foundation.

(bbb) “ Valid Claim ” shall mean any claim from an issued and unexpired Patent that (a) has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be taken or has been taken within the time allowed for appeal, (b) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, and (c) provides exclusionary and enforceable rights with respect to the claimed subject matter.

(ccc) “ Withholding Taxes ” shall have the meaning set forth in Section 3.1(a).

## **2. LICENSE GRANT.**

### **2.1 Non-Exclusive License Grant to Licensee .**

Subject to the terms of this Agreement , Coley shall grant, and hereby grants, to Licensee and Licensee hereby accepts, a non-exclusive, royalty-bearing license, with the right to grant sublicenses as defined in Section 2.2, below, under the Patents, including the patents listed in

Exhibit A which are subject to the terms of the OHRI Agreement and the UIRF Agreement (i) to Exploit the Licensed Product in the Field in the Territory and (ii) to Manufacture or have Manufactured the Compound in connection with such Exploitation of the Licensed Product .

## 2.2 Right to Grant Sublicenses.

### (a) Sublicensees.

Licensee shall have the right to grant sublicenses to Sublicensees solely to Exploit the Licensed Product on behalf of Licensee provided that: (i) it shall be a condition of any such sublicense that the Sublicensee agrees to be bound by all of the applicable obligations set forth in this Agreement; (ii) if Licensee grants such sublicense, Licensee shall be deemed to have guaranteed that such Sublicensee shall fulfill all of Licensee's obligations under this Agreement applicable to the subject matter of such sublicense; and (iii) such sublicense shall not reduce or delay payments otherwise due and owing to Coley by Licensee under this Agreement

### (b) Large Pharmaceutical Company.

Licensee shall have the right to grant one sublicense of all of the provisions of this Agreement to a Large Pharmaceutical Company provided that: (i) it shall be a condition of the sublicense that the Large Pharmaceutical Company agrees to be bound by all of the applicable obligations set forth in this Agreement; (ii) if Licensee grants such sublicense, Licensee shall be deemed to have guaranteed that such Large Pharmaceutical Company shall fulfill all of Licensee's obligations under this Agreement applicable to the subject matter of such sublicense; and (iii) the sublicense shall not reduce or delay payments otherwise due and owing to Coley by Licensee under this Agreement.

Any sublicense agreement with a Large Pharmaceutical Company shall provide in the event of an early termination of this Agreement (other than a termination for convenience by Licensee pursuant to Section 6.2 (a) or by Coley pursuant to Section 6.2 (b) (ii)) for the termination of the sublicense and the conversion of the sublicense to a license directly between Coley and the Large Pharmaceutical Company on substantially the same terms as this Agreement. Further, if Licensee has agreed to grant a sublicense to a Large Pharmaceutical Company and the Large Pharmaceutical Company has already negotiated a license to Exploit Coley's Patents for use as vaccine adjuvants (a "Prior VaxImmune Agreement"), Coley agrees to consider and to negotiate in good faith with the Large Pharmaceutical Company to incorporate one or more of the non-financial provisions of the Prior VaxImmune Agreement into an amendment of this Agreement which would authorize the incorporation of the new, non-financial provisions to Exploit the Licensed Product in the Field in the Territory and to Manufacture or have Manufactured the Compound in connection with such Exploitation of the Licensed Product. For the avoidance of doubt, any such amendment shall not alter the financial, Field, Compound or Licensed Product provisions in this Agreement.

## 2.3 **Limitations .**

Except as specifically provided in Section 2.1 (including the right to grant sublicenses pursuant to Section 2.2), Licensee shall have no rights to use the Patents for any other purpose. Licensee acknowledges and agrees that Coley's right to terminate the Agreement in the event that

Licensee takes any of the actions described in Section 6.2 (c) was expressly bargained for and agreed to by the parties and is a necessary condition for obtaining and maintaining the licenses provided in this Section 2. No other rights, express or implied, are granted to Licensee pursuant to this Agreement except as expressly granted herein.

#### 2.4 Option.

Effective upon written notice to Coley, Licensee may remove from this Agreement any Patents that issue or are granted after the Effective Date.

### 3. PAYMENTS AND ROYALTIES.

#### 3.1 Up-Front Payment .

In partial consideration of (i) Coley's investment in the Patents and (ii) the license granted to Licensee pursuant to Section 2.1, Licensee shall make a non-refundable, non-creditable up-front license fee payment of Five Million Dollars (\$5,000,000.00). Such up-front license fee shall be payable by Licensee within two business days of the execution of this Agreement by both Parties.

#### 3.2 Regulatory Milestone Payments .

At any point in time when a Regulatory Milestone (as defined below) is achieved for the Licensed Product by either Licensee, its Affiliates or Sublicensees, Licensee shall promptly notify Coley of the achievement of said Regulatory Milestone and shall pay Coley the amount corresponding to the Regulatory Milestone achieved hereunder (the "Regulatory Milestones") set forth below (each, a "Regulatory Milestone Payment"). Each Regulatory Milestone Payment shall be immediately due and payable by Licensee. Each Regulatory Milestone Payment shall be payable only once.

<b>Regulatory Milestone Payments</b>	<b>Regulatory Milestone Payment</b>
US FDA Regulatory Approval	\$2,500,000.00
First EU Major Market Country Regulatory Approval	\$2,500,000.00

#### 3.3 Royalty Payments.

(a) Royalty Payments Due. Licensee and its Sublicensees shall pay to Coley royalty payments on the Net Sales of the Licensed Product in the amounts set forth below ("Royalty Payments"):

(i) With respect to Net Sales of the Licensed Product during the period in which the Licensed Product is covered by a Valid Claim, Licensee shall pay Coley a royalty of three percent (3.0%) of such Net Sales.

Royalty Payments shall be due for sale of the Licensed Product under this Section 3.3(a) if there is a Valid Claim in either the country in which the Licensed Product is sold or in the country in which the Licensed Product is Manufactured. In any event, only one (1) Royalty Payment shall be due under this Section 3.3(a) for the Licensed Product sold even if more than one Valid Claim covers the Licensed Product. Royalty Payments shall not be subject to any offsets or credits for royalties or payments made to Third Parties by Licensee for Third Parties' technologies which are utilized or incorporated into or otherwise required to be paid regarding the Licensed Product. Coley shall be solely responsible for any payments owed to UIRF and OHRI due to the rights granted to Licensee pursuant to Section 2.1.

(b) Tender of Royalty Payments and Royalty Reports. Within sixty (60) days after the conclusion of each Royalty Quarter, Licensee shall tender payment of any Royalty Payments due under this Agreement and shall concurrently deliver to Coley a report on the Net Sales activity of Licensee during such Royalty Quarter (the "Royalty Report"). If no Royalty Payment is due, the Royalty Report shall so state. All such Royalty Reports shall be considered Confidential Information of Licensee under this Agreement. Royalty Reports shall contain at least the following information:

(i) Net Sales of the Licensed Product sold by Licensee and Sublicensee(s) on a country-by-country basis (including number of units sold during the applicable Royalty Quarter); and

(ii) total Royalty Payments due with respect to Net Sales of the Licensed Product sold by Licensee and Sublicensee(s) in each country.

(c) Period During Which Royalties Are Payable. Royalty Payment obligations under this Section 3.3 shall become effective on a country-by-country basis upon the First Commercial Sale of the Licensed Product and continue thereafter until there are no Valid Claims covering the Licensed Product in such country. Upon expiration of the period during which Licensee or Sublicensee is obligated to make Royalty Payments with respect to the Licensed Product, on a country-by-country basis, the rights granted to Licensee pursuant to Section 2.1 with respect to the Licensed Product shall become perpetual, irrevocable, fully paid-up and royalty-free.

### **3.4 Withholding; Payments.**

(a) Any payments made by Licensee or Sublicensee to Coley under this Agreement shall be reduced by the amount that Licensee or Sublicensee is required to withhold pursuant to any applicable tax law ("Withholding Taxes"). Licensee shall submit reasonable proof of payment of the Withholding Taxes to Coley within a reasonable period of time after such Withholding Taxes are remitted to the proper taxing authority.

