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): August 7, 2019

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.)**

2100 Powell Street, Suite 900
Emeryville, CA 94608
(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))**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading symbol(s):**	**Name of each exchange on which registered:**
Common Stock, $0.001 par value	DVAX	The Nasdaq Stock Market LLC

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 August 7, 2019, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended June 30, 2019. 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 August 7, 2019, titled "Dynavax Announces Second Quarter 2019 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: August 7, 2019

By: /s/ DAVID JOHNSON
David Johnson
Vice President

Exhibit 99.1

DYNAVAX

Dynavax Announces Second Quarter 2019 Financial Results

- Second quarter 2019 HEPLISAV-B® net product revenue of $8.3 million
- Updated net product revenue guidance of $32-$36 million for full year 2019
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

Emeryville, CA – August 7, 2019 – Dynavax Technologies Corporation (NASDAQ: DVAX), a biopharmaceutical company focused on commercializing novel vaccines, today reported financial results for the second quarter ended June 30, 2019.

“HEPLISAV-B net product revenue was $8.3 million for the second quarter of this year, which was in line with our expectations,” said Ryan Spencer, Co-President and Senior Vice President of Commercial for Dynavax. “Hepatitis B is a highly infectious and potentially fatal disease, which can be prevented with effective vaccination. Although hepatitis B vaccines have been available for decades, recently cases of hepatitis B have been on the rise. We believe there is a need for a vaccine that provides higher and faster rates of protection, and that HEPLISAV-B, as the only two-dose hepatitis B vaccine approved by the FDA, has the potential to become the standard of care hepatitis B adult vaccine in the U.S. and we are focused on reaching that goal.”

Second Quarter and Recent Business Highlights

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

- Second quarter 2019 sales of $8.3 million compared to $5.6 million in the first quarter 2019
- The company has achieved sales into 6 of the 7 top national retail pharmacy chains, and contracting efforts are underway to secure additional pharmacy partners
- More than 1,790 individual customers have purchased HEPLISAV-B since launch
- 17 of the top 20 Integrated Delivery Networks (IDNs) have made HEPLISAV-B available to order
- 668 of our targeted accounts, which represent 59% of the total doses in our targeted customers, have made HEPLISAV-B available to order
- 187 of the top 300 targeted customers have ordered HEPLISAV-B

Financial Results

Product Revenue, Net. Dynavax’s first commercial product, HEPLISAV-B, was launched in the first quarter of 2018. Net product revenue for the second quarter of 2019 was $8.3 million, compared to $1.3 million for the second quarter of 2018. Net product revenue for the six months ended June 30, 2019, was $13.9 million, compared to $1.4 million for the six months ended June 30, 2018. Product revenue from sales is recorded at the net sales price, which reflects reductions for estimated product returns, chargebacks, discounts and other fees.

Cost of Sales - Product. Cost of sales - product, for the second quarter of 2019 was $2.1 million, compared to $5.2 million for the second quarter of 2018. Cost of sales - product, for the six months ended June 30, 2019, was $3.9 million, compared to $5.4 million for same period in 2018. The quarter ended June 30, 2018 included costs relating to excess capacity at the company's manufacturing facility in Düsseldorf, Germany, which were previously included in research and development expense. The 2018 excess capacity charge is a result of costs associated with resuming operating activities at the Düsseldorf facility after receiving regulatory approval of pre-filled syringes ("PFS") of HEPLISAV-B in late March 2018. Included in cost of sales – product for both periods are fill, finish and overhead costs for HEPLISAV-B incurred after U.S. Food and Drug Administration (FDA) approval. A higher percentage of HEPLISAV-B inventory sold in 2019 used components manufactured after FDA approval compared to 2018, when most of the expense associated with product sold was expensed to research and development prior to approval. The company expects HEPLISAV-B cost of sales will increase in future periods, both in absolute dollars and as a percentage of product revenue, as we produce and then sell inventory that reflects the full cost of manufacturing the product.

R&D Expenses. Research and development expenses for the second quarter of 2019 were $16.2 million, compared to $16.3 million for the second quarter of 2018. Research and development expenses for the six months ended June 30, 2019, were $37.4 million, compared to $35.2 million for the same period in 2018. In May 2019, the company announced a strategic organizational restructuring to align its operations around its vaccine business and significantly curtail further investment in immuno-oncology research and development.

SG&A Expenses. Selling, general and administrative expenses for the second quarter of 2019 were $17.9 million, compared to $15.7 million for the second quarter of 2018. Selling, general and administrative expenses for the six months ended June 30, 2019 were $36.2 million, compared to $32.5 million for the same period in 2018. The increase was due primarily to additional personnel in support of HEPLISAV-B commercial activities.

