Novavax Reports Second Quarter 2024 Financial Results and Operational Highlights

August 8, 2024

- *Achieved total revenue of $415 million in the second quarter of 2024 and ended the period with $1.1 billion in Cash*
- *Filed with the U.S. FDA and EMA for authorization of updated 2024-2025 formula COVID-19 vaccine*
- *Received $570 million in upfront payment and equity investment from Sanofi; progressed operationalization of Sanofi partnership*
- *Phase 3 trial initiation for COVID-19-Influenza Combination and stand-alone influenza vaccines planned for Q4 2024; data expected by mid-2025*
- *Company to host conference call today at 8:30 a.m. ET*

GAITHERSBURG, Md., Aug. 8, 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 second quarter ended June 30, 2024.

"This is an exciting time for Novavax, and we have been keenly focused on evolving our operating model to leverage our key drivers of value," said John C. Jacobs, President and Chief Executive Officer, Novavax. "We intend to drive future value for the business through not only the Sanofi partnership, but also through our late-stage combination and influenza assets. We plan to unveil a new and expanded clinical pipeline by the end of this year and leverage both the pipeline and our proven technology to drive additional partnerships and deals and to ultimately drive significant, long-term value for our shareholders."

Second Quarter 2024 and Recent Highlights

During the second quarter, Novavax continued executing against its four key priorities for the remainder of 2024.

Priority #1: Successful Execution of Sanofi Partnership

Novavax has taken steps to enable a successful operationalization of the collaboration and license agreement (the Sanofi Agreement) with Sanofi Pasteur Inc. (Sanofi).

- Effective January 1, 2025, Sanofi will assume primary commercial responsibility for Novavax's updated 2024-2025 formula COVID-19 vaccine (NVX-CoV2705) in the U.S., Europe and select major markets not currently subject to Novavax Advance Purchase Agreements (APAs) or existing partnership agreements.
- Received $500 million upfront payment and an approximately $70 million equity investment from Sanofi.
- Novavax is eligible to receive up to $700 million in development, regulatory and launch milestones for activities related to commercializing Nuvaxovid™ and advancing Sanofi's flu-COVID-19 combination vaccine candidate plus royalties. In addition, Novavax is eligible to receive royalties associated with any other Nuvaxovid combination vaccine Sanofi chooses to develop.
- For each additional Sanofi vaccine product developed under the non-exclusive license with Novavax's Matrix-M adjuvant technology, Novavax is eligible to receive additional launch and sales milestones of up to $210 million per product plus ongoing product royalties.

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

Novavax continued to leverage its technology platform to drive value creation.

- On track to initiate the Phase 3 immunogenicity trial for both COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates in the fourth quarter of 2024, with data expected by mid-2025.
- Conducting pipeline prioritization activities to determine Novavax's lead portfolio programs.

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

Novavax continued to progress its cost reduction program to create a more lean and agile organization and accelerate its focus on Research and Development (R&D).

- On track with global restructuring and cost reduction plan with an approximately 34% reduction in combined R&D and Selling, General and Administrative (SG&A) expenses in the second quarter of 2024 compared to the same period for 2023.
- Prepared to initiate an additional cost reduction program to reduce R&D plus SG&A expenses, with a portion of expenses to be reimbursed by Sanofi under the Sanofi Agreement. Novavax plans to continue assessing existing capabilities to further refine the shape, size and scope of its organization this year and into 2025.
- Targeting full year combined R&D and SG&A expenses to be below $500 million for full year 2025 and below $350 million for full year 2026. Novavax expects greater than $50 million of such expenses in 2025 to be reimbursed by Sanofi under the Sanofi Agreement, resulting in adjusted combined R&D and SG&A expenses, net of Sanofi reimbursement costs under the Sanofi Agreement, of below $450 million for full year 2025.

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

Novavax expects to deliver its updated 2024-2025 formula COVID-19 vaccine to the market by the start of the season.

U.S. Market:

- Submitted an Emergency Use Authorization (EUA) amendment to the U.S. Food and Drug Administration (FDA).
- Advanced manufacturing of pre-filled syringe presentation of updated 2024-2025 formula COVID-19 vaccine following FDA strain selection guidance. Expect doses will be ready to ship upon receipt of EUA.
- FDA accepted the Biologics License Application (BLA) for Novavax's COVID-19 vaccine with a Prescription Drug User Fee Act date of April 2025.
- Advanced retail pharmacy contract negotiations to enhance access for the 2024-2025 vaccination season.