(b) Any payments due under this Section 3 shall be made in dollars, using a mutually acceptable method of payment. With respect to sales of

the Licensed Product invoiced in a currency other than dollars, the Net Sales and amounts due to Coley hereunder shall be expressed in the domestic currency of the Person making the sale, together with the dollar equivalent of the amount payable to Coley. For each Royalty Quarter and each currency, such dollar equivalent shall be calculated using an exchange rate equal to the arithmetic average of the daily exchange rates for such Royalty Quarter listed in *The Wall Street Journal*, Eastern United States Edition, or, if not so available, as otherwise agreed by the Parties.

(c) Payments shall be made via wire transfer to:

Bank of America  
100 Federal St.  
Boston, MA 02110  
Beneficiary: Coley Pharmaceutical Group, Inc.  
Account #[ ]  
ABA [ ]

### 3.5 Late Payments .

Any payments due under this Section 3 that are not made on or before the date specified under the terms of this Agreement shall bear interest, to the extent permitted by law, at a rate equal at all times to the prime rate of interest announced publicly from time to time by Citibank, N.A., plus two percent (2 %), but in no case higher than the maximum rate permitted by applicable law, for the number of days delinquent.

### 3.6 Audit of Records .

(a) Records. Licensee and Sublicensees shall keep and maintain records of sales, importations, and other dispositions of the Licensed Product. The records required by this Section 3.6 shall be maintained and available for inspection for a period of five (5) years following the Royalty Year to which they pertain.

(b) Audit. Coley shall have the right, at Coley's expense, to examine, through an independent certified public accounting firm reasonably acceptable to Licensee, those records of Licensee and Sublicensee as may be reasonably necessary to confirm the accuracy of the Royalty Reports. Any such examination shall be made only upon not less than ten (10) business day's prior written notice to Licensee or Sublicensee, as the case may be, during regular business hours, and within three (3) years after the end of Royalty Period; provided, however, that such examination shall not take place more often than once per Royalty Year and shall not cover such records for more than the preceding three (3) Royalty Years. Such accounting firm shall disclose to Coley only the final audited Royalty Payment amounts to be paid by Licensee or Sublicensee. Upon the completion of an audit hereunder for any Royalty Year, the calculation of amounts payable with respect to such year shall be binding and conclusive upon Coley, and

Licensee and its Sublicensees shall be released from any liability or accountability with respect to amounts payable for such year.

(c) Audit Costs. In the event that any such inspection shows an underreporting or an underpayment in excess of five percent (5%) for any Royalty Year, then (i) Licensee or Sublicensee, as the case may be, shall pay the reasonable costs of such examination charged by such accounting firm and in any event shall pay any additional sum, including interest charges as provided in Section 3.5 on any such additional sum shown to be due to Coley and (ii) such audit will not count against the one audit per Calendar Year limit set forth in Section 3.6 (b) above.

#### **4. DEVELOPMENT; DILIGENCE OBLIGATIONS.**

**4.1 Diligence Generally** . Licensee shall use commercially reasonable efforts consistent with the efforts and resources normally used for a product of its own discovery of similar market potential at a similar stage in its product life, taking into account the competitiveness of the market place, the proprietary position of the product, the regulatory structure involved, the profitability of the applicable products and other relevant factors (“Commercially Reasonable Efforts”), (a) to pursue the Exploitation of the Licensed Product in the U.S. and in one or more EU Major Market Countries and (b) to undertake investigations and actions required to obtain appropriate Regulatory Approval therefor. The Parties agree that the diligence obligations set forth in this Section 4.1 shall not be applicable to any sublicense granted by Licensee to a Large Pharmaceutical Company pursuant to Section 2.2 (b) and the Parties further agree that Licensee’s due diligence obligations shall be deemed to have been met during the term of the sublicense to the Large Pharmaceutical Company.

#### **5. SUPPLY OF MATERIALS; MARKING.**

##### **5.1 Manufacture of Compound and Manufacturing Information .**

(a) Supply of Compound . Coley shall not be obligated to supply any quantities of the Compound to Licensee or Sublicensee(s).

(b) Licensee agrees that, to the extent required by the Iowa Agreement and applicable law, the Licensed Product produced for sale in the United States and embraced by a Valid Claim under a Patent Right listed on Exhibit A with UIRF identified as an Assignee will be Manufactured substantially in the United States, unless any waiver of such requirement is obtained.

(c) Manufacturing Information . In the event that Licensee or Sublicensee(s) Manufacture(s) or has a Third Party Manufacture Compound and uses information and/or intellectual property rights which result in a Regulatory Authority mandating changes to specifications for any immunomodulatory oligonucleotide and, as a result, Coley is unable to obtain or Manufacture reasonable quantities of other immunomodulatory oligonucleotides and/or other immunomodulatory oligonucleotides in

compliance with the mandate by such Regulatory Authority with respect to such materials, Licensee or Sublicensee(s), as the case may be, shall use commercially reasonable efforts to provide Coley and its licensees with a license on commercially reasonable terms to the necessary information and/or intellectual property rights to Manufacture the Compound and/or other immunomodulatory oligonucleotides in compliance with such specifications for any immunomodulatory oligonucleotide or the applicable mandate. In the event that Coley or Sublicensee(s) Manufacture(s) or has a Third Party Manufacture Compound and uses information and/or intellectual property rights which result in a Regulatory Authority mandating changes to specifications for the Compound and, as a result, Licensee or its Sublicensee(s) is unable to obtain or Manufacture reasonable quantities of the Compound in compliance with the mandate by such Regulatory Authority with respect to such materials, Coley shall use commercially reasonable efforts to provide Licensees and its sublicensees with a license on commercially reasonable terms to the necessary information and/or intellectual property rights to Manufacture the Compound in compliance with such specifications for the Compound or the applicable mandate.

## **5.2 Marking.**

Licensee shall comply with the requirements as to the marking of the Licensed Product set forth in Article 7 of the Iowa Agreement.

## 6. TERM AND TERMINATION.

### 6.1 Term .

The term of this Agreement shall begin on the Effective Date and, unless earlier terminated pursuant to this Section 6, continue on a country-by country basis until the expiration or termination of the last Valid Claim with respect to such country (the “Term”).

### 6.2 Termination .

(a) Termination by Either Party; Termination by Licensee . Upon a material breach of this Agreement by either Party, the non-breaching Party may provide written notice to the breaching Party specifying the material breach. If the breaching Party fails to cure the material breach during a ninety (90) day period (or in the case of a material breach of Section 4.1, a one hundred eighty day (180) period) following the date on which the notice of breach is provided then the non-breaching Party shall have the right to terminate this Agreement. If such breach is not reasonably cured within such ninety (90) days but (1) the breaching Party is making a bona fide effort to cure any such breach, such termination shall be delayed in order to permit the breaching Party a reasonable period of time to remedy the breach, or (2) if the breaching Party initiates a dispute resolution proceeding pursuant to Section 11.3 with respect to such breach prior to the expiration of such ninety (90) day period, then such termination shall not become effective until fifteen (15) days following the final conclusion of the dispute resolution proceeding if termination is permitted by such resolution. Licensee shall have the right to terminate this Agreement for convenience upon thirty (30) days prior written notice to Coley.

#### (b) Termination by Coley .

(i) Coley shall have the right upon written notice to Licensee to terminate this Agreement for non-payment of any amount due hereunder from Licensee to Coley if such non-payment shall continue uncured for a period ending (1) thirty (30) days following notice of such non-payment given by Coley to Licensee or, (2) if Licensee initiates a dispute resolution proceeding pursuant to Section 11.3 with respect to such payment prior to the expiration of such thirty (30) day period, then fifteen (15) days following the final conclusion of the dispute resolution proceeding if termination is permitted by such resolution.

