DYNAVAX TECHNOLOGIES CORP
Form 10-Q
November 08, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

or

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

For the transition period from to .

Commission file number: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Delaware 33-0728374

(State or other jurisdiction of (IRS Employer

incorporation or organization) Identification No.)
2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

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

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

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

Large accelerated filer ¨ Accelerated filer x

Non-accelerated filer ¨ Smaller reporting company ¨

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

As of November 5, 2013, the registrant had outstanding 262,625,110 shares of common stock.

INDEX

DYNAVAX TECHNOLOGIES CORPORATION

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.

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. Forward-looking statements are based on our beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may , will , should , could , would, expect, plan, anticipate, believe, estim predict, potential, future, intend, certain, and similar expressions intended to identify forward-looking statement forward-looking statements include discussions regarding our business and financing strategies, research and development, preclinical and clinical product development efforts, intellectual property rights and ability to commercialize our product candidates, as well as the timing of the clinical development and potential regulatory approval of our products, the effect of GAAP accounting pronouncements, the potential for entry into collaborative arrangements, uncertainty regarding our future operating results and prospects for profitability, anticipated sources of funds as well as our plans, objectives, expectations and intentions. Our actual results may vary materially from those in such forward-looking statements as a result of various factors that are identified in Item 1A Risk Factors and elsewhere in this document. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update any forward-looking statements.

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Dynavax Technologies Corporation

Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	September 30, 2013 (unaudited)	December 31, 2012 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 12,191	$ 7,599
Marketable securities available-for-sale	64,283	117,531
Accounts receivable	2,159	1,005
Prepaid expenses and other current assets	1,120	2,052
Total current assets	79,753	128,187
Property and equipment, net	8,454	7,965
Goodwill	2,532	2,475
Restricted cash	657	652
Other assets	302	473
Total assets	$ 91,698	$ 139,752
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,289	$ 2,166
Accrued liabilities	8,148	10,063
Deferred revenues	6,126	6,785
Total current liabilities	15,563	19,014
Deferred revenues, noncurrent	2,751	5,283
Other long-term liabilities	988	629
Total liabilities	19,302	24,926
Commitments and contingencies (Note 5)		
Stockholders equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized and no shares issued and outstanding at September 30, 2013 and December 31, 2012		
Common stock: $0.001 par value; 350,000 and 250,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 183,055 and 182,792 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	183	183
Additional paid-in capital	561,687	550,729
Accumulated other comprehensive loss:		
Unrealized gain on marketable securities available-for-sale	22	45
Cumulative translation adjustment	(341)	(640)

Total accumulated other comprehensive loss		(319)		(595)
Accumulated deficit		(489,155)		(435,491)
Total stockholders equity		72,396		114,826
Total liabilities and stockholders equity	$	91,698	$	139,752

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Collaboration revenue	$ 1,110	$ 1,050	$ 3,349	$ 3,602
Grant revenue	1,700	1,219	3,855	3,188
Service and license revenue	117	605	1,200	1,118
Total revenues	2,927	2,874	8,404	7,908
Operating expenses:				
Research and development	11,770	12,850	38,739	36,631
General and administrative	5,807	7,121	22,243	18,871
Unoccupied facility expense	918		918	
Total operating expenses	18,495	19,971	61,900	55,502
Loss from operations	(15,568)	(17,097)	(53,496)	(47,594)
Interest income	37	91	163	208
Interest expense	(24)	(589)	(83)	(1,765)
Other expense	(120)	(196)	(248)	(255)
Net loss	$ (15,675)	$ (17,791)	$ (53,664)	$ (49,406)
Basic and diluted net loss per share	$ (0.09)	$ (0.10)	$ (0.29)	$ (0.30)
Weighted-average shares used to compute basic and diluted net loss per share	183,022	177,870	182,960	167,039

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	$ (15,675)	$ (17,791)	$ (53,664)	$ (49,406)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities available-for-sale	18	59	(23)	32
Cumulative translation adjustment	473	249	299	38

Other comprehensive income	491	308	276	70
Total comprehensive loss	$ (15,184)	$ (17,483)	$ (53,388)	$ (49,336)

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2013	2012
Operating activities		
Net loss	$ (53,664)	$ (49,406)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	986	898
Gain on disposal of property and equipment	4	6
Accretion of discounts and amortization of premiums of marketable securities	692	970
Interest associated with long-term note payable to Holdings		1,642
Unoccupied facility expense	918	
Stock compensation expense	10,847	6,294
Changes in operating assets and liabilities:		
Accounts receivable	(1,154)	5,842
Prepaid expenses and other current assets	932	(1,289)
Restricted cash and other assets	166	(74)
Accounts payable	(877)	(462)
Accrued liabilities and other long term liabilities	(2,489)	1,011
Deferred revenues	(3,191)	(1,649)
Net cash used in operating activities	(46,830)	(36,217)
Investing activities		
Purchases of marketable securities	(48,573)	(169,634)
Proceeds from maturities of marketable securities	101,105	127,085
Purchases of property and equipment, net	(1,316)	(1,727)
Net cash provided by (used in) investing activities	51,216	(44,276)
Financing activities		
Payments and proceeds from issuances of common stock and warrants, net of issuance costs	(143)	71,124
Proceeds from exercise of stock options and restricted stock awards	30	1,789
Proceeds from employee stock purchase plan	224	307
Net cash provided by financing activities	111	73,220
Effect of exchange rate on cash and cash equivalents	95	(18)
Net increase (decrease) in cash and cash equivalents	4,592	(7,291)
Cash and cash equivalents at beginning of year	7,599	31,941
Cash and cash equivalents at end of year	$ 12,191	$ 24,650
Supplemental disclosure of cash flow information		
Non-cash investing and financing activities:		
Disposal of fully depreciated property and equipment	$ 8	$ 29
Net change in unrealized gain on marketable securities	$ (23)	$ 32

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), a clinical-stage biopharmaceutical company that discovers and develops novel products to prevent and treat infectious and inflammatory diseases and cancer. Our lead product candidate is HEPLISAV , a hepatitis B vaccine product candidate in Phase 3 development.

In addition to HEPLISAV, our pipeline comprises clinical-stage product candidates including an autoimmune program partnered with GlaxoSmithKline, an asthma program partnered with AstraZeneca AB and a cancer immunotherapy program as well as a preclinical development program utilizing nanoparticle adjuvant technology. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer.

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 only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2012, 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, 2012, as filed with the Securities and Exchange Commission (the SEC).

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries, Rhein Biotech GmbH (Rhein or Dynavax Europe) and Dynavax International, B.V. All significant intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

Liquidity and Financial Condition

We have incurred significant operating losses and negative cash flows from operations since our inception. As of September 30, 2013, we had cash, cash equivalents and marketable securities of $76.5 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as of September 30, 2013 and anticipated revenues and funding from existing agreements.

