# Dynavax Reports Third Quarter 2023 Financial Results and Raises Full Year Revenue Guidance

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- *Generated quarterly HEPLISAV-B® vaccine net product revenue of $62.3 million, a 66% year-over-year increase*
- *Raising full year HEPLISAV-B net product revenue guidance to $210 - $220 million, compared to prior range of $200 - $215 million*
- *Cash and investments increased to $720 million at quarter end; expects positive free cash flow for full year*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, Calif., Nov. 2, 2023 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, today reported financial results and provided a business update for the quarter ended September 30, 2023.

"We're pleased to report yet another record quarter of HEPLISAV-B revenue driven by continued market share growth and overall expansion of the adult hepatitis B market, demonstrating progress toward our goal of establishing HEPLISAV-B as the leading adult hepatitis B vaccine in the U.S., a market opportunity we believe will continue to expand to over $800 million by 2027," said Ryan Spencer, Chief Executive Officer of Dynavax. "In addition to HEPLISAV-B, we are focused on advancing our pipeline of innovative vaccine candidates, pursuing strategic opportunities to accelerate our growth, and continuing to drive strong financial performance, reflecting the solid foundation we've established for sustained success."

**BUSINESS UPDATES**

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

*HEPLISAV-B vaccine is the first and only adult hepatitis B vaccine approved in the U.S., the European Union and Great Britain that enables series completion with only two doses in one month. Hepatitis B vaccination is universally recommended for adults aged 19-59 in the U.S.*

- HEPLISAV-B achieved net product revenue of $62.3 million for the third quarter of 2023, an increase of 66% compared to $37.5 million for the third quarter of 2022.
- HEPLISAV-B total market share in the U.S. increased to approximately 41%, compared to approximately 32% at the end of the third quarter of 2022.
- HEPLISAV-B market share in the Integrated Delivery Networks (IDNs) and Large Clinics segment increased to approximately 54% at the end of the third quarter of 2023, compared to approximately 43% for the same quarter in 2022.
- HEPLISAV-B market share in the retail pharmacy segment increased to approximately 53% at the end of the third quarter of 2023, compared to 43% for the same quarter in 2022.
- A supplemental Biologic License Application (sBLA) for HEPLISAV-B vaccination of adults on hemodialysis is currently under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) action date expected on May 13, 2024.

*Clinical Pipeline*
*Dynavax is advancing a pipeline of differentiated product candidates that leverage its CpG 1018® adjuvant, which has demonstrated its ability to enhance the immune response with a favorable tolerability profile in a wide range of clinical trials and real-world commercial use.*

**Shingles vaccine program:**
*Z-1018 is an investigational vaccine candidate being developed for the prevention of shingles in adults aged 50 and older.*

- Dynavax recently received Type B meeting feedback from the FDA on the Z-1018 clinical development plan and expects to submit an Investigational New Drug Application (IND) to the FDA to support the initiation of a Phase 1/2 trial of Z-1018 in the first half of 2024.

**Tdap vaccine program:**
*Tdap-1018 is an investigational vaccine candidate intended for active booster immunization against tetanus, diphtheria, and pertussis (Tdap).*

- Dynavax plans to submit an Investigational New Drug Application (IND) to the FDA to support the initiation of a Phase 2 human challenge study of Tdap-1018 in mid-2024.

**Plague vaccine program:**
*Dynavax is developing a plague (rF1V) vaccine candidate adjuvanted with CpG 1018 currently in a Phase 2 clinical trial in collaboration with, and fully funded by, the U.S. Department of Defense.*

- Dynavax and the U.S. Department of Defense recently executed a contract modification to support advancement of the plague vaccine candidate into a nonhuman primate challenge study, which was initiated in August, with the agreement now totaling $33.7 million through 2025.
- Dosing has been completed in a randomized, active-controlled Phase 2 clinical trial evaluating immunogenicity, safety, and tolerability, with top line data anticipated in 2024.

