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

Form 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 8, 2018

Dynavax Technologies Corporation
(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

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

2929 Seventh Street, Suite 100
Berkeley, CA 94710-2753
(Address of principal executive offices, including zip code)

(510) 848-5100
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ **Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)**

☐ **Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)**

☐ **Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))**

☐ **Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))**

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.02. Results of Operations and Financial Condition

On May 8, 2018, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended March 31, 2018. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

The information with respect to item 2.02 in this current report and its accompanying exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this current report and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Dynavax, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is furnished herewith:

99.1 Press Release, dated May 8, 2018, titled "Dynavax Reports First Quarter 2018 Financial Results."

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dynavax Technologies Corporation

Date: May 9, 2018

By: /s/ DAVID JOHNSON
David Johnson
Vice President

DYNAVAX
INNOVATING IMMUNOLOGY

DYNAVAX REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS

Update on Initial Progress of HEPLISAV-B® Commercial Launch

Conference Call to be held at 4:30pm ET/1:30pm PT

BERKELEY, CA – May 8, 2018 – Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the first quarter ended March 31, 2018. The net loss for the quarter ended March 31, 2018, was $39.0 million, or $0.63 per share, compared to $25.3 million, or $0.60 per share, for the quarter ended March 31, 2017. Cash, cash equivalents and marketable securities totaled $250.8 million at March 31, 2018.

Recent Highlights

HEPLISAV-B® [Hepatitis B Vaccine, Recombinant (Adjuvanted)]

- CDC's Advisory Committee on Immunization Practices' (ACIP) recommendation of HEPLISAV-B published in Morbidity and Mortality Weekly Report (MMWR) supports payer coverage, removing a major barrier for adoption
- 100% of Medicare-insured lives, 74% of commercially-insured lives, and 60% of lives under state Medicaid plans have HEPLISAV-B specific Current Procedural Terminology (CPT) code loaded, are referencing the correct price, and have confirmed provider claims will be reimbursed. These coverage metrics have been achieved just two weeks after the publication of the MMWR
- In first 60 days following sales force launch in late February, the field sales team met with two-thirds of targeted key accounts, representing over half of addressable market

Immuno-Oncology

- Data abstract for Phase 1b/2 study investigating SD-101 in combination with KEYTRUDA® in advanced melanoma selected for Poster Discussion Session at 2018 American Society of Clinical Oncology (ASCO) Annual Meeting
- Data from ongoing Phase 1b/2 study of SD-101 and KEYTRUDA combination therapy presented at the 2018 American Association for Cancer Research (AACR) Annual Meeting
    - Meaningful response in advanced head and neck squamous cell carcinoma – overall response rate of 33% (6 out of 18) (38% among patients who received at least one scan on study)
    - Well-tolerated in advanced melanoma, showed no increase in frequency of immune-related adverse events over individual monotherapies, nor evidence of a unique safety signal; 86% (6 out of 7) of initial responses naïve to anti-PD-1/L1 treatment were ongoing after a median of 18 months of follow up

Financials

- $250.8 million in cash, cash equivalents and marketable securities at end of first quarter, with $75 million available from February 2018 term loan agreement
- Funds commercialization of HEPLISAV-B to time of expected positive cash flow and supports further immuno-oncology clinical research

“We have made significant progress since the beginning of the year,” said Eddie Gray, Chief Executive Officer. “Our sales force has begun engaging with most of our larger potential customers. We are delighted by the level of initial interest reinforcing our view that HEPLISAV-B will become the standard of care for adult hepatitis-B vaccination and reach a goal of obtaining positive cash flow by the end of 2019.”

“In addition, we see substantial potential upside from our immuno-oncology programs. SD-101 has been shown to generate antitumor activity in three tumor types while being well tolerated. We have funding to continue supporting new clinical trials and advancement of SD-101 into a registrational study in 2018,” Mr. Gray concluded.

Additional Financial Results

Net product revenue was $0.2 million for the quarter ended March 31, 2018, which consists of sales of HEPLISAV-B in the U.S. Product Revenue from sales is recorded at the net sales price which includes estimates of product returns, chargebacks, discounts and other fees.

Cost of sales, product was $0.2 million for the quarter ended March 31, 2018 and consists of certain fill, finish and fixed overhead costs for HEPLISAV-B incurred after FDA approval.

Cost of sales, amortization of intangible assets was $2.4 million for the quarter ended March 31, 2018 and consists of amortization of the intangible asset recorded as a result of milestone and sublicense payments relating to HEPLISAV-B.

Research and development expenses for the quarter ended March 31, 2018 and 2017, were $19.0 million and $16.3 million, respectively. The increase in 2018 reflects increased compensation and related personnel costs related to the ongoing development of SD-101, DV281 and earlier stage oncology programs, costs associated with resuming operating activities at our Dusseldorf production facility and costs associated with manufacturing of pre-filled syringes prior to regulatory approval.

Selling, general and administrative expenses for the quarter ended March 31, 2018 and 2017, were $16.9 million and $6.5 million, respectively. The increase is due to an overall increase in HEPLISAV-B sales, marketing and commercial activities, including full-deployment of a contract sales force, post-marketing studies and consultants for commercial development services.