We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV, various human clinical trials for our product candidates and protection of our intellectual property. In order to continue development of our product candidates, including HEPLISAV, and depending upon the cost and timing of an additional clinical study for HEPLISAV, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient additional funding may not be available on acceptable terms, or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV program or our other development programs while we seek strategic alternatives.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results may differ materially from these estimates and assumptions. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, research and development activities, stock-based compensation, asset impairment, contingencies and the valuation of certain liabilities.

Summary of Significant Accounting Policies

There have been no significant changes in our significant accounting policies during the nine months ended September 30, 2013, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

Revenue Recognition

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

On January 1, 2011, we adopted on a prospective basis Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) 2009-13, Multiple-Deliverable Revenue Arrangements, which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated.

Non-refundable upfront fees received for license and collaborative agreements entered into prior to January 1, 2011 and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our expected performance period. Revenue is recognized on a ratable basis, unless we determine that another methodology is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

On January 1, 2011, we elected to prospectively adopt the milestone method as described in FASB ASU 2010-17, Milestone Method of Revenue Recognition. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity s performance or a specific outcome resulting from the entity s performance and (iii) if

achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether the development milestones meet the criteria to be considered substantive. The conditions include: (i) the development work is contingent on either of the following: (a) the vendor s performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor s performance to achieve the milestone; (ii) it relates solely to past performance and; (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt, provided that collection is reasonably assured and the other revenue recognition criteria have been satisfied.

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

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

Recent Accounting Pronouncements

In February 2013, the FASB issued ASU 2013-02, Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income. This ASU expands the presentation of changes in accumulated other comprehensive income. The new guidance requires an entity to disaggregate the total change of each component of other comprehensive income either on the face of the statement of operations or as a separate disclosure in the financial statement footnotes. ASU 2013-02 is effective for fiscal years beginning after December 15, 2012. The Company adopted this guidance in the first quarter of 2013 and the adoption did not have any impact on our financial position, results of operations or cash flows as there were no amounts reclassified out of accumulated other comprehensive income during the periods ended September 30, 2013 and 2012.

2. Fair Value Measurements

The Company defines 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 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 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.

Recurring Fair Value Measurements

The following table represents the fair value hierarchy for our financial assets measured at fair value on a recurring basis as of September 30, 2013 and December 31, 2012 (in thousands):

	Level 1	Level 2	Level 3	Total
September 30, 2013				
Money market funds	$ 9,598	$	$	$ 9,598
U.S. government agency securities		62,283		62,283
U.S. treasury securities		2,500		2,500
Total	$ 9,598	$ 64,783	$	$ 74,381

	Level 1	Level 2	Level 3	Total
December 31, 2012				
Money market funds	$ 3,140	$	$	$ 3,140
U.S. government agency securities		119,233		119,233
U.S. treasury securities		500		500
Municipal securities		715		715
Total	$ 3,140	$ 120,448	$	$ 123,588

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

U.S. Government agency securities, U.S. treasury securities and municipal 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.

3. Cash, cash equivalents and marketable securities

The following is a summary of cash, cash equivalents and marketable securities available-for-sale as of September 30, 2013 and December 31, 2012 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
September 30, 2013				
Cash and cash equivalents:				
Cash	$ 2,093	$	$	$ 2,093
Money market funds	9,598			9,598
U.S. government agency securities	500			500
Total cash and cash equivalents	12,191			12,191
Marketable securities available-for-sale:				
U.S. treasury securities	2,500			2,500
U.S. government agency securities	61,761	22		61,783
Total marketable securities available-for-sale	64,261	22		64,283
Total cash, cash equivalents and marketable securities	$ 76,452	$ 22	$	$ 76,474
December 31, 2012				
Cash and cash equivalents:				
Cash	$ 1,542	$	$	$ 1,542
Money market funds	3,140			3,140
Municipal securities	2,202			2,202
U.S. government agency securities	715			715
Total cash and cash equivalents	7,599			7,599
Marketable securities available-for-sale:				
U.S. government agency securities	116,986	46	(1)	117,031
U.S. treasury securities	500			500
Total marketable securities available-for-sale	117,486	46	(1)	117,531
Total cash, cash equivalents and marketable securities	$ 125,085	$ 46	$ (1)	$ 125,130

The following is a summary of the amortized cost and estimated fair value of marketable securities available-for-sale, by contractual maturity (in thousands):

	September 30, 2013	
	Amortized Cost	Estimated Fair Value

Mature in one year or less	$ 55,761	$ 55,778
Mature after one year through two years	8,500	8,505
	$ 64,261	$ 64,283

We have classified our entire investment portfolio as available-for-sale. We view our available-for-sale portfolio as 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 income (loss) in stockholders equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

·Whether the investment has been in a continuous realized loss position for over 12 months;

·the duration to maturity of our investments;

- our intention to hold the investments to maturity and if it is not more likely than not that we will be required to sell the investment before recovery of the amortized cost basis;

- 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. Financing Agreements

On March 29, 2013, we entered into an At Market Issuance Sales Agreement (the Agreement) with MLV & Co. LLC (MLV) under which we may offer and sell our common stock having aggregate sales proceeds of up to $50,000,000 from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be 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 agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our 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 MLV a commission of up to 3.0% of the gross sales proceeds of any common stock sold through MLV under the Agreement. No sales of our common stock have taken place under this Agreement as of September 30, 2013.

5. Commitments and Contingencies

We lease our facilities in Berkeley, California (Berkeley Lease) and Düsseldorf, Germany (Düsseldorf Lease) under operating leases that expire in June 2018 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space. The sublease income is offset against our rent expense.

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded a one-time estimated unoccupied facility expense of $0.9 million for the three and nine months ended September 30, 2013, representing the present value of the rent payments and other costs associated with the lease, net of estimated sublease income, for the remaining life of the operating lease.

Total net rent expense related to our operating leases for the three months ended September 30, 2013 and 2012, was $0.6 million and $0.4 million, respectively. Total net rent expense related to our operating leases for the nine months ended September 30, 2013 and 2012, was $1.4 million and $1.3 million, respectively. Deferred rent was $0.6 million as of both September 30, 2013 and December 31, 2012.

Future minimum payments under the non-cancelable portion of our operating leases at September 30, 2013, excluding payments from sublease agreements, are as follows (in thousands):

Years ending December 31,	
2013 (remaining months)	$ 559
2014	2,223
2015	2,272
2016	2,323
2017	2,372
Thereafter	3,794
Total	$ 13,543

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, royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of September 30, 2013, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $6.3 million through 2015. 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.

Under the terms of our exclusive license agreements with The Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales, if any, of certain products originating from the licensed technologies.