**THIRD QUARTER 2023 FINANCIAL HIGHLIGHTS**

**Total Revenues and Net Product Revenue.**

- HEPLISAV-B vaccine net product revenue was $62.3 million for the third quarter of 2023, compared to $37.5 million for the third quarter of 2022, representing year-over-year growth of 66%. The increase was primarily due to higher sales volume driven by both continued improvement in market share and higher utilization of adult hepatitis B vaccines related to the ACIP universal recommendation.
- Other revenue was $7.2 million for the third quarter of 2023, compared to $3.9 million in the same period of 2022. Other revenue primarily includes revenue from our plague vaccine agreement with the U.S. Department of Defense. The increase was primarily driven by the advancement into a nonhuman primate challenge study.
- No CpG 1018 adjuvant product revenue was recorded in the third quarter of 2023, compared to $126.3 million in the third quarter of 2022, due to completion of all obligations and product delivery under the Company's CpG 1018 adjuvant COVID-19 collaboration agreements as of December 31, 2022.
- Total revenues for the third quarter of 2023 were $69.5 million, compared to $167.7 million for the third quarter of 2022.

**Cost of Sales - Product.** Cost of sales - product for HEPLISAV-B in the third quarter of 2023 increased to $13.2 million, compared to $11.5 million for the third quarter of 2022. The increase was primarily due to higher sales volume driven by continued improvement in HEPLISAV-B market share, offset by lower per-unit manufacturing costs as the result of previous process improvements. Total cost of sales – product for the third quarter of 2023 decreased to $13.2 million, compared to $61.3 million in the third quarter of 2022. The decrease is primarily due to no CpG 1018 adjuvant cost of sales - product for the third quarter of 2023 as a result of completing all obligations and product delivery under the prior CpG 1018 adjuvant collaboration agreements as of December 31, 2022.

**Research and Development Expenses (R&D).** R&D expenses for the third quarter of 2023 increased to $14.1 million, compared to $13.0 million for the third quarter of 2022. The increase was primarily driven by continued investments in advancing our clinical and preclinical development programs and collaborations.

**Selling, General, and Administrative Expenses (SG&A).** SG&A expenses for the third quarter of 2023 increased to $38.1 million, compared to $32.0 million for the third quarter of 2022. The increase was primarily driven by higher compensation and related personnel costs and an overall increase in targeted commercial and marketing efforts designed to increase HEPLISAV-B market share and maximize the opportunities presented by the ACIP's universal recommendation.

**Net income.** GAAP net income was $14.3 million, or $0.11 per share (basic) and $0.10 per share (diluted) in the third quarter of 2023, compared to GAAP net income of $63.8 million, or $0.50 per share (basic) and $0.43 per share (diluted) in the third quarter of 2022.

**Cash and Marketable Securities.** Cash, cash equivalents and marketable securities were $720.4 million as of September 30, 2023.

**2023 FINANCIAL GUIDANCE**
Full year 2023 financial guidance has been revised to consist of the following expectations:

- HEPLISAV-B net product revenue between approximately $210 - $220 million, compared to the prior range of approximately $200 - $215 million.
- Research and development expenses between approximately $50 - $60 million, compared to the prior range of approximately $55 - $70 million.
- Selling, general and administrative expenses between approximately $145 - $155 million, compared to the prior range of approximately $135 - $155 million.

**Conference Call and Webcast Information**
Dynavax will host a conference call and live audio webcast on Thursday, November 2, 2023, at 4:30 p.m. ET/1:30 p.m. PT. The live audio webcast may be accessed through the "Events & Presentations" page on the "Investors" section of the Company's website at https://investors.dynavax.com/events-presentations. A replay of the webcast will be available for 30 days following the live event.

To dial into the call, participants will need to register for the call using the caller registration link. It is recommended that participants dial into the conference call or log into the webcast approximately 10 minutes prior to the call.

**Important U.S. Product Information**
HEPLISAV-B is indicated for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older.

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

**Important U.S. Safety Information (ISI)**
Do not administer HEPLISAV-B to individuals with a history of a 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%).

**About Dynavax**
Dynavax is a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. The Company has two commercial products, HEPLISAV-B® vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted], which is approved in the U.S., the European Union and Great Britain for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older, and CpG 1018® adjuvant, currently used in multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 adjuvant as a premier vaccine adjuvant with adjuvanted vaccine clinical programs for shingles and Tdap, and through global collaborations, currently focused on adjuvanted vaccines for COVID-19, plague, seasonal influenza and universal influenza. For more information about our marketed products and development pipeline, visit www.dynavax.com and follow Dynavax on LinkedIn.

