Novavax Reports Third Quarter 2024 Financial Results and Operational Highlights

November 12, 2024

- *U.S. FDA removes clinical hold on Investigational New Drug application for COVID-19-Influenza Combination and stand-alone influenza vaccine candidates*
- *Achieved total revenue of $85 million in the third quarter of 2024*
- *Ended the third quarter of 2024 with $1 billion in cash and receivables*
- *Received authorization from U.S. FDA and European Commission for updated 2024-2025 formula COVID-19 vaccine in individuals aged 12 and older*
- *Outlined R&D strategy based on its proven technology platform*
- *Updates full year 2024 financial guidance*
- *Company to host conference call today at 8:30 a.m. ET*

GAITHERSBURG, Md., Nov. 12, 2024 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced its financial results and operational highlights for the third quarter ended September 30, 2024.

"Novavax continues to focus on our corporate growth strategy of driving value from additional business development activities and organic R&D using our proven technology platform," said John C. Jacobs, President and Chief Executive Officer, Novavax. "In addition to progress on our other value drivers, this past quarter, we made significant progress defining our R&D strategy as we look to expand beyond COVID-19 and influenza. We intend to develop our early-stage pipeline with a disciplined approach, as we focus on areas where our technology can have a positive impact on public health and generate value."

Third Quarter 2024 and Recent Highlights

During the third quarter, Novavax continued executing against its four key priorities.

Priority #1: Successful Execution of Sanofi Partnership

- Advanced preparation for Sanofi to assume lead commercial responsibility of Nuvaxovid™ COVID-19 vaccine for 2025-2026 vaccination season in the U.S., Europe and select major markets not currently subject to Novavax Advanced Purchase Agreements (APAs) or existing partnership agreements.
- On track for the Novavax pediatric clinical trial database lock for the first cohort in the fourth quarter of 2024, achievement triggers a $50 million milestone payment.

Priority #2: Drive Incremental Value from Novavax's Proven Technology Platform

- In November 2024, the U.S. Food and Drug Administration (FDA) removed the clinical hold on Novavax's Investigational New Drug (IND) application for its COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates. Novavax is working to initiate the Phase 3 immunogenicity clinical trial for CIC and stand-alone influenza candidates as soon as possible.
- Signed a Matrix-M adjuvant related agreement with a leading pharmaceutical company to enable exploration of our technology for the potential advancement of their pipeline candidates.
- Outlined guiding principles of new Research & Development (R&D) strategy based on its proven technology platform and announced the appointment of Ruxandra Draghia-Akli, MD, PhD as Executive Vice President and Head of R&D.
- Continued to advance pandemic influenza and respiratory syncytial virus (RSV) pre-clinical programs towards IND readiness, with a focus on RSV-combination options.

Priority #3: Continue Evolution of Novavax and Reduce Operating Expenses

- On track with cost structure improvements, including an approximate 26% reduction in combined R&D and Selling, General and Administrative (SG&A) expenses in the third quarter of 2024 compared to the same period for 2023.
- Targeting full year combined R&D and SG&A expenses of approximately $500 million for full year 2025 and approximately $350 million for full year 2026. A portion of these expenses are expected to be reimbursed under the

Sanofi Agreement. The full year 2026 target spend reflects a reduction of approximately $1.4 billion and 80% as compared to full year 2022.

Priority #4: Deliver an Updated COVID-19 Vaccine for the 2024-2025 Vaccination Season

U.S. Market:

- Received Emergency Use Authorization (EUA) from the U.S. FDA in individuals aged 12 and older.
- Entered the market with an improved product presentation and broader access -Nuvaxovid™ available in pre-filled syringe presentation in over 30,000 locations across major pharmacy retailers and regional grocers in the U.S.
- Novavax's COVID-19 vaccine Biologics License Application (BLA) Prescription Drug User Fee Act with an action date of April 2025 and updated to include both JN.1 variant and pre-filled syringe presentation. Achievement of BLA approval triggers a $175 million milestone payment from Sanofi.

Global Markets:

- Received global authorizations including in the European Union, Canada, and Taiwan.