6. Collaborative Research and Development Agreements

GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop and commercialize toll-like receptor (TLR) inhibitors. Under the terms of the arrangement, we agreed to conduct research and early clinical development in up to four programs: the Lead TLR 7/9 program, a Follow-On TLR 7/9 program, and up to two other TLR programs. In 2011 we began development of a TLR8 program as one of the two additional programs under the collaboration.

We are currently conducting a Phase 1 clinical trial in the Lead TLR 7/9 program with DV1179 in systemic lupus erythematosus patients. The Company is not currently performing any activities on the Follow-On TLR 7/9 program or the TLR8 program. GSK has not yet chosen to initiate development of the remaining program under the agreement.

GSK can exercise its exclusive option to license each program. If GSK exercises an option, GSK would carry out further development and commercialization of the corresponding products. If GSK exercises their option on the Lead TLR 7/9 program, then we are eligible to receive payments of up to approximately $125 million, comprised of contingent option exercise payments and additional payments based on GSK s achievement of certain development, regulatory and commercial objectives.

We are also eligible to receive up to $60 million if aggregate worldwide annual net sales milestones are achieved and tiered royalties ranging from the mid single digit to mid-teens on sales of any products originating from the collaboration. We have retained an option to co-develop and co-promote one product under this agreement.

We received an initial payment of $10 million in 2008. The deliverables under this arrangement did not have stand-alone value and so did not qualify as separate units of accounting. In 2011, we earned and recognized $12 million in substantive development milestone payments related to the initiation of Phase I and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients. In 2011, we earned and recognized $3 million in substantive development milestone payments related to the initiation of development of theTLR8 program.

Revenue from the initial payment from GSK was deferred and is being recognized over the expected period of performance under the agreement, which is estimated to be seven years.

The following table summarizes the revenues recognized under our agreement with GSK (in thousands):

	Three months Ended September 30,		Nine months Ended September 30,	
	2013	2012	2013	2012
Initial payment	$ 357	$ 357	$ 1,071	$ 1,071

As of September 30, 2013 and December 31, 2012, deferred revenue relating to the initial payment was $3.2 million and $4.2 million, respectively.

Absent early termination, the agreement will expire when all of GSK s payment obligations expire. Either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement. Either party may terminate the agreement in the event of insolvency of the other party. GSK also has the option to terminate the agreement without cause upon prior written notice within a specified window of time dependent upon the stage of clinical development of the programs.

AstraZeneca

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

In October 2011, we amended our agreement with AstraZeneca to provide that we will conduct initial clinical development of AZD 1419. Under the terms of the amended agreement, AstraZeneca will fund all program expenses to cover the cost of development activities through Phase 2a, estimated to total approximately $20 million. We received an initial payment of $3 million to begin the clinical development program. In the first quarter of 2012, we received a $2.6 million payment to advance AZD1419 into preclinical toxicology studies and these toxicology studies were completed in the third quarter of 2012. We and AstraZeneca have agreed to advance AZD 1419 towards a Phase 1 clinical trial, which resulted in a development funding payment of $6 million, received in the fourth quarter of 2012. If AstraZeneca chooses to advance the program following completion of Phase 2a, we will receive a $20 million milestone payment and AstraZeneca will retain its rights to develop the candidate therapy and to commercialize the resulting asthma product. We are eligible to receive additional milestone payments, which we have determined to be substantive milestones, of up to approximately $100 million, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization, we are eligible to receive tiered royalties ranging from the mid to high single-digits based on product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

Revenue from the initial payment was deferred and is being recognized over the expected period of performance under the agreement, which is approximately 50 months. Revenue from the development funding payment is being recognized as the development work is performed.

The following table summarizes the revenues earned under our agreement with AstraZeneca (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Initial payment	$ 180	$ 180	$ 540	$ 540
Performance of research activities	573	513	1,738	1,991
Total	$ 753	$ 693	$ 2,278	$ 2,531

As of September 30, 2013 and December 31, 2012, total deferred revenue from the initial payment and development funding payments was $5.7 million and $7.7 million, respectively.

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

National Institutes of Health (NIH) and Other Funding

We have been awarded various grants from the NIH and the NIH s National Institute of Allergy and Infectious Disease (NIAID) in order to fund research. The awards are related to specific research objectives and we earn revenue as the related research expenses are incurred. We have earned revenue during the periods ended September 30, 2013 and 2012 from the following awards:

- September 2013, NIH awarded us $0.2 million to fund research in developing TLR antagonists for therapy of hepatic fibrosis and cirrhosis.

- June 2012, NIH awarded us $0.6 million to fund research in screening for inhibitors of TLR8 for treatment of autoimmune diseases.

- May 2012, NIH awarded us $0.4 million to fund development of TLR8 inhibitors for treatment of rheumatoid arthritis.

- July 2011, NIH awarded us $0.6 million to fund research in preclinical models of skin autoimmune inflammation.

- August 2010, NIAID awarded us a grant to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against the hepatitis B virus. This study will be one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program. We have been awarded a total of $1.4 million under this grant.

- July 2010, NIH awarded us $0.6 million to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus.

- September 2008, NIAID awarded us a five-year $17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract supports adjuvant development for anthrax as well as other disease models.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
NIAID contracts	$ 1,465	$ 1,100	$ 3,125	$ 2,840
All other NIH contracts	235	119	730	348
Total grant revenue	$ 1,700	$ 1,219	$ 3,855	$ 3,188

7. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, outstanding options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Outstanding warrants, stock options and stock awards to purchase approximately 31,100,000 and 34,400,000 shares of common stock as of September 30, 2013 and 2012, respectively, were excluded from the calculation of diluted net loss per share for the quarters ended September 30, 2013 and 2012, because the effect of their inclusion would have been anti-dilutive.

8. Stockholders Equity

On May 29, 2013, the stockholders of the Company approved an amendment to the Company s 2011 Equity Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under the plan by 10,000,000.

Option activity under our stock-based compensation plans during the nine months ended September 30, 2013 was as follows (in thousands except per share amounts):

	Shares Underlying Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2012	13,806	$ 3.38		
Options granted	5,542	2.71		
Options exercised	(74)	1.41		
Options cancelled:				
Options forfeited (unvested)	(2,028)	3.33		
Options cancelled (vested)	(381)	3.56		
Balance as of September 30, 2013	16,865	$ 3.17	5.35	$ 310
Vested and expected to vest as of September 30, 2013	16,272	$ 3.18	4.97	$ 310
Exercisable as of September 30, 2013	10,977	$ 3.35	3.37	$ 307

Restricted stock unit activity under our stock-based compensation plans during the nine months ended September 30, 2013 was as follows (in thousands except per share amounts):

	Number of Shares	Weighted-Average Grant-Date Fair Value
Balance as of December 31, 2012	1,755	$ 4.23
Granted	250	1.23
Vested		
Forfeited or expired	(230)	4.23
Balance as of September 30, 2013	1,775	$ 3.81

The aggregate intrinsic value of the restricted stock units outstanding as of September 30, 2013, based on our stock price on that date, was $2.1 million.