Conference Call and Webcast Information

Dynavax will hold a conference call today at 4:30pm ET/1:30pm PT. To access the call, participants must dial (866) 548-4713 in the U.S. or (323) 794-2093 internationally, and use the conference ID 8635193. The live call will be webcast and can be accessed in the "Investors and Media" section of the company's website at www.dynavax.com. A replay of the webcast will be available for 30 days following the live event.

A replay of the conference call will be available for two weeks and can be accessed by dialing (844) 512-2921 in the U.S. or (412) 317-6671 internationally. The conference ID for the replay will be 8635193.

About Hepatitis B
Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer and death. The hepatitis B virus is 50 to 100 times more infectious than HIV,[i] and transmission is on the rise. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally.[ii] There is no cure for hepatitis B, but effective vaccination can prevent the disease.

In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The CDC recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[iii] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 with diabetes as soon as possible after their diagnosis, and for people age 60 and older with diabetes at their physician's discretion.[iv] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.[v]

About HEPLISAV-B
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

Indication and Use
HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

Important Safety Information (ISI)
Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient reported adverse reactions reported within 7 days of vaccination were injection site pain (23% to 39%), fatigue (11% to 17%) and headache (8% to 17%).

For full Prescribing Information for HEPLISAV-B, click here.

About MEL-01 (KEYNOTE-184)
The dose-escalation and expansion study of SD-101 in combination with KEYTRUDA includes patients with histologically or cytologically confirmed unresectable Stage IIIc/IV melanoma. The primary endpoints of the trial are MTD and evaluation of the safety of intratumoral SD-101 in combination with KEYTRUDA. In addition, the trial is investigating response as assessed by the investigator according to

RECIST v1.1, biomarker assessments and duration of response. Patients previously treated with anti-PD-1 and other immunotherapies are included.

About SD-101
SD-101, the Company's lead clinical candidate, is a proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. Dynavax is evaluating this intratumoral TLR9 agonist in several clinical studies to assess its safety and activity, including a Phase 2 study in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy, in patients with metastatic melanoma and in patients with head and neck squamous cell cancer, in a clinical collaboration with Merck. Dynavax maintains all commercial rights to SD-101.

About DV281
DV281 is Dynavax's proprietary investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases. DV281 is similar in biological activity and mechanism of action to Dynavax's Phase 2 immunotherapy candidate, SD-101, but has been optimized for administration as an aerosol. Both SD-101 and DV281 are designed to activate plasmacytoid dendritic cells and stimulate T cells specific for antigens released from dying tumor cells. TLR9 agonists such as DV281 and SD-101 have been shown to stimulate potent Type 1 interferon induction along with maturation of dendritic cells to effective antigen-presenting cells; both activities are important for the induction of effective anti-tumor immunity. Dynavax has initiated dosing in a phase 1B dose escalation clinical trial of DV281 in patients with non-small cell lung cancer.

About Dynavax
Dynavax is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company’s first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the United States. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit www.dynavax.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding the commercialization of HEPLISAV-B. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether the company will be able to continue building the commercial infrastructure required to successfully launch HEPLISAV-B; whether payers will provide timely reimbursement for HEPLISAV-B; whether prescribers and other key decision-makers will switch to HEPLISAV-B; whether potential claims against us, including those based on patent rights of others, will result in an injunction against sales or otherwise impact commercialization and sales; and the uncertain clinical development process, the outcome, cost and timing of our product development activities, our ability to obtain and maintain regulatory approval of our product candidates. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Dynavax in general, see risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, even if new information becomes available. Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

Contact:
David Burke
Director, IR & Corporate Communications
510.665.7269

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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8. Fig 3.2
[iii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iv] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.
[v] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

DYNAVAX TECHNOLOGIES CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Revenues:		
Product revenues, net	$ 165	$ -
Grant revenue	-	148
Total revenues	**165**	**148**
Operating expenses:		
Cost of sales - product	205	-
Cost of sales - amortization of intangible assets	2,417	-
Research and development	18,966	16,345
Selling, general and administrative	16,891	6,472
Restructuring	-	2,783
Total operating expenses	**38,479**	**25,600**
Loss from operations	(38,314)	(25,452)
Other income (expense):		
Interest income	740	145
Interest expense	(1,161)	-
Other (expense) income, net	(223)	20
Net loss	**$ (38,958)**	**$ (25,287)**
Basic and diluted net loss per share	**$ (0.63)**	**$ (0.60)**
Weighted average shares used to compute basic and diluted net loss per share	**61,744**	**41,830**

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	March 31, 2018	December 31, 2017
Assets		
Cash, cash equivalents and marketable securities	$ 250,780	$ 191,854
Property and equipment, net	17,064	16,619
Intangible assets, net	18,662	1,306
Goodwill	2,309	2,244
Other assets	6,518	6,762
Total assets	**$ 295,333**	**$ 218,785**
Liabilities and stockholders' equity		
Total current liabilities	$ 23,542	$ 18,593
Total long-term liabilities	105,904	643
Stockholders' equity	165,887	199,549
Total liabilities and stockholders' equity	**$ 295,333**	**$ 218,785**