(ii) Coley may terminate this Agreement in the event that Licensee or its Affiliates take any action, direct or indirect: (a) to challenge the validity, scope, or enforceability of the Patents licensed to Licensee hereunder; or (b) to oppose, object to, provoke an interference toward or initiate or support any re-examination proceedings challenging the Patents; provided that it shall not be grounds for terminating this Agreement if Licensee challenges the validity, scope, or enforceability of the Patents licensed to Licensee hereunder in defense of an action for infringement of the Patents brought by Coley arising from Licensee’s activities outside of the scope of this Agreement.

#### (c) Termination for Insolvency .

(i) To the extent permitted by law, upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a

substantial portion of the assets for the benefit of creditors (a “ Bankruptcy Event ”) by either Party, Coley, in the case of a Bankruptcy Event by Licensee, or Licensee, in the case of a Bankruptcy Event by Coley, may terminate this Agreement; provided, however, that, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the subject Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

(ii) This Section 6.2(c) is without prejudice to any rights the non-Affected Party may have arising under any bankruptcy, reorganization, insolvency or similar laws, and Licensee expressly reserves the right to maintain its license in effect pursuant to Section 11.17 with respect to a Bankruptcy Event involving Coley.

(d) No Limitation on Other Rights. Nothing in this Agreement shall be construed to limit the rights of Licensee, upon a material breach by Coley, to maintain its license in full force and effect and pursue any remedies otherwise available at law or equity.

### **6.3 Effects of Expiration or Termination .**

(a) Surviving Provisions. The provisions of Sections 3 (with respect to payment obligations accruing prior to the date of expiration or termination), 6, 7, 8, 9, 10, and 11 shall survive expiration or termination of this Agreement for any reason.

(b) Licensee Rights. Subject to the provisions of Section 6.3(a), (i) upon expiration of the Term, the rights granted to Licensee pursuant to Section 2.1 shall become perpetual, irrevocable, fully paid-up and royalty-free, and (ii) subject to the following sentence, upon termination of this Agreement by Coley pursuant to Section 6.2(a), 6.2(b) or 6.2(c) , the rights granted to Licensee pursuant to Section 2.1 shall terminate. Upon termination of this Agreement by Coley pursuant to Section 6.2(a), 6.2(b) or 6.2(c), (i) Licensee shall have the right to exhaust supplies of the Licensed Product then in inventory and (ii) Licensee shall with respect to any sales of the Licensed Product made prior to the termination of this Agreement or pursuant to clause (i) of this sentence, continue to provide Royalty Reports and to pay royalties on all Net Sales of the Licensed Product as required hereunder.

(c) Obligations Survive. Any termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to termination.

## **7. CONFIDENTIALITY.**

### **7.1 Nondisclosure Obligation .**

Each Party shall use the Confidential Information of the other Party only in accordance with the activities contemplated by this Agreement and shall not disclose to any Third Party any

Confidential Information of the other Party, without the prior written consent of the other party or as expressly provided below. This obligation shall not apply to Confidential Information that:

(a) is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party to the Receiving Party, as documented by business records;

(b) at the time of disclosure or thereafter becomes published or otherwise part of the public domain without breach of this Agreement by the Receiving Party;

(c) is subsequently disclosed to the Receiving Party by a Third Party who has the right to make such disclosure; or

(d) is developed by the Receiving Party independently of Confidential Information received from the Disclosing Party and such independent development can be properly demonstrated by the Receiving Party.

## **7.2 Permitted Disclosures .**

Notwithstanding the provisions of Section 7.1, a Receiving Party may make the following disclosures of Confidential Information received from the Disclosing Party:

(a) disclosures to governmental or other regulatory agencies in order to gain approval to conduct Licensed Product trials or to market the Licensed Product, but such disclosure may be only to the extent reasonably necessary to obtain such authorizations upon consultation with the other Party;

(b) disclosures to agents, consultants, Affiliates and/or other Third Parties as necessary for the research and development, Manufacturing and/or marketing of the Licensed Product, or to complete a Permitted Assignment (as defined in Section 11.1), (or for such Persons to determine their interest in performing such activities or such Permitted Assignment), in accordance with this Agreement on the condition that such Third Parties are or agree to be bound by confidentiality obligations substantially as restrictive and long as those contained in this Agreement; or

(c) disclosures required by law or court order, provided that notice is promptly delivered to the Disclosing Party in order to provide it with an opportunity to seek a protective order or other similar order with respect to such Confidential Information and the Receiving Party thereafter discloses only the minimum information reasonably required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the Disclosing Party.

## **7.3 Partial Disclosures .**

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because one or more individual elements of such Confidential Information are in the public domain or in the possession of such Party unless every feature of the Confidential Information has been disclosed in accordance with the provisions herein.

#### **7.4 Publicity .**

Neither Coley nor Licensee shall issue any press release or other public disclosure relating to this Agreement except as mutually agreed. The joint press release announcing the execution of this Agreement shall be substantially in the form as Exhibit D attached. Notwithstanding any other provision contained in this Section 7.4, either Party may make such public disclosure relating to this Agreement as may be required by applicable law. Prior to any public disclosure relating to this Agreement pursuant to the preceding sentence, the Party proposing to make such disclosure shall provide reasonable notice thereof and the proposed contents of such disclosure to the other Party and shall consult in good faith with the other Party regarding the timing and contents of any such disclosure.

### **8. MAINTENANCE AND ENFORCEMENT OF PATENTS.**

#### **8.1 Responsibility for Patents .**

Coley, by counsel it selects, shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain all Patents in Coley's name and in countries designated by Coley at the sole discretion of Coley.

#### **8.2 Infringement by Third Parties .**

The Parties agree to provide each other written notice promptly after becoming aware of any infringement of the Patents in the Field (irrespective of the delivery method used for the vaccine). Coley shall have the right, but not the obligation, under its own control and at its own expense, to prosecute any Third Party infringement of the Patents and/or to defend the Patents in any declaratory judgment action brought by a Third Party which alleges invalidity, unenforceability, or non-infringement of the Patents. Subject to Section 8.4 below, Coley may enter into any settlement, consent judgment, or other voluntary final disposition of any infringement or declaratory judgment action hereunder without the prior written consent of Licensee.

#### **8.3 Infringement Claims .**

If the Manufacture, sale or use of the Compound as used in the Licensed Product in the Field results in any claim, suit or proceeding filed by a Third Party alleging patent infringement by Coley or Licensee or Sublicensee, such Party shall promptly notify the other Party in writing. In

the event that one Party is sued subject to Section 8.4, the Party subject to such claim shall have the exclusive right to defend and control the defense of any such claim, suit or proceeding, at its own expense, using counsel of its own choice; provided, however, that if Coley or Licensee and Coley together are sued with respect to the Licensed Product sold by Licensee or Sublicensee, Coley shall have the exclusive right to take control of such defense. Licensee shall have the right to retain its own counsel at its sole cost and expense, and shall have the right to consult with Coley in any proceeding under this Section 8.3. The Party subject to the claim shall keep the other Party hereto reasonably informed of all material developments in connection with any such claim, suit or proceeding.

The Party not subject to the claim shall cooperate in all reasonable respects with the Party subject to the claim in the defense of the claim.

#### **8.4 Settlements.**

No settlements, consent judgments, or other voluntary final dispositions of a dispute adversely affecting the rights or obligations of a Party or Sublicensee, including the rights or obligations of the Party under this Agreement, shall be entered into in connection with any dispute, claim or proceeding described in Section 8.2 or 0 without the prior written consent of the adversely affected Party or Sublicensee, such consent not to be unreasonably withheld or delayed. Without limiting the foregoing, no settlements, consent judgments, or other voluntary final dispositions of any dispute, claim or proceeding described in Section 8.2 or 0 adversely affecting the rights or obligations of Coley under the Patents shall be entered into without the prior written consent of Coley, such consent not to be unreasonably withheld or delayed. The Parties shall comply with the provisions of Section 8.4 of the Iowa Agreement with respect to any settlement, consent judgment, or other voluntary final disposition of any suit relating to the subject matter of this Agreement.