As of September 30, 2013, approximately 2,600,000 shares underlying stock options and restricted stock units awards with performance-based vesting criteria were outstanding.

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

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

	Stock Options Three Months Ended September 30,		Stock Options Nine Months Ended September 30,		Employee Stock Purchase Plan Nine Months Ended September 30,	
	2013	2012	2013	2012	2013	2012
Weighted-average fair value	$ 1.15	$ 3.34	$ 2.43	$ 3.30	$ 0.93	$ 3.80
Risk-free interest rate	1.9%	0.6%	1.1%	0.5%	0.2%	0.2%
Expected life (in years)	5.6	4.0	5.9	4.0	1.3	1.0
Volatility	1.5	1.6	1.4	1.6	0.8	1.6

Expected volatility is based on historical volatility of our stock price. The expected life of options granted is estimated based on historical option exercise and employee termination data, giving consideration to options that have not yet completed a full life cycle. Our senior management, who hold a majority of the options outstanding, and other employees were grouped and considered separately for valuation purposes. The expected life of the options for senior management is six years and for other employees five and a half years. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield is zero percent for all years and is based on our history and expectation of dividend payouts. All stock option awards to non-employees are accounted for at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model.

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value-based measurement is amortized to expense on a straight-line basis over the vesting periods. For equity awards with performance-based vesting criteria, the fair value-based measurement is amortized to expense over the remaining vesting period commencing when the achievement of the vesting criteria becomes probable.

We recognized stock-based compensation expense of $2.8 million and $1.9 million for the three months ended September 30, 2013 and 2012, respectively. Stock-based compensation expense for the three months ended September 30, 2013 includes $1.0 million related to severance arrangements. We recognized stock-based compensation expense of $10.8 million and $6.3 million for the nine months ended September 30, 2013 and 2012, respectively. Stock-based compensation during the nine months ended September 30, 2013 included $5.1 million related to severance arrangements. The Company recorded stock-based compensation expense for awards to non-employees of $0.4 million for the nine months ended September 30, 2013.

The components of stock-based compensation expense were (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development	$ 1,001	$ 824	$ 3,351	$ 2,565
General and administrative	1,844	1,079	7,496	3,729

Total	$ 2,845	$ 1,903	$ 10,847	$ 6,294

As of September 30, 2013, the total unrecognized compensation cost related to non-vested equity awards including all awards with time-based vesting amounted to $12.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.93 years. Additionally, as of September 30, 2013, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria not deemed probable of vesting amounted to $5.0 million.

Employee Stock Purchase Plan

As of September 30, 2013, 996,000 shares have been reserved and approved for issuance under the Purchase Plan, subject to adjustment for a stock split, any future stock dividend or other similar change in our common stock or capital structure. To date, employees have acquired 828,414 shares of our common stock under the Purchase Plan including 129,690 shares during the nine months ended September 30, 2013. As of September 30, 2013, 167,586 shares of our common stock remained available for future purchases.

Warrants

As of September 30, 2013, warrants to purchase an aggregate of approximately 12,500,000 shares of our common stock were outstanding. The warrants are exercisable at a weighted average price of $1.96 per share. During the nine months ended September 30, 2013 and September 30, 2012, warrants were exercised to purchase an aggregate of approximately 84,000 and 4,700,000 shares of our common stock, respectively.

9. Subsequent Events

On October 30, 2013, we sold 79,570,000 shares of our common stock at a price of $1.075 per share and 43,430 shares of the Company s Series B Convertible Preferred Stock (Series B) at a price of $1,075.00, in separate, concurrent underwritten public offerings. The sale of common stock and Series B resulted in aggregate net proceeds to us of approximately $125 million after deducting estimated commissions and offering expenses.

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 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, 2012.

Overview

Dynavax Technologies Corporation (we, our, us, Dynavax or the Company), a clinical-stage biopharmaceutical company that discovers and develops novel products to prevent and treat infectious and inflammatory diseases and cancer. Our lead product candidate is HEPLISAV , a hepatitis B vaccine product candidate in Phase 3 development.

In addition to HEPLISAV, our pipeline comprises clinical-stage product candidates including an autoimmune program partnered with GlaxoSmithKline, an asthma program partnered with AstraZeneca AB and a cancer immunotherapy program as well as a preclinical development program utilizing nanoparticle adjuvant technology. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer.

Recent Developments

Following discussions with the U.S. Food and Drug Administration (FDA), we recently finalized the design of a new clinical study of HEPLISAV. The study is intended to provide a sufficiently-sized safety database for the FDA to complete its review of Dynavax s Biologics License Application (BLA). It will be a Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV compared with Engerix-B® in adults 18 to 70 years of age. The study will include 5,500 HEPLISAV subjects and 2,500 Engerix-B subjects, stratified by age and diabetes diagnosis. HEPLISAV subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months.

The primary objectives of the study will be: (1) to evaluate the overall safety of HEPLISAV with respect to clinically significant adverse events and (2) to demonstrate the noninferiority of the peak seroprotection rate (SPR) induced by HEPLISAV versus Engerix-B in subjects with type 2 diabetes mellitus. All HEPLISAV subjects will be evaluated for safety for one year following the second dose and all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee. Immunogenicity assessments will be conducted in a subset of subjects, including those with type 2 diabetes. We intend to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015 and estimate the external costs of the study to be in the range of $50-55 million.

In Europe, our Marketing Authorization Application for HEPLISAV is currently under review by the European Medicines Agency s (EMA). In late 2012, we received the 120-Day List of Questions which relate to Suitability of different patient populations, Safety database, Good Manufacturing Practices (GMP) and Good Clinical Practices

(GCP) matters. In the early summer EMA added to the list of questions, resetting the clock for our response. EMA has also inspected several study sites, Dynavax and our clinical contract research organization. The focus of the GCP inspection was HBV-17, a 500 patient study in CKD patients that is part of the EMA application but not the US application. We are currently preparing our response to the 120-Day Questions and expect to submit the response before the end of 2013. EMA will consider our responses and in the first quarter of 2014 is expected to issue the 180-Day List of Outstanding Issues (LOI). We anticipate that the discussion regarding the patient group who would most likely benefit, and some of the GMP/GCP matters will need to be resolved following issuance of the 180-Day LOI.

