DYNAVAX TECHNOLOGIES CORP
Form 10-Q
November 05, 2015

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, 2015

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission file number: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

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

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 2, 2015, the registrant had outstanding 38,425,277 shares of common stock.

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DYNAVAX TECHNOLOGIES CORPORATION

FORWARD-LOOKING STATEMENTS

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

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

This Quarterly Report on Form 10-Q includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Quarterly Report on Form 10-Q may be trademarks or registered trademarks of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Dynavax Technologies Corporation

Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	September 30, 2015 (unaudited)	December 31, 2014 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 103,031	$ 49,511
Marketable securities available-for-sale	117,666	73,141
Accounts receivable	1,163	727
Prepaid expenses and other current assets	2,489	4,058
Total current assets	224,349	127,437
Property and equipment, net	11,606	7,924
Goodwill	2,106	2,277
Restricted cash	615	632
Other assets	231	20
Total assets	$ 238,907	$ 138,290
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,359	$ 1,159
Accrued research and development	7,861	6,938
Accrued liabilities	5,952	6,317
Deferred revenues	3,558	5,865
Total current liabilities	19,730	20,279
Deferred revenues, net of current portion	6,988	6,900
Long-term debt	-	9,559
Other long-term liabilities	1,001	1,070
Total liabilities	27,719	37,808
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock: $0.001 par value		
Authorized: 5,000 shares; Issued and outstanding:		
Series B Convertible Preferred Stock — no shares and 43 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	-	-
Common stock: $0.001 par value; 69,500 shares authorized at September 30, 2015 and December 31, 2014; 38,425 and 26,307 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	38	26
Additional paid-in capital	886,575	695,058
Accumulated other comprehensive loss	(2,560)	(1,669)

Accumulated deficit	(672,865)	(592,933)
Total stockholders' equity	211,188	100,482
Total liabilities and stockholders' equity	$238,907	$138,290

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,	
	2015	2014	2015	2014
Revenues:				
Collaboration revenue	$829	$1,795	$2,230	$6,199
Grant revenue	359	414	608	2,546
Service and license revenue	-	-	527	10
Total revenues	1,188	2,209	3,365	8,755
Operating expenses:				
Research and development	24,105	28,072	66,011	64,942
General and administrative	5,524	4,083	15,481	12,325
Unoccupied facility expense	-	131	-	386
Total operating expenses	29,629	32,286	81,492	77,653
Loss from operations	(28,441)	(30,077)	(78,127)	(68,898)
Other income (expense):				
Interest income	33	42	78	162
Interest expense	(62)	-	(572)	-
Other income, net	17	216	360	300
Loss on extinguishment of debt	(1,671)	-	(1,671)	-
Net loss	$(30,124)	$(29,819)	$(79,932)	$(68,436)
Basic and diluted net loss per share	$(0.82)	$(1.13)	$(2.43)	$(2.60)
Weighted average shares used to compute basic and diluted net loss per share	36,532	26,291	32,880	26,288

Dynavax Technologies Corporation

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended September	Nine Months Ended September 30,

	30, 2015	2014	2015	2014
Net loss	$(30,124)	$(29,819)	$(79,932)	$(68,436)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities available-for-sale	5	(1)	4	69
Cumulative foreign currency translation adjustments	162	(921)	(895)	(1,027)
Total other comprehensive income (loss)	167	(922)	(891)	(958)
Total comprehensive loss	$(29,957)	$(30,741)	$(80,823)	$(69,394)

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$(79,932)	$(68,436)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	958	1,016
Gain on disposal of property and equipment	-	(24)
Accretion of discounts and amortization of premiums on marketable securities	476	714
Unoccupied facility expense	-	386
Accretion of debt discount related to debt financing	(115)	-
Cash-settled portion of stock-based compensation expense	387	-
Stock compensation expense	6,502	4,532
Loss on extinguishment of debt	1,671	-
Changes in operating assets and liabilities:		
Accounts receivable	(436)	900
Prepaid expenses and other current assets	1,569	(2,203)
Restricted cash and other assets	(211)	(575)
Accounts payable	273	3,284
Accrued liabilities and other long term liabilities	364	4,334
Deferred revenues	(2,219)	(799)
Net cash used in operating activities	(70,713)	(56,871)
Investing activities		
Purchases of marketable securities	(127,918)	(44,807)
Proceeds from maturities of marketable securities	82,920	99,500
Purchases of property and equipment, net	(4,246)	(1,207)
Net cash (used in) provided by investing activities	(49,244)	53,486
Financing activities		
Proceeds from issuance of common stock, net	183,899	-
Payment of debt	(10,990)	-
Proceeds from exercise of stock options and restricted stock awards	237	13
Proceeds from exercise of warrants	222	-
Proceeds from Employee Stock Purchase Plan	291	130
Net cash provided by financing activities	173,659	143
Effect of exchange rate changes on cash and cash equivalents	(182)	(224)
Net increase (decrease) in cash and cash equivalents	53,520	(3,466)
Cash and cash equivalents at beginning of period	49,511	23,122
Cash and cash equivalents at end of period	$103,031	$19,656
Supplemental disclosure of cash flow information		
Non-cash investing and financing activities:		
Cash paid during the year for interest	$720	$-