#### **8.5 Recoveries and Damages .**

Any recoveries and damages received as a result of a dispute, claim or proceeding described in Section 8.2 or 8.3 or any settlement, consent judgment, or other voluntary final disposition thereof shall first go toward reimbursing the Parties or Sublicensee for their respective costs and expenses of such suit. Thereafter, any remainder shall be retained by or paid to Licensee or Sublicensee as lost sales or lost profits, as the case may be, and Licensee or Sublicensee shall pay Coley the applicable royalty with respect to such amounts.

#### **8.6 Subject to Iowa Agreement .**

To the extent related to Patents under the Iowa agreement, the provisions of this Section 8 are subject to in all respects the provisions of the Iowa Agreement, including Article 8 thereof.

### **9. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PARTIES.**

#### **9.1 Representations and Warranties of Each Party to the Other .**

Each Party hereby represents and warrants to the other Party hereto, effective as of the Effective Date, that:

(a) Such Party is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;

(b) The execution and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;

(c) Such Party has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, including the right, power and authority to grant the licenses granted herein;

(d) The execution and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any loan agreement, guaranty, financing agreement, agreement affecting the Licensed Product or the Compound, or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which it or any of its property is bound;

(e) The execution and performance by such Party of this Agreement and its compliance with the terms and provisions hereof do not and will not violate any law or regulation applicable to it; and

(f) This Agreement has been duly authorized by all necessary corporate action on the part of such Party, has been executed and delivered by such Party and constitutes such Party's legal, valid and binding obligation, enforceable against such Party in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles.

## 9.2 Covenants of Licensee .

Licensee hereby covenants with Coley that:

(a) It will comply with all of the obligations applicable to sublicensees of Coley under the Iowa Agreement and OHRI Agreement;

(b) Licensee will not market or actively promote the Licensed Product for off-label use outside the Field; and

(c) Licensee agrees not to take any further action, direct or indirect, in connection with current patent opposition proceedings in Europe for the Patents, shall withdraw its participation in such proceedings, and shall not initiate any additional opposition proceedings for the Patents currently in opposition proceedings by the European Patent Office. Licensee agrees to take any actions

reasonably requested by Coley in connection with its withdrawal from opposition proceedings , shall not directly or indirectly oppose, object to, provoke an interference toward or initiate or support any re-examination proceedings challenging the Patents and agrees to withdraw any challenge to the Patents, other than in defense of an action for infringement of the Patents.

### 9.3 Representations, Warranties and Covenants of Coley .

Coley hereby represents, warrants and covenants to Licensee, effective as of the Effective Date, that:

(a) Coley owns or possesses adequate licenses or other rights to use the Patents in the Field and to grant the rights and licenses herein; and

(b) (i) The Patents existing as of the Effective Date are subsisting and have not been held by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part; (ii) there are no claims, judgments or settlements against or amounts with respect thereto owed by Coley or any of its Affiliates relating to the Patents, (iii) except as listed in Exhibit E, no claim or litigation has been brought or threatened by any Person alleging (A) that any Patent is invalid or unenforceable or (B) the Patents or the disclosing, copying, making, assigning, licensing or Exploitation of the Patents or products embodying the Patents, including the Exploitation of the Licensed Product, violates, infringes or otherwise conflicts with any intellectual property or proprietary right of any Third Party; (iv) the conception, development and reduction to practice of the Patents existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person; and (v) it has not received notice of any claim or litigation asserted or commenced against it that would have an adverse effect on the rights granted to Licensee under this Agreement.

(c) (i) The OHRI Agreement and Iowa Agreement are in full force and effect, Coley has the right to grant any and all sublicenses granted under this Agreement under each of the OHRI Agreement and Iowa Agreement and (ii) Coley has not received notice of termination and is not aware of any facts or information that would, with the passage of time result in the termination of the OHRI Agreement or Iowa Agreement, respectively.

(d) Except as may be listed on Exhibit A , to the best of Coley's knowledge, there are no patents or patent applications owned or controlled by Coley as of the effective date of this Agreement that, but for the licenses granted in this Agreement, would be infringed by the Exploitation of the Licensed Product by the Licensee or its Sublicensees. If any such patent or patent application is identified during the Term, at Licensees option it shall be included in the Patents licensed under this Agreement, without the payment of additional consideration by Licensee to Coley.

## 9.4 Bayh-Dole .

Both Parties acknowledge that the U.S. Public Health Service may have certain rights, as provided in Bayh-Dole (Public Law 96-517 of 1980), to the Patents.

## 10. INDEMNIFICATION AND LIMITATION OF LIABILITY.

### 10.1 Indemnification by Licensee .

Licensee shall indemnify, defend and hold harmless Coley, and each of its employees, officers, directors and agents (each, a “Coley Indemnified Party”), from and against any and all liability, loss, damage, cost, and expense, including reasonable attorneys’ fees and reasonable expenses of litigation (collectively, a “Liability”), arising out of any Third Party Claim which the Coley Indemnified Party may incur, suffer or be required to pay to the extent resulting from or arising in connection with (i) the breach by Licensee of any covenant, representation or warranty contained in this Agreement; (ii) any negligent or wrongful act or omission of Licensee (its directors, officers, or agents, or distributors thereof) which is the proximate cause of injury, death or property damage to a Third Party; (iii) actual or asserted violations of any applicable law or regulation (other than patent or other intellectual property law or regulation) by Licensee, Sublicensees or distributors by virtue of which the Licensed Product in the Field Manufactured, distributed or sold by Licensee, Sublicensees or distributors shall be alleged or determined to be adulterated, misbranded, mislabeled or otherwise not in compliance with any such applicable law or regulation; (iv) claims for bodily injury, death, product liability, warranty of fitness or merchantability, or property damage attributable to the development, Manufacture, distribution, sale or use of the Licensed Product in the Field by Licensee, Sublicensees or distributors; or (v) a recall of the Licensed Product in the Field Manufactured, distributed or sold by Licensee, Sublicensees or distributors ordered by a governmental agency or required by a confirmed product failure as reasonably determined by Licensee, Sublicensees or distributors; except to the extent that such Liability arises in connection with or is otherwise attributable to (A) a breach by Coley of this Agreement or (B) any manufacturing agreement into which Coley may enter pursuant to Section 5.1 or (C), in the case of clauses (ii) through (v), any negligent act or omission or intentional misconduct on the part of Coley or any Liability for which Coley is required to provide indemnification under Section 10.2.

### 10.2 Indemnification by Coley .

Coley shall indemnify, defend and hold harmless Licensee and its employees, officers, directors and agents and its Sublicensees (each, a “Licensee Indemnified Party”) from and against any Liability arising out of any Third Party Claim, which Licensee Indemnified Party may incur, suffer or be required to pay to the extent resulting from or arising in connection with (i) the breach by Coley of any covenant, representation or warranty contained in this Agreement; (ii) any negligent or wrongful act or omission by Coley (or any of its licensees, licensors or their respective directors, officers, or agents, or distributors thereof) which is the proximate cause of injury, death or property damage to a Third Party; (iii) any Third Party Claim that the granting of the rights and licenses herein by Coley violates any rights of any Third Party, or (iv) claims for

bodily injury, death, product liability, warranty of fitness or merchantability, or property damage attributable to the development, Manufacture, distribution, sale or use of the Compound or pharmaceutical products incorporating the Compound by Coley, any of its licensees other than Licensee or their respective agents or distributors; except to the extent that such Liability arises in connection with or is otherwise attributable to (A) a breach by Licensee of this Agreement or (B), in the case of clauses (ii) through (v), any negligent act or omission or intentional misconduct on the part of Licensee or any Liability for which Licensee is required to provide indemnification under Section 10.1 .