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 (GAAP) for interim financial information. 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, including those related to revenue recognition, research and development activities, stock-based compensation, asset impairment, contingencies and the valuation of certain liabilities. 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. Actual results may differ 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, 2013, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

Results of Operations

Revenues

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

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

	Three Months Ended September 30,		Increase (Decrease) from 2012 to 2013		Nine Months Ended September 30,		Increase (Decrease) from 2012 to 2013	
Revenues:	2013	2012	$	%	2013	2012	$	%
Collaboration revenue	$ 1,110	$ 1,050	$ 60	6%	$ 3,349	$ 3,602	$ (253)	(7)%
Grant revenue	1,700	1,219	481	39%	3,855	3,188	$ 667	21%
Service and license revenue	117	605	(488)	(81)%	1,200	1,118	$ 82	7%
Total revenues	$ 2,927	$ 2,874	$ 53	2%	$ 8,404	$ 7,908	$ 496	6%

Total revenues for the three months ended September 30, 2013 increased by $0.1 million, or 2%, as compared to the same quarter of 2012. Grant revenue increased by $0.5 million as compared to the same period in 2012 primarily due to our NIAID contract for adjuvant development. Service and license revenue for the third quarter of 2013 decreased by $0.5 million as compared to the same period in 2012 due to timing of royalties collected on licensed technology by Rhein Biotech GmbH (Rhein or Dynavax Europe).

Total revenues for the nine months ended September 30, 2013 increased by $0.5 million, or 6%, as compared to the same period of 2012. Collaboration revenue for the first nine months of 2013 decreased as compared to the same period in 2012 due to the completion of certain research activities under our collaboration agreement with AstraZeneca. Grant revenue for the first nine months of 2013 increased as compared to the same period in 2012 due to

activities under our NIAID contract for adjuvant development.

Research and Development Expense

Research and development expense consists primarily of compensation and related personnel costs, which include benefits, recruitment, travel and supply costs; outside services; allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings and manufacturing of our product candidates. For the nine months ended September 30, 2013 and 2012, approximately 74% and 73%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our lead product candidate, HEPLISAV. The remainder of our research and development expense results primarily from early-stage programs under collaborative research and development agreements.

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

	Three Months Ended September 30,		Increase (Decrease) from 2012 to 2013		Nine Months Ended September 30,		Increase (Decrease) from 2012 to 2013	
Research and development expense	2013	2012	$	%	2013	2012	$	%
Compensation and related personnel costs	$ 4,831	$ 5,159	$ (328)	(6)%	$ 15,780	$ 15,075	$ 705	5%
Outside services	4,469	5,542	(1,073)	(19)%	15,193	15,049	144	1%
Facility costs	1,469	1,325	144	11%	4,415	3,942	473	12%
Non-cash stock-based compensation	1,001	824	177	21%	3,351	2,565	786	31%
Total research and development expense	$ 11,770	$ 12,850	$ (1,080)	(8)%	$ 38,739	$ 36,631	$ 2,108	6%

Research and development expense for the three months ended September 30, 2013 decreased by $1.1 million, or 8%, as compared to the same period in 2012. Outside services decreased by $1.1 million primarily due to lower clinical trial expense. Facility costs increased by $0.1 million due to repairs and maintenance of our manufacturing facility and depreciation on recently purchased manufacturing equipment. Non-cash stock-based compensation costs increased by $0.2 million due to accelerated vesting of stock options related to management continuity and severance agreements with certain employees.

Research and development expense for the nine months ended September 30, 2013 increased by $2.1 million, or 6%, as compared to the same period in 2012. During the nine months ended September 30, 2013, we recorded $0.4 million of severance expense and $0.7 million of non-cash stock-based compensation expense for accelerated vesting of stock options related to management continuity and severance agreements with certain employees. Facility costs increased by $0.5 million due to repairs and maintenance of our manufacturing facility and depreciation on recently purchased manufacturing equipment.

General and Administrative Expense

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

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

General and administrative expense	Three Months Ended September 30, 2013	2012	Increase (Decrease) from 2012 to 2013 $	%	Nine Months Ended September 30, 2013	2012	Increase (Decrease) from 2012 to 2013 $	%
Compensation and related personnel costs	$ 2,301	$ 2,539	$ (238)	(9)%	$ 9,080	$ 6,842	$ 2,238	33%
Outside services	925	2,481	(1,556)	(63)%	3,302	6,137	(2,835)	(46)%
Legal costs	567	866	(299)	(35)%	1,895	1,750	145	8%
Facility costs	170	156	14	9%	470	413	57	14%
Non-cash stock-based compensation	1,844	1,079	765	71%	7,496	3,729	3,767	101%
Total general and administrative expense	$ 5,807	$ 7,121	$ (1,314)	(18)%	$ 22,243	$ 18,871	$ 3,372	18%

General and administrative expense for the three months ended September 30, 2013 decreased by $1.3 million, or 18%, as compared to the same period in 2012. Outside services decreased by $1.6 million compared to the same period in the prior year due to reduced marketing expenses. General corporate and patent related legal expenses decreased by $0.3 million compared to the same period in the prior year. During the three months ended September 30, 2013, we recorded $1.0 million of non-cash stock-based compensation expense for accelerated vesting of stock options related to management continuity and severance agreements with certain employees.

General and administrative expense for the nine months ended September 30, 2013 increased by $3.4 million, or 18%, as compared to the same period in 2012. During the nine months ended September 30, 2013, we recorded $2.9 million of severance expense and other one-time compensation costs as well as $4.6 million of non-cash stock-based compensation expense for accelerated vesting of stock options related to with the transition of our CEO and certain other employees and executive officers. Outside services decreased by $2.8 million compared to the same period in prior year due to reduced marketing expenses. General corporate and patent related legal expenses increased by $0.1 million compared to the same period in the prior year.

Interest Income, Interest Expense, and Other Expense

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Interest expense in 2012 was related to the $15 million note payable issued to Symphony Dynamo Holdings LLC (Holdings), which was paid on December 31, 2012. Other expense includes gains and losses on foreign currency transactions as well as gains and losses on disposals of property and equipment. The following is a summary of our interest income and expense and other expense (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2012 to 2013		Nine Months Ended September 30,		Increase (Decrease) from 2012 to 2013	
	2013	2012	$	%	2013	2012	$	%
Interest income	$ 37	$ 91	$ (54)	(59)%	$ 163	$ 208	$ (45)	(22)%
Interest expense	$ (24)	$ (589)	$ (565)	(96)%	$ (83)	$ (1,765)	$ (1,682)	(95)%
Other expense	$ (120)	$ (196)	$ (76)	(39)%	$ (248)	$ (255)	$ (7)	(3)%

Interest income for the three and nine months ended September 30, 2013 decreased on a year over year basis due to lower average marketable securities balances.

Interest expense for the three and nine months ended September 30, 2013, decreased over the same periods in 2012 due to the interest recorded for the note payable to Holdings which was repaid on December 31, 2012.