**Forward-Looking Statements**
This press release 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. Forward-looking statements can generally be identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "intend," "will," "may," "plan," "project," "potential," "seek," "should," "think," "will," "would" and similar expressions, or the negatives thereof, or they may use future dates. Forward-looking statements made in this document include statements regarding financial guidance, our plans and strategies, the development and potential approval of vaccines containing CpG 1018 adjuvant by us or by our collaborators, the timing of IND filings, the timing of initiation and completion of clinical studies and the publication of results. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, the risk that actual demand for our products may differ from our expectations, risks related to the timing of completion and results of current clinical studies, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018 adjuvant, whether use of CpG 1018 adjuvant will prove to be beneficial in these vaccines, as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-Q for the quarter ended September 30, 2023 and periodic filings made thereafter, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. These forward-looking statements are made as of the date hereof, are qualified in their entirety by this cautionary statement and we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, 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.

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**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, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Revenues: | | | | |
| HEPLISAV-B product revenue, net | $ 62,318 | $ 37,508 | $ 162,209 | $ 90,998 |
| CpG 1018 adjuvant product revenue, net | - | 126,307 | - | 440,464 |
| Other revenue | 7,196 | 3,920 | 14,479 | 6,729 |
| **Total revenues** | **69,514** | **167,735** | **176,688** | **538,191** |
| Operating expenses: | | | | |
| HEPLISAV-B cost of sales – product | 13,229 | 11,511 | 41,478 | 27,740 |
| CpG 1018 cost of sales – product | - | 49,823 | - | 156,925 |
| Research and development | 14,116 | 12,962 | 40,767 | 33,746 |
| Selling, general and administrative | 38,053 | 32,042 | 111,667 | 100,393 |
| Gain on sale of assets | (1,000) | - | (1,000) | (1,000) |
| Bad debt expense | - | - | 12,313 | - |
| **Total operating expenses** | **64,398** | **106,338** | **205,225** | **317,804** |

| | | | | |
|---|---|---|---|---|
| Income (loss) from operations | 5,116 | 61,397 | (28,537) | 220,387 |
| Other income (expense): | | | | |
| Interest income | 8,462 | 2,562 | 22,437 | 3,588 |
| Interest expense | (1,691) | (1,685) | (5,065) | (5,048) |
| Sublease income | 1,993 | 2,026 | 5,584 | 5,660 |
| Change in fair value of warrant liability | - | - | - | 1,801 |
| Other | 266 | (208) | 218 | (63) |
| Net income (loss) before income taxes | 14,146 | 64,092 | (5,363) | 226,325 |
| Benefit from (provision for) income taxes | 147 | (283) | (1,245) | (902) |
| **Net income (loss)** | **$ 14,293** | **$ 63,809** | **$ (6,608)** | **$ 225,423** |
| **Net income (loss) per share attributable to common stockholders:** | | | | |
| **Basic** | **$ 0.11** | **$ 0.50** | **$ (0.05)** | **$ 1.79** |
| **Diluted** | **$ 0.10** | **$ 0.43** | **$ (0.05)** | **$ 1.51** |
| **Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:** | | | | |
| **Basic** | **128,988** | **127,062** | **128,515** | **125,997** |
| **Diluted** | **154,196** | **151,538** | **128,515** | **150,433** |

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

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and marketable securities | $ 720,416 | $ 624,395 |
| Inventories | 49,412 | 59,446 |
| Other current assets | 65,838 | 233,144 |
| **Total current assets** | **835,666** | **916,985** |
| Total non-current assets | 137,267 | 68,865 |
| **Total assets** | **$ 972,933** | **$ 985,850** |
| **Liabilities and stockholders' equity** | | |
| Total current liabilities | $ 54,264 | $ 150,074 |
| Total long-term liabilities | 313,753 | 254,763 |
| Stockholders' equity | 604,916 | 581,013 |
| **Total liabilities and stockholders' equity** | **$ 972,933** | **$ 985,850** |

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