### 10.3 **Indemnification Procedure .**

Any Person seeking indemnification under this Section 10 (the “ Indemnitee ”) shall promptly notify the Party from whom indemnification is sought (the “ Indemnitor ”) in writing of any Claim, and, subject to Section 8.3, the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to assume the defense thereof with counsel mutually satisfactory (consent not to be unreasonably withheld or delayed) to the other Party by giving written notice to the Indemnitee and the other Party within thirty (30) days after receipt of written notice of such Claim from the Indemnitee; provided, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid (a) by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceeding; or (b) by Indemnitee in all other cases. In no event shall the Indemnitor be liable for any Liabilities that result from any unreasonable delay by the Indemnitee in providing the written notice pursuant to the first sentence of this Section 10.3. In the event that it is ultimately determined that the Indemnitor is not obligated to indemnify, defend or hold harmless an Indemnitee from and against such Claim, the Indemnitee shall reimburse the Indemnitor for any and all costs and expenses (including attorneys’ fees and costs of suit) and any Liabilities incurred by the Indemnitor in its defense of such Claim with respect to the Indemnitee. The Indemnitee and its employees and agents shall reasonably cooperate with, and at the expense of, the Indemnitor and its legal representatives in the investigation of any Claim covered by this Section 10.

### 10.4 **Settlements .**

Neither Party may settle a Claim without the consent of the other Party if such settlement would (a) impose any monetary obligation on the other Party, (b) require the other Party to submit to an injunction, or (c) otherwise limit the other Party’s rights under this Agreement, such consent not to be unreasonably withheld or delayed in the case of clauses (b) and (c). Any payment made by a Party to settle a Claim shall be, unless otherwise provided in Section 10.1 or 10.2, as the case may be, at its own cost and expense.

### 10.5 **Limitation of Liability .**

With respect to any claim by one Party against the other Party arising out of the performance or failure of performance of the other Party under this Agreement, the Parties expressly agree that, except for a Party’s indemnification obligations pursuant to Section 10.1 or 10.2 with respect to Third Party claims, the liability of such Party to the other Party for such breach shall be limited

under this Agreement or otherwise at law or equity to direct damages only and in no event shall a Party be liable for punitive, special, incidental, multiple, exemplary or consequential damages.

#### 10.6 **Insurance** .

(a) Licensee. Prior to or immediately upon the first administration of the Licensed Product in the Field to a human in accordance with this Agreement, and for a period of five (5) years after the last sale of the Licensed Product in the Field hereunder, Licensee shall obtain and/or maintain, at its expense, product liability insurance in amounts which are reasonable and customary in the industry for companies of comparable size and activities. Such product liability insurance shall insure against liability for personal injury, physical injury, and property damage. Licensee shall provide proof of insurance to Coley upon request. Licensee may satisfy this requirement by a representation that it is self-insured and/or maintains Third Party liability insurance in amounts sufficient to meet the foregoing requirement.

(b) Coley. Prior to or immediately upon the first administration of the Licensed Product in the Field to a human in accordance with this Agreement, as notified by Licensee to Coley, and for a period of five (5) years after the last sale of the Licensed Product in the Field hereunder, as notified by Licensee to Coley, Coley shall obtain and/or maintain, at its expense, product liability insurance in amounts which are reasonable and customary in the industry for companies of comparable size and activities. Such product liability insurance shall insure against liability for personal injury, physical injury, and property damage. Coley shall provide proof of insurance to Licensee upon request. Coley may satisfy this requirement by a representation that it is self-insured and/or maintains Third Party liability insurance in amounts sufficient to meet the foregoing requirement.

#### 10.7 **Warranty Disclaimer** .

**EXCEPT AS EXPRESSLY MADE UNDER THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS, NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, WITH RESPECT, IN THE CASE OF COLEY, TO THE PATENTS OR, IN THE CASE OF LICENSEE, TO THE LICENSED PRODUCT OR THE COMPOUND USED THEREIN.**

#### 10.8 **Performance by Subcontractors** .

The Parties recognize that the Licensee may perform some or all of its obligations under this Agreement through Third Party subcontractors, provided, however, that the Licensee shall remain responsible and liable for the performance by its Third Party subcontractors and shall cause its Third Party subcontractors to comply with the provisions of this Agreement in connection therewith.

## **11. MISCELLANEOUS.**

### **11.1 Assignment .**

Neither this Agreement nor any or all of the rights and obligations of a Party shall be assigned, delegated, sold, transferred, sublicensed (except as otherwise provided herein) or otherwise disposed of, by operation of law or otherwise, to any Third Party without the prior written consent of the other Party, which shall not be unreasonably withheld, and any attempted assignment, delegation, sale, transfer, sublicense or other disposition, by operation of law or otherwise, of this Agreement or of any rights or obligations hereunder contrary to this Agreement shall be a material breach of this Agreement by the attempting Party and shall be void and without force or effect; provided, however, that either Party may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets or stock, in the event of its merger or consolidation or change in control or similar transaction, or, in the case of Licensee, in the event of a sale or transfer by Licensee of all or substantially all of its vaccine business related to the Licensed Product in connection with the transfer or sale of all or substantially all of its business related to a Licensed Product (any such transaction described in this proviso, a “Permitted Assignment”). In the event of a Permitted Assignment by Licensee, all Regulatory Milestone Payments under Section 3.2 shall become immediately due and payable. In addition, either Party may, without such consent, assign this Agreement and delegate its rights and obligations hereunder, in whole or in part, to an Affiliate; provided, however, that the Party making any such assignment or delegations shall, notwithstanding such assignment or delegation, remain responsible for the full, complete and faithful performance of its obligations hereunder. This Agreement shall be binding upon, and inure to the benefit of, each Party, and its permitted successors and assigns.

### **11.2 Governing Law .**

This Agreement shall be governed by and construed in accordance with the laws of the state of New York, U.S.A. without regard to its conflict of law rules.

### **11.3 Dispute Resolution .**

In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement, the Parties shall try to settle their differences amicably and in good faith between themselves first, by referring the disputed matter to the respective Chief Executive Officers of each Party, or any direct report designated by such Chief Executive Officer. In the event such executives are unable to resolve such dispute within a thirty (30) day period, either Party may invoke the provisions of this Section 11.3. Except as provided in Section 11.4, any dispute, controversy or claim arising out of or relating to this Agreement, or the breach thereof, including any question regarding this Agreement’s existence, termination or validity, shall be referred to and finally settled by binding arbitration, in accordance with the rules of the American Arbitration Association in force on the date the demand for arbitration is filed. The demand for arbitration may be filed by either Party within a reasonable time after the controversy or claim has arisen, but no later than after the date upon which institution of legal proceedings shall be barred by the applicable statute of limitations. There shall be three (3) arbitrators, each Party to designate one arbitrator and the two Party-designated arbitrators to

select the third arbitrator. The Party initiating recourse to arbitration shall include in its notice of arbitration its appointment of an arbitrator. The place of arbitration shall be New York, New York . The language to be used in the arbitral proceedings shall be English. Any determination by such arbitration shall be final and conclusively binding, and shall not include any damages expressly prohibited by Section 10.5 . Judgment on the arbitral award may be entered in any court having jurisdiction thereof. All costs incurred in connection with such arbitration, including reasonable attorneys' fees, shall be borne by the Party which incurs the costs.

#### **11.4 No Arbitration of Patent Disputes .**

Unless otherwise agreed by the Parties, disputes relating to the scope, validity, enforceability or infringement of Patents shall not be subject to arbitration, and shall be submitted to a court or patent office of competent jurisdiction.

#### **11.5 Injunctive Relief and Jurisdiction .**

Nothing in this Agreement shall be construed to limit or preclude a Party from bringing any action in any court of competent jurisdiction for injunctive or other provisional relief to compel the other Party to comply with its obligations hereunder, whether before or during the pendency of arbitration proceedings. The Parties agree that all such suits may, at the option of either Party, be initiated and maintained before the United States District Court for the Southern or Eastern District of New York U.S.A. and both Parties submit to personal jurisdiction and to the service of process, pleadings and notices in connection with any and all actions seeking such injunctive or provisional relief to the court referred to above. Notwithstanding the foregoing, any dispute regarding the validity, scope or enforceability of patents, trademarks or other intellectual property that is or can be the subject of registration with a governmental entity shall be submitted to a court of competent jurisdiction in the territory in which such rights apply.