Other expense for the three and nine months ended September 30, 2013 and 2012 primarily represents gains and losses on foreign currency transactions due to fluctuations in the value of the Euro compared to the U.S. dollar and withholding taxes paid in Europe.

Liquidity and Capital Resources

As of September 30, 2013, we had $76.5 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 to fund our operations. Our funds are currently invested in short-term money market funds, U.S. government agency securities and U.S. treasury securities.

On October 30, 2013, we sold 79,570,000 shares of our common stock at a price of $1.075 per share and 43,430 shares of the Company s Series B Convertible Preferred Stock (Series B) at a price of $1,075.00 in separate, concurrent underwritten public offerings. The sale of common stock and the Series B resulted in aggregate net proceeds to us of approximately $125 million after deducting estimated commissions and offering expenses.

On March 29, 2013, we entered into an At Market Issuance Sales Agreement (the Agreement) with MLV & Co. LLC (MLV) under which we may offer and sell our common stock having aggregate sales proceeds of up to $50,000,000 from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be 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 agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our 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 MLV a commission of up to 3.0% of the gross sales proceeds of any common stock sold through MLV under the Agreement. No sales of our common stock have taken place under this Agreement as of September 30, 2013.

During the nine months ended September 30, 2013, we used $46.8 million of cash for our operations primarily due to our net loss of $53.7 million, of which $13.4 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, accretion and amortization on marketable securities and unoccupied facility expense. By comparison, during the nine months ended September 30, 2012, we used $36.2 million of cash for our operations primarily due to a net loss of $49.4 million, of which $9.8 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, accretion and amortization on marketable securities and non-cash interest on borrowings. Cash used in our operations for the first nine-months of 2013 increased by $10.6 million compared to cash used in our operations for the first nine-months of 2012, due primarily to a $4.3 million increase in our net loss, a $7.0 million change in accounts receivable due to collections in the first half of 2012 related to payments received from our collaborations with GSK and AstraZeneca and a $4.6 million increase in stock-based compensation expense.

During the nine months ended September 30, 2013, cash provided by investing activities was $51.2 million compared to $44.3 million of cash used in investing activities for the nine months ended September 30, 2012. Cash provided by investing activities during the first nine-months of 2013 included $52.5 million of net proceeds from maturities of marketable securities versus $42.5 million of net purchases of marketable securities during the first nine-months of 2012.

During the nine months ended September 30, 2013, cash provided by financing activities was $0.1 million, compared to $73.2 million for the same period in 2012. Cash provided by financing activities in the first nine-months of 2012 included the sale of 17,500,000 shares of common stock in a public offering for net proceeds of $69.6 million as well as proceeds from stock option and warrant exercises of $3.3 million.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand as of September 30, 2013, and anticipated revenues and funding from existing agreements. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV, various human clinical trials for our product candidates and protection of our intellectual property. In order to continue development of our product candidates, including HEPLISAV, and depending upon the cost and timing of an additional clinical study for HEPLISAV, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

Contractual Obligations

The following summarizes our significant contractual obligations as of September 30, 2013, and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual Obligations:	Total	2013	2014-2015	2016-2017	2018 and Thereafter
Future minimum payments under our operating leases	$ 13,543	$ 559	$ 4,495	$ 4,695	$ 3,794

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

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded a one-time estimated unoccupied facility expense of $0.9 million for the three and nine months ended September 30, 2013, representing the present value of the rent payments and other costs associated with the lease, net of estimated sublease income, for the remaining life of the operating lease.

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

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of September 30, 2013, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $6.3 million through 2015. 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.

Under the terms of our exclusive license agreements with The Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of certain products, if any, originating from the licensed technologies.

Off-balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. The primary objective of our investment activities is to preserve principal while at the same time maximizing the 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 a variety of securities, including short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt or home equity loans. If interest rates were to rise or fall from current levels by 100 basis points or by 125 basis points, the change in our net unrealized loss on investments would be $0.7 million or $0.8 million, respectively.

We do not have derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents and marketable securities, we do not expect any material loss with respect to our investment portfolio.

Foreign Currency Risk. We have certain investments outside the United States for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the condensed consolidated balance sheet as of September 30, 2013, was $0.3 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. As of September 30, 2013, 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 (Exchange Act) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and 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.

The Company s management, under the supervision and with the participation of the Company s Chief Executive Officer and Principal Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company s disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Principal Financial Officer concluded that the Company s disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of period covered by this report are effective at the reasonable assurance level.

(b) Changes in internal controls

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On June 18, 2013, the first of two substantially similar securities class action complaints was filed in the U.S. District Court for the Northern District of California against the Company and certain of its former executive officers. The second was filed on June 26, 2013. On August 22, 2013, these two complaints and all related actions that subsequently may be filed in, or transferred to, the District Court were consolidated into a single case entitled In re Dynavax Technologies Securities Litigation. On September 27, 2013, the Court appointed a lead plaintiff and lead counsel. The complaints allege that between April 26, 2012 and June 10, 2013, the Company and certain of its executive officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with statements related to our product candidate, HEPLISAV. The complaints seek unspecified damages, interest, attorneys fees, and other costs.

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

On August 21, 2013, pursuant to a stipulation between the parties, the State Court stayed the state derivative case pending a decision on the Company s motion to dismiss in the In re Dynavax Technologies Securities Litigation. On October 17, 2013, pursuant to a stipulation between the parties, the federal court stayed the federal derivative case pending a decision on the Company s motion to dismiss in the In re Dynavax Technologies Securities Litigation.

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

ITEM 1A. RISK FACTORS

Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future efforts to obtain regulatory approval, timing of development activities, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors. We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part 1, Item 1A Risk Factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2013.

Risks Related to our Business

The success of our product candidates, in particular HEPLISAV, depends on regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy, consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, 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 United States and in other countries are uncertain, can take many years and require the expenditure of substantial resources.

For our lead product, HEPLISAV, our BLA must be approved by the FDA and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining approval of a BLA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials, including the Phase 3 results, or the development program is satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or a conclusion that the data fails to meet statistical or clinical significance; acceptability of data generated at our clinical trial sites that are monitored by third party clinical research organizations; the results of an FDA or other advisory committee that may recommend against approval of our BLA or may recommend that the FDA or other agencies require, as a condition for approval, additional preclinical studies or clinical trials; and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, in our 2013 Complete Response Letter from the FDA (the Complete Response Letter), HEPLISAV was not approvable for the proposed indication based on insufficient patient safety data for an indication in adults 18-70 years of age without further evaluation of safety. There can be no assurance that additional clinical studies will support approval. The FDA also requested additional data from our process validation program as well as clarifying information on the manufacturing controls and facilities with respect to quality assurance of commercial product. There can be no assurance that Dynavax can successfully produce the requisite data in a timely manner or that the data will be sufficient for approval.