Restructuring and Related Expenses. On May 23, 2019, the company implemented a strategic organizational restructuring to principally align its operations around its vaccine business. The company is exploring strategic alternatives for its immuno-oncology portfolio. The total restructuring costs related to the restructuring are estimated to be $9.4 million, of which $5.3 million is related to severance, other termination benefits and outplacement services and $4.1 million is related to stock-based compensation expense as a result of accelerated vesting of stock awards and extension of exercise period of stock options. During the three months ended June 30, 2019, the company recognized restructuring charges of $8.8 million and the remaining $0.6 million is expected to be recognized by the end of 2019. The workforce reduction is expected to reduce compensation and benefits cost by approximately $16 million annually. After all existing oncology trials and commitments are complete, the company estimates its operating expenditures related to external oncology costs will be reduced by approximately $8 million per quarter as compared to the first quarter ended March 31, 2019.

Net Loss. Net loss for the second quarter of 2019 was $42.7 million, or $0.66 per basic and diluted share, compared to a net loss of $39.4 million, or $0.63 per basic and diluted share, for the second quarter of 2018. Net loss for the six months ended June 30, 2019, was $82.4 million, or $1.28 per basic and diluted share, compared to a net loss of $78.4 million, or $1.26 per basic and diluted share for the six months ended June 30, 2018.

Cash Position. Cash, cash equivalents and marketable securities totaled $140.5 million at June 30, 2019.

2019 HEPLISAV-B Revenue Expectations

Dynavax expects HEPLISAV-B® net product revenue of $32-$36 million for the full year 2019.

Conference Call and Webcast Information

Dynavax will hold a conference call today at 4:30 p.m. ET/1:30 p.m. PT. To access the call, participants may dial (877) 423-9813 (domestic) or (201) 689-8573 (international) and refer to conference ID 13693069. 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.

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. 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.[ii] 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.[iii] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.[iv]

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.

For more information about HEPLISAV-B, visit http://heplisavb.com/.

About Dynavax
Dynavax is a biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers, develops and commercializes novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. For more information, visit www.dynavax.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Dynavax’s full-year 2019 net product revenue guidance and HEPLISAV-B. These forward-looking statements are based upon management’s current expectations, are subject to known

and unknown risks, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation, the uncertainty of future commercial sales and related items that would impact net product sales during 2019; risks related to Dynavax's ability to successfully commercialize HEPLISAV-B, which among other things will require Dynavax to successfully negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and maintain those contractual relationships, maintain and build its commercial infrastructure, and access prescribers and other key health care providers to discuss HEPLISAV-B; risks related to market adoption and competing therapies; and risks related to whether payors will cover and provide timely and adequate reimbursement for HEPLISAV-B. These and other risks and uncertainties are described in Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 under the heading "Risk Factors". Dynavax undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iii] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.
[iv] 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product revenues, net	$ 8,301	$ 1,254	$ 13,928	$ 1,419
Collaboration revenue	-	-	146	-
Total revenues	**8,301**	**1,254**	**14,074**	**1,419**
Operating expenses:				
Cost of sales – product	2,141	5,177	3,941	5,382
Cost of sales - amortization of intangible assets	2,297	2,298	4,570	4,715
Research and development	16,196	16,273	37,402	35,239
Selling, general and administrative	17,861	15,653	36,209	32,544
Restructuring	8,777	-	8,777	-
Total operating expenses	**47,272**	**39,401**	**90,899**	**77,880**
Loss from operations	(38,971)	(38,147)	(76,825)	(76,461)
Other income (expense):				
Interest income	979	1,153	1,714	1,893
Interest expense	(4,598)	(2,691)	(7,332)	(3,852)
Other income (expense), net	(123)	241	58	18
Net loss	**$ (42,713)**	**$ (39,444)**	**$ (82,385)**	**$ (78,402)**
Basic and diluted net loss per share	**$ (0.66)**	**$ (0.63)**	**$ 1.28)**	**$ (1.26)**
Weighted average shares used to compute basic and diluted net loss per share	**65,088**	**62,346**	**64,436**	**62,047**

DYNAVAX TECHNOLOGIES CORPORATION
SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 140,494	$ 145,536
Inventories, net	36,629	19,022
Property and equipment, net	34,393	17,064
Intangible assets, net	7,147	11,717
Goodwill	2,131	2,144
Other assets	46,287	15,401
Total assets	**$ 267,081**	**$ 210,884**
Liabilities and stockholders' equity		
Total current liabilities	$ 44,573	$ 38,033
Total long-term liabilities	211,920	109,786
Stockholders' equity	10,588	63,065
Total liabilities and stockholders' equity	**$ 267,081**	**$ 210,884**