#### **11.6 Waiver .**

Any delay or failure in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time. No waiver of a breach shall be deemed to be a waiver of a different or subsequent breach.

#### **11.7 Independent Relationship .**

Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

#### **11.8 Export Control.**

This Agreement is made subject to any restrictions concerning the export of the Licensed Product or technical information from the United States of America which may be imposed upon or related to the Parties from time to time by the government of the United States of America . Licensee agrees that it will not export, directly or indirectly, any technical information acquired from Coley under this Agreement, and Licensee agrees that it will not export, directly or indirectly, the Licensed Product using such technical information, to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining any consent that may be required by applicable law or regulation.

#### 11.9 Entire Agreement; Amendment .

This Agreement (along with the Exhibits attached hereto) sets forth the complete, final and entire agreement of the Parties relating to the subject matter hereof and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect thereto and supersedes and terminates all prior agreements, writings and understandings between the Parties to the extent they relate to the subject matter hereof, including the term sheet agreed to by the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as are set forth herein or otherwise contemplated by this Section 11.9. No terms or provisions of this Agreement shall be varied or modified and no subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

#### 11.10 Notices .

Each notice required or permitted to be given or sent under this Agreement shall be in writing and delivered personally or given by facsimile transmission (with confirmation copy by registered first-class mail) or by registered or certified mail (return receipt requested) or internationally-recognized overnight courier, to the Parties at the addresses and facsimile numbers indicated below.

If to Coley, to:

Coley Pharmaceutical Group, Inc.  
Wellesley Gateway  
93 Worcester Street, Suite 101  
Wellesley, MA 02481, U.S.A.  
Attention: President and CEO  
Facsimile: 1-781-431-6403

with a copy to:

Coley Pharmaceutical Group, Inc.  
Wellesley Gateway  
93 Worcester Street, Suite 101  
Wellesley, MA 02481, U.S.A.  
Attention: Senior Vice President and General Counsel  
Facsimile: 1-781-431-6403

If to Licensee, to: Dynavax Technologies Corporation

2929 Seventh Street, Suite 100  
Berkeley, California 94710  
Attn: Chief Executive Officer

with a copy to: Dynavax Technologies Corporation  
2929 Seventh Street, Suite 100  
Berkeley, California 94710  
Attn: General Counsel

All notices, requests, reports, approvals or other communications required or permitted under this Agreement shall be in writing (except in the case of verbal communications and teleconferences updating either Party as to the status of work hereunder), and shall be deemed given (a) when delivered personally; (b) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (c) one (1) day after deposited with a commercial express courier specifying next day delivery, with written verification of receipt. No notice of default or termination shall be deemed effective unless delivered by two (2) of the aforementioned delivery routes. Either Party may change its address or its facsimile number by giving the other Party written notice, delivered in accordance with this Section 11.10.

#### **11.11 Force Majeure .**

Failure of any Party to perform its obligations under this Agreement (except the obligation to make payments when properly due) shall not subject such Party to any liability or place them in breach of any term or condition of this Agreement to the other Party if such failure is caused by any cause beyond the reasonable control of such non-performing Party, including acts of God, fire, explosion, flood, drought, war (whether or not declared), terrorism, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule materials, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right unless such governmental order or regulation was the direct result of a Party's failure to comply with applicable law; provided, however, that the Party affected shall promptly notify the other Party of the condition constituting force majeure as defined herein and shall exert reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed. If a condition constituting force majeure as defined herein exists for more than ninety (90) consecutive days, the Parties shall meet to negotiate a mutually satisfactory solution to the problem, if practicable.

#### **11.12 Severability .**

If any provision of this Agreement is declared invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that, except to the extent that either Party would be adversely affected thereby, this Agreement shall endure except for the part declared invalid or unenforceable by order of such court; provided, however, that in the event that the terms and conditions of this Agreement are materially altered, the Parties will, in good faith, renegotiate the terms and conditions of this Agreement to reasonably substitute a valid and enforceable

provision consistent with the intent of this Agreement for such invalid or unenforceable provision.

#### **11.13 Further Actions .**

Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

#### **11.14 Headings .**

The captions to the several Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Sections hereof.

#### **11.15 Waiver of Rule of Construction .**

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting party shall not apply.

#### **11.16 Counterparts .**

This Agreement may be executed in any number of counterparts, each of which shall be an original as against either Party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument. Copies of executed counterparts of this Agreement transmitted by facsimile shall be considered original executed counterparts provided receipt of such facsimile is confirmed.

#### **11.17 Bankruptcy.**

All rights and licenses granted under this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. Licensee, as a holder of such rights under this Agreement, shall retain and may fully exercise any or all of its rights and elections under the Bankruptcy Code. In the event of commencement of a bankruptcy proceeding by or against Coley under the Bankruptcy Code, Licensee shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed by Licensee hereunder, and all embodiments of such intellectual property, if not already in its possession, shall be promptly delivered to Licensee.

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

**Coley Pharmaceutical Group, Inc.**

**Dynavax Technologies Corporation**

By:  /s/ Robert L. Bratzler

By:  /s/ Dino Dina

Title:  President & CEO

Title:  President & CEO

## EXHIBIT A

### Patents Claiming Priority to Patent Application Serial No. 08/276,358 filed July 1994

Patent #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
70001 US00	US 08/386,063	02/07/95	KRIEG KLINMAN Steinberg	UIRF PHS Coley-US	Immunomodulatory Oligonucleotides	Issued US 6,194,388 B1 02/27/2001 CIP of 08/276,358
0001 WO00 Australia Austria Belgium Canada Canada 01 Denmark Europe France Germany Greece Ireland Italy Japan Liechtenstein Luxembourg Monaco Netherlands Portugal Spain Sweden Switzerland Kingdom	Australia 19127/95 Austria E328890 Belgium 95911630.2 Canada 2194761 Canada 2560114 Denmark 95911630.2 Europe 95911630.2 France 95911630.2 Germany 95911630.2 Greece 95911630.2 Ireland 95911630.2 Italy 0772619 Japan 8-504991 Liechtenstein 95911630.2 Luxembourg 95911630.2 Monaco 95911630.2 Netherlands 95911630.2 Portugal 0772619 Spain 0772619 Sweden 95911630.2 Switzerland 95911630.2 United Kingdom 0772619	02/07/95	KRIEG KLINMAN Steinberg	UIRF PHS Coley-US	Immunomodulatory Oligonucleotides	Granted AU 713040 Granted 0772619 Granted 0772619 Granted 2194761 Pending – Published as PCT Granted 0772619 Granted 0772619 Granted 0772619 Granted 69535036.6-08 Granted 0772619 Granted 0772619 Granted 0772619 Granted 0772619 Granted 0772619 Granted JP 3468773 Granted 0772619 Granted 0772619 Granted 0772619 Granted 0772619 Granted 0772619 Granted 0772619 Granted 0772619 Granted 0772619
70037AU00	Australia 16407/00	02/14/00	KRIEG KLINMAN Steinberg	UIRF PHS Coley-US	Immunomodulatory Oligonucleotides	Granted AU 754463 DIV of AU 713040
70054 EP00 ig Kong 70055 EP00 ig Kong 70056 EP00 ig Kong	EP 01202811.4 Hong Kong 02104747.6 EP 01202813.0 Hong Kong 02104746.7 EP 01202814.8 Hong Kong 02103584.4	02/07/95	KRIEG KLINEMAN steinberg	UIRF PHS Coley-US	Immunostimulatory Oligonucleotides	Published Published Published Published Published Published DIV of EP 95911630.2
70004 US00	US 08/738,652	10/30/96	KRIEG Kline KLINMAN Steinberg	UIRF UIRF PHS Coley-US	Immunostimulatory Nucleic Acid Molecules	Issued 6,207,646 B1 03-27-2001 CIP of US 6,194,388, C1039.70001
70005 US00	US 08/960,774	10/30/97	KRIEG KLINMAN Steinberg	UIRF PHS Coley-US	Immunostimulatory Nucleic Acid Molecules	Issued US 6,239,116 B1 05/29/01 CIP of C1039.70004