Third Quarter 2024 Financial Results

- **Total revenue** for the third quarter of 2024 was $85 million, compared to $187 million in the same period in 2023. Product sales of $38 million for the third quarter 2024 related to primarily U.S. market commercial sales. Licensing, royalties and other revenue of $46 million in the third quarter of 2024 related to a combination of activities under the Sanofi Agreement and adjuvant sales.
- **Cost of sales** for the third quarter of 2024 was $61 million, compared to $99 million in the same period in 2023. These quarters included $28 million and $74 million, respectively, related to excess, obsolete or expired inventory, losses on firm purchase commitments under third-party supply agreements and unutilized manufacturing capacity.
- **R&D expenses** for the third quarter of 2024 were $87 million, compared to $106 million in the same period in 2023. The decrease was primarily due to reductions in manufacturing and clinical research-related spend.
- **SG&A expenses** for the third quarter of 2024 were $71 million, compared to $107 million for the same period in 2023. The decrease was primarily due to cost reduction activities, partially offset by commercialization expenses for Nuvaxovid.
- **Net loss** for the third quarter 2024 was $121 million, compared to a net loss of $131 million in the same period in 2023.
- **Cash, cash equivalents, marketable securities and restricted cash(Cash)** were $924 million as of September 30, 2024, compared to $584 million as of December 31, 2023.

Financial Framework

Novavax is updating its Full Year 2024 Financial Guidance and expects to achieve the following objectives.

Full Year 2024 Guidance

? $ in millions	**Prior** (as of Aug. 8, 2024)	**Updated** (as of Nov. 12, 2024)
Total Revenue	$700 - $800	$650 - $700
Product Sales [1]	$275 - $375	$175 - $225
Licensing, Royalties and Other Revenue [2]	$425	$475
Combined R&D and SG&A	$700 - $750	$700 - $750

1. *Full year 2024 product sales guidance reflects approximately $100 million in APA dose deliveries in 1H 2024 and $75 million to $125 million of commercial market sales in 2H 2024.*
2. *Full year 2024 Licensing, royalties and other revenue guidance includes $450 million of revenue recognition from the $500 million Sanofi agreement upfront payment and $25 million in royalty and other revenue from partner-related activities.*

Conference Call

Novavax will host its quarterly conference call today at 8:30 a.m. ET. To join the call without operator assistance, you may register and enter your phone number at https://emportal.ink/3Y6irHGto receive an instant automated call back. You may also dial direct to be entered to the call by an operator. The dial-in numbers for the conference call are (800) 836-8184 (Domestic) or (+1) (646) 357-8785 (International). Participants will be prompted to request to join the Novavax, Inc. call. A replay of the conference call will be available starting at 11:30 a.m. ET on November 12, 2024, until 11:59 p.m. ET on November 19, 2024. To access the replay by telephone, dial (888) 660-6345 (Domestic) or (+1) (646) 517-4150

(International) and use passcode 62491 #.

A webcast of the conference call can also be accessed on the Novavax website at ir.novavax.com/events. A replay of the webcast will be available on the Novavax website until December 12, 2024.

Trade Name in the U.S.
The trade name Nuvaxovid has not been approved by the U.S. FDA.

About Novavax
Novavax, Inc. (Nasdaq: NVAX) promotes improved health by discovering, developing and commercializing innovative vaccines to help protect against serious infectious diseases. Novavax, a global company based in Gaithersburg, Md., U.S., offers a differentiated vaccine platform that combines a recombinant protein approach, innovative nanoparticle technology and Novavax's patented Matrix-M adjuvant to enhance the immune response. The Company's portfolio includes its COVID-19 vaccine and its pipeline includes CIC and stand-alone influenza vaccine candidates. In addition, Novavax's adjuvant is included in the University of Oxford and Serum Institute of India's R21/Matrix-M malaria vaccine. Please visit novavax.com and LinkedIn for more information.