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

Failure to receive approval or significant delay in being able to provide the safety and manufacturing information required for approval of our BLA for HEPLISAV would have a material adverse effect on our business and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product may restrict to whom we and our potential partners, if any, may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

Before granting product approval, the FDA must determine that our or our third party contractor s manufacturing facilities meet current 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 current 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 candidate than we currently expect before granting regulatory approval, if regulatory approval is granted at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

Our registration and commercial timelines depend on further discussions with the FDA and corresponding foreign regulatory agencies and requirements and requests they may make for additional data or completion of additional

clinical trials. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- potentially limit the markets for those products;

· adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;

· cause us to abandon the development of the affected product candidate; or

· limit our ability to obtain additional financing on acceptable terms, if at all.

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

We expect to commence additional trials of HEPLISAV and other product candidates in the future. Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain IRB or other 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.

We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they 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.

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

In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, and different standards of medical care. Foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs.

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 cGMP and other requirements in foreign countries, and may require large numbers of participants.

The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

· deficiencies in the trial design;

- deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;

- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;

- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;

- the time required to determine whether the product candidate is effective may be longer than expected;

- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;

- the product candidate may appear to be no more effective than current therapies;

- the quality or stability of the product candidate may fail to conform to acceptable standards;

- our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;

- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;

- our liability to obtain regulatory approval to conduct a clinical trial;

- lack of adequate funding to continue the clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;

- our inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or

- our inability to retain participants who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger populations, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management s time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by an independent data safety monitoring board, or 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 and most of our earlier stage programs rely on ISS-based technology. Serious adverse event data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.

HEPLISAV incorporates our 1018 ISS compound and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. Most of our clinical product candidates contain ISS, and if a common safety risk across therapeutic areas were identified, it may hinder our ability to enter into potential collaboration arrangements or commercialize our product candidates. If adverse event data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

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

Although certain of our employees have commercialization experience, as a company we currently have no sales, marketing or distribution capabilities. HEPLISAV product sales are currently expected to generate a substantial portion of our future revenue, if HEPLISAV is approved. To commercialize HEPLISAV, we must either develop sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services, which will require resources and time and we may not be able to enter into these arrangements on acceptable terms. If we decide to market HEPLISAV directly, we must commit significant resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. In particular, significant resources may be necessary to successfully market, sell and distribute HEPLISAV to patients with diabetes, a group recently recommended by the CDC and ACIP to receive hepatitis B vaccination. Moreover, our pricing and reimbursement strategies with respect to our initial approval plans for HEPLISAV may significantly impact our ability to achieve commercial success in this potential patient population.

Factors that may inhibit our efforts to commercialize HEPLISAV directly or indirectly with a partner if approved 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 administer 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;
- our inability to expand and sustain qualified manufacturing capacity to meet demand, in particular if there is a significant increase in demand due to the recommendation to vaccinate persons with diabetes if we should obtain approval to market to those patients;
- our inability to determine appropriate pricing and reimbursement strategies for HEPLISAV in the potential patient populations that may use HEPLISAV, particularly in the diabetes market; and
- possible claims against us, including enjoining sales of HEPLISAV, based on the patent rights of others; and
- unanticipated delays, costs and expenses associated with manufacturing and commercialization of our products, including costs of maintaining and scaling up manufacturing capabilities and creating and sustaining an independent sales and marketing organization in various territories.

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, 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, 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 ISS we will require for commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including ISS, certain antigens, the combination of ISS and the antigens, and the formulation, fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development or commercialization efforts.

We have relied on a limited number of suppliers to produce ISS for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV. To date, we have manufactured only small quantities of ISS and 1018 ISS ourselves for development purposes. If we

were unable to maintain our existing supplier for 1018 ISS, 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. We or other third parties may not be able to produce 1018 ISS at a cost, quantity and quality that are available from our current third-party supplier.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of biological products is a time-consuming and complex process, which must be performed in compliance with current GMP regulations.

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

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

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

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

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

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

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

We may introduce certain of our product candidates, including HEPLISAV, in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States 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 submitted HEPLISAV for marketing approval in Europe. The Complete Response Letter from the FDA and requirement to provide additional safety data may result in further consideration of our MAA in Europe and we may not obtain foreign regulatory approvals on a timely basis, if at all. Specifically, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

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

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

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

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

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

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

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

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

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

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

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

We will 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, if approved. Failure to obtain a collaborative relationship for HEPLISAV, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this product. We also will

need to enter into or maintain collaborative relationships to provide funding to support our other research and development programs. 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.

The financial terms of future collaborative licensing or financing arrangements could result in dilution of our share value.

Funding from collaboration partners and other parties may in the future involve issuance of our equity securities. Because we do not currently have any such arrangements, we cannot be certain how the terms under which such shares are issued will be determined or when such determinations will be made. The current market for financing or collaborative arrangements often involves the issuance of warrants as additional consideration in establishing the purchase price of the equity securities issued. Any such issuance could result in dilution in the value of our issued and outstanding shares.

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

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious and inflammatory diseases. For example, if it is approved, HEPLISAV will compete in the United States with established hepatitis B vaccines marketed by Merck and GSK and outside the United States with vaccines from those companies and several additional established pharmaceutical companies. 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.

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.

As we advance HEPLISAV through the development stage towards 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. In addition, we expect to enhance our senior management group as we prepare to become a commercial organization. Our future financial performance and our ability to commercialize HEPLISAV 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 development 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 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. 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;

- 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; and

- state law equivalents of each of the above federal laws, 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 payer, including commercial insurers.

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 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 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 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.

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.

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.

Two class action complaints brought by purported stockholders and one purported stockholder derivative complaint 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, 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 in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials 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. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials 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. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, 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.

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 $489.2 million as of September 30, 2013. 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 Rhein. 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 our addition of infrastructure and operations to support regulatory approval and commercialization of HEPLISAV.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV can be further developed, financed or commercialized in a timely manner without significant additional studies or patient data or significant expense; whether current development efforts will be sufficient to support approval of HEPLISAV; or if approved, whether the market for HEPLISAV will be sufficient for us to reach profitability. The 2013 Complete Response Letter from the FDA for HEPLISAV means that our efforts to achieve product revenues are delayed and there can be no assurance that we will 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, is approved, to commence sales and marketing activities.

To continue development of our product candidates and, if it is approved, to launch HEPLISAV, we may 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 commercialization of our product candidates, particularly HEPLISAV;

·various human clinical trials for our product candidates; and

·protection of our intellectual property.

We currently estimate that we have sufficient resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as well as anticipated revenues and funding from existing agreements.