GS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
70005 WO00 Australia (DIV) Canada Chile China Europe 01 Europe 02 Japan Korea New Zealand Singapore	97249/01 Canada 2270345 Chile 2983-2005 China 97199352.1 Europe 06115801.0 Europe 06115792.1  Japan 520784/98 South Korea 7003873 New Zealand 335397 Singapore 9901798-0	04/21/99  04/29/99  04/15/99   04/30/99  04/15/99 04/17/99	KRIEG KLINMAN STEINBERG WEINER*	UIRF UIRF PHS Coley-US UIRF	Immunostimulatory Nucleic Acid Molecules	Pending – Published as PCT Published Published Published Published Published Published Pending – Published as PCT Granted NZ 335397 Granted SG 65171
70083 US00	US 10/690,495	10/21/03	KRIEG KLINMAN Steinberg	UIRF PHS Coley-US	Immunomodulatory Oligonucleotides	Published
70083 US01	US 10/769,626 2004/0162258	1/30/04	KRIEG KLINMAN	UIRF PHS	Immunomodulatory Oligonucleotides	Published
70083 US02	US 10/787,737 2004/0171150	2/26/04	STEINBERG	Coley-US		Published
70083 US03	US 10/788,199 2004/0181045	2/26/04				Published
70083 US04	US 10/788,191 2004/0152656	2/26/04				Published
70083 US05	US 10/789,536 2004/0152657	2/26/04				Published
70083 US06	US 10/789,051 2004/0142469	2/26/04				Published
70083 US07	US 10/789,353 2004/0162262	2/26/04				Published
70083 US08	US 10/847,650 2005/0004062	5/17/04				Published
70083 US09	US 10/888,885 2005/0009774	7/9/04				Published
70083 US10	US 10/888,089 2005/0037403	7/9/04				Published
70083 US11	11/067,516 2005/0239736	2/23/05	KRIEG KLINMAN	UIRF PHS	Immunomodulatory Oligonucleotides	Published
70083 US12	11/128,127 2005/0244380	5/11/05	STEINBERG	Coley-US		Published
70083 US13	11/127,797 2005/0245477	5/11/05				Published
70083 US14	11/127,803 2005/0244379	5/11/05				Published
70083 US15	11/296,644	12/7/05				Published
70084 US00	US 10/649,584	08/25/03	KRIEG KLINMAN steinberg	UIRF PHS Coley-US	Methods and Products for Treating HIV Infection	Published CON of CIP application filed 10/09/99

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
70042 US00	US 09/630,319	07/31/00	KRIEG KLINMAN STEINBERG	UIRF PHS Coley-US	Methods for Treating and Preventing of Infectious Disease	Allowed CON of C1039.70005
70077 US00	US 10/619,279	07/14/03	KRIEG KLINMAN Steinberg	UIRF PHS Coley-US	Immunostimulatory Nucleic Acid Molecules	Allowed CON of C1039.70021 Issue Fee Paid 02/23/07
7077 US01	11/071,836 US -2005-0182017-A1	03/03/05	KRIEG	UIRF	Immunostimulatory Nucleic Acid Molecules	Published CON of C1039.70077
70077 CL00	Chile 2984-2005	11/15/05	KRIEG	UIRF	Immunostimulatory Nucleic Acid Molecules	Pending

### CpG activates Dendritic Cells, ex-vivo therapy

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
70061 US00	US 10/161,229	06/03/02	KRIEG HARTMANN	UIRF UIRF	Immunostimulatory Nucleic Acid Molecules for Activating Dendritic Cells	Published DIV of C1039.70017

### ISIS Patents Assigned to Coley – Describes and Claims Immune stimulation by phosphorothioate ODN

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
70014 US00	US 08/467,930	06/06/95	HUTCHERSON Glover	Coley-US Coley-US	Immune Stimulation By Phosphorothioate Oligonucleotide Analogs	Issued US 5,663,153 09/02/97 CIP of US 08/217,988
70016 US00	US 09/009,634	01/20/98	HUTCHERSON Glover	Coley-US Coley-US	Immune Stimulation By Phosphorothioate Oligonucleotide Analogs	Issued US 6,729,230 4/27/04 CON of C1037.70015
70049 US00	10/643,141 US 05-0075302-A1	8/18/03	HUTCHERSON Glover	Coley-US Coley-US	Immune Stimulation By Phosphorothioate Oligonucleotide Analogs	Published CON of C1037.70016

### CpG + Cytokines, optionally an antigen

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
9.70049 US01	US 11/110,189	4/19/05	KRIEG WEINER	UIRF UIRF	Methods and Products for Stimulating the Immune System Using Immunotherapeutic Oligonucleotides and Cytokines	Published DIV of DIV of application filed 04/02/99

### CpG induces INF-alpha

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
9.70044 US01	US 11/056,463 US 05-0169888-A1	02/11/05	HARTMANN BRATZLER KRIEG	Coley-DE Coley-US UIRF	Methods Related to Immunostimulatory Nucleic Acid-Induced Interferon	Published DIV of C1039.70044

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
9.70044 US02	US 11/179,008	07/08/05	HARTMANN BRATZLER KRIEG	Coley-DE Coley-US UIRF	Methods Related to Immunostimulatory Nucleic Acid-Induced Interferon	Published CON of C1039.70044
9.70044 WO00 Canada Israel Italy Japan Mexico New Zealand Singapore South Africa Spain Switzerland United Kingdom	Canada 2,386,019 Israel 148844 Japan 2001526199 MX 20021003059	09/27/00	HARTMANN BRATZLER KRIEG	Coley-DE Coley-US UIRF	Methods Related to Immunostimulatory Nucleic Acid-Induced Interferon	Pending – Published as PCT Pending – Published as PCT Published Pending – Published as PCT

### Mucosal adjuvant

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
1.70006 US00	US 09/316,199	05/21/99	McCLUSKIE Davis	OHRI OHRI	Methods and Products for Inducing Mucosal Immunity	Pending
1.70006 US01	US 10/888,886	7/19/04	McCLUSKIE Davis	OHRI OHRI	Methods and Products for Inducing Mucosal Immunity	Published
1.70006 WO00 Canada Brazil Europe 01 Hong Kong Israel Japan	Canada 2328894 Brazil P19910643-4 Europe 06118586.4 HK 01105556.4 Israel 139813 Japan 2000-550515	05/21/99	McCLUSKIE Davis	OHRI OHRI	Methods and Products for Inducing Mucosal Immunity	Published Published Published Published Pending – Published as PCT Published

### CpG administered at least 3 days prior to antigen

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
1.70002 US01	10/877,369 2004/0234512A1	06/25/04	Wagner LIPFORD	Coley-DE Coley-DE	Methods for Regulating Hematopoiesis Using Immunostimulatory CpG-Oligonucleotides	Published CON of application filed 02/02/99
1.70002 US02	10/876,965 2004/0235778A1	06/25/04	Wagner LIPFORD	Coley-DE Coley-DE	Methods for Regulating Hematopoiesis Using Immunostimulatory CpG-Oligonucleotides	Published CON of C1041.70002
1.70002 US03	10/876,892 2004/0235777A1	06/25/04	Wagner LIPFORD	Coley-DE Coley-DE	Methods for Regulating Hematopoiesis Using Immunostimulatory CpG-Oligonucleotides	Published CON of C1041.70002
1.70002 WO00 Canada Hong Kong Israel Japan	Canada 2328406 HK 06114179.8 Israel 139646 Japan 2000-547969	05/14/99	Wagner LIPFORD	Coley-DE Coley-DE	Methods for Regulating Hematopoiesis Using CpG-Oligonucleotides	Published Published Pending – Published as PCT Published
1.70002 EP01	05108933	9/28/05	Wagner LIPFORD	Coley-DE Coley-DE	Methods for Regulating Hematopoiesis Using CpG-Oligonucleotides	Published CON of C1041.70002 EP