Non-GAAP Financial Measures
The Company has used a non-GAAP financial measure in this press release, which is adjusted combined R&D and SG&A expenses, net of Sanofi reimbursement costs under the Sanofi Agreement. Non-GAAP financial measures refer to financial information adjusted from financial measures prepared in accordance with accounting principles generally accepted in the United States (GAAP). The Company believes that the presentation of this adjusted financial measure is useful to investors as it provides additional information on comparisons between periods by including certain items that affect overall comparability. The Company uses this non-GAAP financial measure for business planning purposes and to consider underlying trends of its business and believes presenting this measure also provides useful information to investors and others for understanding and evaluating trends in the Company's expenses in the same manner as the Company's management. Non-GAAP financial measures should be considered in addition to, and not as an alternative for, the Company's reported results prepared in accordance with GAAP. The use of this non-GAAP financial measure may differ from similar measures reported by other companies and may not be comparable to other similarly titled measures.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its mission; its corporate strategy and operating plans, objectives and prospects; its value drivers and near-term priorities, its partnerships, including expectations with respect to potential royalties, milestones, and cost reimbursement, and plans for additional potential partnering activities; its expectations regarding manufacturing capacity, timing, production and delivery for its COVID-19 vaccine; the development of Novavax's clinical and preclinical product candidates and innovation expansion opportunities; the conduct, timing and potential results from clinical trials and other preclinical studies; scope, timing and outcome of future and pending regulatory filings and actions, including the potential BLA approval for Novavax's COVID-19 vaccine; potential market sizes and demand for its COVID-19 vaccine and product candidates; full year 2024 financial guidance; and the amount and impact of Novavax's cost reduction plans; and Novavax's future financial or business performance. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, Novavax's ability to successfully and timely manufacture, market, distribute, or deliver its updated 2024-2025 formula COVID-19 vaccine and the impact of its not having received a BLA from the FDA for the 2024-2025 vaccination season; challenges related to Novavax's partnership with Sanofi and in pursuing additional partnership opportunities; challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification, assay validation and stability testing, necessary to satisfy applicable regulatory authorities; challenges or delays in conducting clinical trials or studies for its product candidates; challenges or delays in obtaining regulatory authorization for its product candidates, including for future COVID-19 variant strain changes, its CIC vaccine candidate, its stand-alone influenza vaccine candidate or other product candidates; manufacturing, distribution or export delays or challenges; Novavax's substantial dependence on Serum Institute of India Pvt. Ltd. and Serum Life Sciences Limited for co-formulation and filling Novavax's COVID-19 vaccine and the impact of any delays or disruptions in their operations; difficulty obtaining scarce raw materials and supplies including for its proprietary adjuvant; resource constraints, including human capital and manufacturing capacity; constraints on Novavax's ability to pursue planned regulatory pathways, alone or with partners; challenges in implementing its global restructuring and cost reduction plan; challenges in obtaining commercial adoption and market acceptance of its updated 2024-2025 formula COVID-19 vaccine or any COVID-19 variant strain containing formulation, or for its CIC vaccine candidate and stand-alone influenza vaccine candidate or other product candidates; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities, including requirements to deliver doses that may require Novavax to refund portions of upfront and other payments previously received or result in reduced future payments pursuant to such agreements and challenges in amending or terminating such agreements; challenges related to the seasonality of vaccinations against COVID-19; challenges related to

the demand for vaccinations against COVID-19 or influenza; challenges in identifying and successfully pursuing innovation expansion opportunities; Novavax's expectations as to expenses and cash needs may prove not to be correct for reasons such as changes in plans or actual events being different than its assumptions; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax's Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent Quarterly Reports on Form 10-Q, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov and www.novavax.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

NOVAVAX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share information)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	**2024**	2023
	(unaudited)		**(unaudited)**	
Revenue:				
Product sales	**$ 38,210**	$ 2,231	**$ 140,438**	$ 279,937
Licensing, royalties and other	**46,302**	19,833	**453,413**	23,046
Grants	--	164,922	--	389,380
Total revenue	**84,512**	186,986	**593,851**	692,363
Expenses:				
Cost of sales	**60,619**	98,929	**166,070**	188,792
Research and development	**87,164**	106,229	**286,789**	572,805
Selling, general and administrative	**70,747**	107,460	**258,843**	313,709
Total expenses	**218,530**	312,618	**711,702**	1,075,306
Loss from operations	**(134,018)**	(125,632)	**(117,851)**	(382,943)
Interest expense	**(4,236)**	(2,859)	**(12,490)**	(10,299)
Other income (expense), net	**15,922**	(2,982)	**27,307**	26,912
Loss before income tax expense (benefit)	**(122,332)**	(131,473)	**(103,034)**	(366,330)
Income tax expense (benefit)	**(1,032)**	(697)	**3,435**	343
Net Loss	**$ (121,300)**	$ (130,776)	**$ (106,469)**	$ (366,673)
Net loss per share:				
Basic and diluted	**$ (0.76)**	$ (1.26)	**$ (0.71)**	$ (3.94)
Weighted average number of common shares outstanding:				
Basic and diluted	**160,049**	103,429	**149,486**	93,046

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	September 30, 2024	December 31, 2023
	(unaudited)	
Cash and cash equivalents	**$ 573,630**	**$ 568,505**
Marketable securities	**335,901**	--
Total restricted cash	**14,957**	**15,305**

Total current assets	**1,103,680**	**1,143,888**
Working capital	**(77,319)**	**(491,250)**
Total assets	**1,712,483**	**1,797,490**
Convertible notes payable	**169,265**	**168,016**
Total stockholders' deficit	**(526,436)**	**(716,927)**

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