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. Additional equity 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 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 addition, we must make timely payments or meet diligence obligations to maintain any such licenses in effect. 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 recombinant HBsAg, a component of HEPLISAV. In addition, the Institut Pasteur also owns or has exclusive licenses to patents relating to aspects of production of recombinant HBsAg. While some of these patents have expired or will soon expire outside the United States, they remain in force in the United States. To the extent we are able to commercialize HEPLISAV in the United States 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 the commercialization of HEPLISAV 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 ISS 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 of ISS other than with respect to HEPLISAV, 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 United States, 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 United States 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 United States, 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 communications from the FDA or other regulatory agencies, for example as evidenced by our stock decline of over 30% following our 2013 announcement of a Complete Response Letter from the FDA and the requirement of additional safety data;

- 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;

- 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;

- our ability to maintain continued listing on the NASDAQ markets or similar exchanges; 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 litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility. We may in the future be the target of such litigation. Securities 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, 2013, we had 183,055,110 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.

In addition, we have filed shelf registration statements on Form S-3 under the Securities Act of 1933, as amended, to register securities that we may choose to issue in the future and on Form S-8 to register the shares of our common stock reserved for issuance under our stock option plans.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit

Number	Document
1.1[1]	At Market Issuance Sales Agreement, dated March 29, 2013, by and between Dynavax Technologies Corporation and MLV & Co. LLC.
1.2[2]	Underwriting Agreement, dated October 25, 2013.
1.3[2]	Underwriting Agreement, dated October 25, 2013.
3.1[3]	Sixth Amended and Restated Certificate of Incorporation.
3.2[3]	Amended and Restated Bylaws.
3.3[4]	Form of Certificate of Designation of Series A Junior Participating Preferred Stock.
3.4[5]	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.5[6]	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.6[7]	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation.
3.7[16]	Certificate of Designation of Series B Convertible Preferred Stock.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5,3.6 and 3.7 above.
4.2[8]	Registration Rights Agreement.
4.3[8]	Form of Warrant.
4.4[9]	Form of Specimen Common Stock Certificate.
4.5[3]	Rights Agreement dated as of November 5, 2008, by and between Dynavax Technologies Corporation and Mellon Investor Services LLC.
4.6[3]	Form of Right Certificate.
4.7[10]	Form of Restricted Stock Unit Award Agreement.
4.8[11]	Form of Amended Warrant.
4.9[12]	Form of Warrant.
4.10[13]	Registration Rights Agreement dated as of September 20, 2010, by and between Dynavax Technologies Corporation and Aspire Capital Fund, LLC.
4.11[16]	Form of Specimen Preferred Stock Certificate.
10.76[14]	Consulting Agreement dated as of March 29, 2013, by and between Solutio Partners and Dynavax Technologies Corporation.
10.77[14]	Termination letter dated as of March 29, 2013, by and between Stephen Tuck and Dynavax Technologies Corporation.
10.78[15]	Employment Agreement dated as of April 3, 2013, by and between Eddie Gray and Dynavax Technologies Corporation.
10.79[15]	Management Continuity and Severance Agreement dated as of April 3, 2013, by and between Eddie Gray and Dynavax Technologies Corporation.
10.80[15]	Consulting Agreement dated as of May 1, 2013, by and between Dino Dina, M.D. and Dynavax Technologies Corporation.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase.
101.LAB XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on March 29, 2013.
(2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on October 28, 2013.

(3) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 333- 109965).

(4) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on November 6, 2008.

(5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 4, 2010.

(6) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 5, 2011.

(7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on May 30, 2013.

(8) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.

(9) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.

(10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 6, 2009.

(11) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 16, 2010.

(12) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on April 13, 2010.

(13) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on September 20, 2010.

(14) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on April 4, 2013.

(15) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on May 3, 2013.

(16) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on October 31, 2013.

The certifications attached as Exhibits 32.1 and 32.2 accompanying 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 Registrant 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 Quarterly Report on 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 8, 2013 By: /s/ EDDIE GRAY
Eddie Gray
Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2013 By: /s/ MICHAEL OSTRACH
Michael Ostrach
Vice President
(Principal Accounting and Financial Officer)

EXHIBIT INDEX

Exhibit Number	Document
1.1[(1)]	At Market Issuance Sales Agreement, dated March 29, 2013, by and between Dynavax Technologies Corporation and MLV & Co. LLC.
1.2[(2)]	Underwriting Agreement, dated October 25, 2013.
1.3[(2)]	Underwriting Agreement, dated October 25, 2013.
3.1[(3)]	Sixth Amended and Restated Certificate of Incorporation.
3.2[(3)]	Amended and Restated Bylaws.
3.3[(4)]	Form of Certificate of Designation of Series A Junior Participating Preferred Stock.
3.4[(5)]	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.5[(6)]	Certificate of Amendment of Amended and Restated

	Certificate of Incorporation.
3.6[7]	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation.
3.7[16]	Certificate of Designation of Series B Convertible Preferred Stock.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 above.
4.2[8]	Registration Rights Agreement.
4.3[8]	Form of Warrant.
4.4[9]	Form of Specimen Common Stock Certificate.
4.5[3]	Rights Agreement dated as of November 5, 2008, by and between Dynavax Technologies Corporation and Mellon Investor Services LLC.
4.6[3]	Form of Right Certificate.
4.7[10]	Form of Restricted Stock Unit Award Agreement.
4.8[11]	Form of Amended Warrant.
4.9[12]	Form of Warrant.

4.10[13]	Registration Rights Agreement dated as of September 20, 2010, by and between Dynavax Technologies Corporation and Aspire Capital Fund, LLC.
4.11[16]	Form of Specimen Preferred Stock Certificate.
10.76[14]	Consulting Agreement dated as of March 29, 2013, by and between Solutio Partners and Dynavax Technologies Corporation.
10.77[14]	Termination letter dated as of March 29, 2013, by and between Stephen Tuck and Dynavax Technologies Corporation.
10.78[15]	Employment Agreement dated as of April 3, 2013, by and between Eddie Gray and Dynavax Technologies Corporation.
10.79[15]	Management Continuity and Severance Agreement dated as of April 3, 2013, by and between Eddie Gray and Dynavax

	Technologies Corporation.
10.80[15]	Consulting Agreement dated as of May 1, 2013, by and between Dino Dina, M.D. and Dynavax Technologies Corporation.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension

	Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on March 29, 2013.

(2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on October 28, 2013.

(3) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 333-109965).

(4) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on November 6, 2008.

(5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 4, 2010.

(6) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 5, 2011.

(7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on May 30, 2013.

(8) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.

(9) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.

(10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 6, 2009.

(11) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 16, 2010.

(12) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on April 13, 2010.

(13) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on September 20, 2010.

(14) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on April 4, 2013.

(15) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on May 3, 2013.

(16) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on October 31, 2013.

The certifications attached as Exhibits 32.1 and 32.2 accompanying 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 Registrant 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 Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.