### CpG optimized nucleic acid vectors

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
9.70009 WO00 Europe Hong Kong	EP 98924828.1 HK 00107687.3	05/20/98	Davis KRIEG SCHORR WU	OHRI UIRF Coley-DE OHRI	Vectors and Methods for Immunization or Therapeutic Protocols	Published Published
9.70057US01	US 10/838,659	05/03/04	davis KRIEG SCHORR WU	OHRI UIRF Coley-DE OHRI	Vectors and Methods for Immunization or Therapeutic Protocols	Published

### Infectious disease combinations

WGS #	SN	FILING DATE	INVENTORS	ASSIGNEE	TITLE	STATUS
7.70051 US00	10/666,733 US2004/0131628A1	09/19/03	BRATZLER PETERSEN	Coley-US Coley-US	Nucleic Acids for the Treatment of Disorders Associated with Microorganisms	Published CON of application filed 03/08/01

EXHIBIT B  
Iowa Agreement

REFERENCE IS MADE TO EXHIBIT 10.16 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

REFERENCE IS MADE TO EXHIBIT 10.17 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

EXHIBIT C  
OHRI Agreement

REFERENCE IS MADE TO EXHIBIT 10.18 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

REFERENCE IS MADE TO EXHIBIT 10.19 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

EXHIBIT D

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## **News Release**

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For Immediate Release

### **Coley Pharmaceutical Group Grants Dynavax License for Commercialization of HEPLISAV™**

**Wellesley, MA and Berkeley, CA, June 28, 2007** – Coley Pharmaceutical Group, Inc. (Nasdaq: COLY) and Dynavax Technologies Corporation (Nasdaq: DVAX) today announced they have entered into a license agreement relating to certain TLR Therapeutics™ patents from Coley.

Under the terms of the agreement, Dynavax receives a non-exclusive license under Coley's immunostimulatory oligonucleotide patent estate for the commercialization of HEPLISAV™, a hepatitis B prophylactic vaccine, currently in Phase 3 clinical trials. Coley will receive a \$5 million up-front payment. Coley is also eligible to receive up to an additional \$5.0 million upon regulatory approvals of HEPLISAV, as well as royalty payments for any future sales of HEPLISAV.

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### **About HEPLISAV and Hepatitis B**

HEPLISAV is currently being evaluated in a Phase 3 clinical trial in Canada and in Europe. The multi-center trial, known as PHAST ( Phase 3 Heplis Av Short-regimen Trial), is comparing a two-dose regimen of HEPLISAV administered at 0 and 1 month to the conventional three-dose regimen of Engerix-B®. The enrollment target of the study is approximately 2,000 subjects, ages 11 to 55 years. Dynavax expects to submit a BLA in 2008 for approval of the product with a database of approximately 4,000 patients

In several previous clinical studies, HEPLISAV has been shown to provide seroprotection against hepatitis B faster and with fewer doses than conventional hepatitis B vaccines. Additionally, HEPLISAV has provided 100% seroprotection in all subjects who have received the full regimen, including those who are difficult-to-immunize.

### **About Coley's TLR Therapeutics™**

Coley's TLR Therapeutics are a new class of investigational drug candidates that target certain immune cells through Toll-like receptors. The patents licensed today to Dynavax relate to Coley's Toll-like receptor 9 (TLR9) agonist technology that induce enhanced antigen-specific antibody and T-cell immune responses when used in combination with vaccines. Coley's TLR9 agonist drug candidate has been included in approximately 35 clinical trials of vaccines in development for use in various cancer indications, infectious diseases and biowarfare defense. The most advanced clinical program with Coley's TLR9 agonist vaccine adjuvant candidate is a forthcoming Phase III clinical trial under the direction of GlaxoSmithKline (GSK) as part of a treatment for resectable, early stage lung cancer.

### **About Coley Pharmaceutical Group**

Coley Pharmaceutical Group, Inc. is an international biopharmaceutical company, headquartered in Wellesley, Massachusetts, USA, that discovers and develops TLR Therapeutics™, a new class of investigational drug candidates that direct the human immune system to fight cancers, asthma and allergic diseases and to enhance the effectiveness of vaccines. Coley has established a pipeline of TLR Therapeutic product candidates currently advancing through clinical development with partners and has additional product candidates in preclinical development. Coley has product development, research and license agreements with Pfizer, sanofi-aventis, GSK, Novartis Vaccines, Merck and the United States government. For further information on Coley Pharmaceutical Group please visit [www.coleypharma.com](http://www.coleypharma.com).

### **About Dynavax**

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. The company's TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. Dynavax's pipeline includes: HEPLISAV, a hepatitis B vaccine in Phase 3; TOLAMBA(TM), a ragweed allergy immunotherapeutic; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. A preclinical asthma and COPD program is partnered with AstraZeneca. The National Institutes of Health (NIH) partially funds preclinical work on a vaccine for influenza; Symphony Dynamo, Inc., funds the company's colorectal cancer trials and a preclinical hepatitis C therapeutic program. While the NIH and Symphony provide program support, Dynavax has retained rights to seek strategic

partners for future development and commercialization. For more information, please visit <http://www.dynavax.com> .

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### **Safe Harbor Statements**

Certain statements in this news release concerning Coley's business are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, those relating to royalty payments for any future product sales involving HEPLISAV. Any or all of the forward-looking statements in this press release may turn out to be wrong. They can be affected by inaccurate assumptions Coley might make or by known or unknown risks and uncertainties, including, but not limited to: the early stage of product development; uncertainties as to the future success of ongoing and planned clinical trials; the risk that results from early stage clinical trials may not be indicative of results in later stage trials; the unproven safety and efficacy of products under development; intellectual property rights and litigation; competitive products; and other risks identified in Coley's filings with the Securities and Exchange Commission including, but not limited to, Coley's Annual Report on Form 10-K for the fiscal year ended December 31, 2006. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially. Coley undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise, except as required by applicable law.

This press release contains forward-looking statements concerning Dynavax that are subject to a number of risks and uncertainties, including statements about Dynavax's HEPLISAV hepatitis B vaccine and financial terms of its agreement with Coley. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in Dynavax's business, including difficulties or delays in development; achieving the objectives of collaborative and licensing efforts; and obtaining regulatory approval for HEPLISAV ; the scope and validity of patent protection; possible claims based on the patent rights of others; the ability to obtain additional financing to support operations; and other risks detailed in the "Risk Factors" section of Dynavax's Quarterly Report on Form 10-Q. Dynavax undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

TLR Therapeutics is a trademark of Coley Pharmaceutical Group. HEPLISAV is a trademark of Dynavax Technologies Corporation. All other trademarks are the property of their respective holders.

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**Rule 13a-14(a) Certification of Chief Executive Officer**

## CERTIFICATIONS

I, Eddie Gray, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

By: \_\_\_\_\_ / s/ EDDIE GRAY

**Eddie Gray**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

Date: November 3, 2017

**Rule 13a-14(a) Certification of Principal Financial Officer**

## CERTIFICATIONS

I, Michael Ostrach, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

By: \_\_\_\_\_ / s / MICHAEL OSTRACH  
**Michael Ostrach**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

Date: November 3, 2017

**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Eddie Gray, Chief Executive Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017 (the "Periodic Report"), to which this Certificate is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(ii) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned has set his hand hereto as of the 3<sup>rd</sup> day of November, 2017.

By: \_\_\_\_\_ / s/ EDDIE GRAY  
**Eddie Gray**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Michael Ostrach, Chief Financial Officer of Dynavax Technologies Corporation (the “Company”), hereby certify that, to the best of my knowledge:

(i) The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2017 (the “Periodic Report”), to which this Certificate is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(ii) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned has set his hand hereto as of the 3<sup>rd</sup> day of November, 2017.

By: \_\_\_\_\_ / s / MICHAEL OSTRACH  
**Michael Ostrach**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.