Disposal of fully depreciated property and equipment	$171	$675
Net change in unrealized gain on marketable securities	$4	$69

See accompanying notes.

Dynavax Technologies Corporation

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company") is a clinical-stage biopharmaceutical company that uses toll-like receptor ("TLR") biology to discover and develop novel vaccines and therapeutics. Our development programs are organized under our three areas of focus: vaccine adjuvants, cancer immunotherapy, and autoimmune and inflammatory diseases. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

Basis of Presentation

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which we consider necessary to present fairly our financial position and the results of our operations and cash flows. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. Interim-period results are not necessarily indicative of results of operations or cash flows to be expected for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2014, has been derived from audited financial statements at that date, but excludes disclosures required by GAAP for complete financial statements.

The unaudited condensed consolidated financial statements and these notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission (the "SEC").

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries, Dynavax GmbH (formerly known as Rhein Biotech GmbH) and Dynavax International, B.V. Dynavax International, B.V. was dissolved in January 2015. All significant intercompany accounts and transactions, among consolidated entities, have been eliminated. We operate in one business segment: the discovery and development of biopharmaceutical products.

Liquidity and Financial Condition

We have incurred significant operating losses and negative cash flows from operations since our inception. As of September 30, 2015, we had cash, cash equivalents and marketable securities of $220.7 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, 2015, anticipated revenues and funding from existing collaboration agreements.

We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B™ and our investigational cancer immunotherapeutic product candidate, SD-101, human clinical trials for our other product candidates and additional applications and advancement

of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic collaboration and licensing arrangements and/or future public or private debt and equity financings. Sufficient additional funding may not be available on acceptable terms, or at all. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or our other development programs while we seek strategic alternatives.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from these estimates.

Reverse Stock Split

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

Summary of Significant Accounting Policies

There have been no significant changes in our significant accounting policies during the nine months ended September 30, 2015, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

Revenue Recognition

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

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

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

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

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when all revenue recognition criteria have been satisfied.

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

Research and Development Expenses and Accruals

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

We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. Our accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company’s prior period accrued estimates for clinical trial activities through September 30, 2015.

Recent Accounting Pronouncements

Accounting Standards Update 2014-09

In May 2014, the FASB issued guidance codified in ASC 606, Revenue Recognition — Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This Accounting Standards Update (“ASU”) is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). The Company is currently evaluating the impact of the provisions of ASC 606 on its financial statements.

Accounting Standards Update 2014-15

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

Accounting Standards Update 2015-03

In April 2015, the FASB issued ASU No. 2015-03, Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. This

ASU will be effective for the Company in fiscal year 2016. The Company does not expect that the adoption of this standard will have a significant impact on its financial statements.

2. Fair Value Measurements

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

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

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

Recurring Fair Value Measurements

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 (in thousands):

	Level 1	Level 2	Level 3	Total
September 30, 2015				
Money market funds	$61,748	$-	$ -	$61,748
U.S. government agency securities	-	49,911	-	49,911
Corporate debt securities	-	103,875	-	103,875
Total	$61,748	$153,786	$ -	$215,534

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

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

U.S. Government agency securities and corporate debt securities are measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing

for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

There were no transfers between Level 1 and Level 2 during the nine months ended September 30, 2015.

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, 2015 and December 31, 2014 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
September 30, 2015				
Cash and cash equivalents:				
Cash	$ 5,163	$ -	$ -	$ 5,163
Money market funds	61,748	-	-	61,748
Corporate debt securities	36,119	4	(3)	36,120
Total cash and cash equivalents	103,030	4	(3)	103,031
Marketable securities available-for-sale:				
U.S. government agency securities	49,909	4	(2)	49,911
Corporate debt securities	67,753	80	(78)	67,755
Total marketable securities available-for-sale	117,662	84	(80)	117,666
Total cash, cash equivalents and marketable securities	$ 220,692	$ 88	$ (83)	$ 220,697
December 31, 2014				
Cash and cash equivalents:				