Global Markets:

- For 2024, made decision to conduct lean and targeted commercial launch in Europe in select key countries including Germany, Italy and Poland.
- Submitted marketing authorization amendments to the European Medicines Agency (EMA) and expect doses will be ready to ship upon receipt of market authorization.

Second Quarter 2024 Financial Results

- **Total revenue** for the second quarter of 2024 was $415 million, compared to $424 million in the same period in 2023. Second quarter 2024 licensing, royalties and other revenue includes $391 million associated with the $500 million upfront payment received under the Sanofi Agreement.
- **Cost of sales** for the second quarter of 2024 was $46 million, compared to $56 million in the same period in 2023. These quarters included $24 million and $31 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 second quarter of 2024 were $107 million, compared to $219 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 second quarter of 2024 were $101 million, compared to $94 million for the same period in 2023. The increase was primarily due to certain fees paid in association with signing the Sanofi Agreement.
- **Net income** for the second quarter 2024 was $162 million, compared to a net income of $58 million in the same period in 2023.
- **Cash, cash equivalents, marketable securities and restricted cash (Cash)** were $1.1 billion as of June 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

			Reflects revenue recognition of Sanofi Payment	
? $ in millions	**Prior** (as of May 10, 2024)			**Updated** (as of August 8, 2024)
Combined Revenue and Sanofi Agreement Payments	$970 - $1,170		Total Revenue	$700 - $800
Total Revenue[1]	$400 - $600		Product Sales[3]	$275 - $375
Initial Sanofi Agreement Payments[2]	~$570		Licensing, Royalties and Other Revenue[4]	~$425

Combined R&D and SG&A	$700 - $750		Combined R&D and SG&A[5]	$700 - $750

1. *Prior full year 2024 Total Revenue guidance includes product sales, royalties and other revenue and did not reflect revenue attributable to the initial payments received from Sanofi pursuant to the Sanofi Agreement in the second quarter of 2024. Prior full year 2024 Total Revenue guidance reflects APA expected dose delivery schedules of $150 million to $250 million and non-APA related revenue of $250 million to $350 million, subject to updated variant manufacturing and regulatory approvals, from a combination of commercial market product sales plus royalties and other revenue from partner-related activities.*
2. *Initial Sanofi Agreement payments received in the second quarter of 2024 include a non-refundable $500 million upfront payment and a $69 million equity investment in Novavax.*
3. *Full year 2024 product sales guidance reflects approximately $100 million in APA dose deliveries in 1H 2024 and $175 million to $275 million of commercial market sales expected in 2H 2024, subject to updated variant manufacturing and regulatory approvals.*
4. *Full year 2024 guidance for Licensing, royalties and other revenue includes $400 million of revenue recognition from the $500 million Sanofi agreement upfront payment and $25 million in royalty and other revenue from partner-related activities.*
5. *Combined R&D and SG&A expenses expected at the higher end of the range to account for the Sanofi Agreement transaction costs.*

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/3XTduSS to 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 August 8, 2024, until 11:59 p.m. ET on August 15, 2024. To access the replay by telephone, dial (888) 660-6345 (Domestic) or (+1) (646) 517-4150 (International) and use passcode 414036 #.

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 September 8, 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 influence 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 near-term priorities including a successful transition under the Sanofi partnership, driving incremental value from Novavax's technology platform, delivering an updated 2024-2025 formula COVID-19 vaccine for the start of the 2024-2025 vaccination season in a pre-filled syringe presentation, launching a Phase 3 trial for CIC and stand-alone influenza in the fourth quarter of 2024, with data expected by mid-2025, and reducing operations expenses, including by initiating an additional cost reduction program, the anticipated timing of potential BLA approval for Novavax's prototype COVID-19 vaccine and XBB COVID-19 vaccine and EUA for Novavax's updated 2024-2025 formula COVID-19 vaccine, potential royalties and milestones under the agreement with Sanofi, its operating plans, objectives and prospects, updated full year 2024 financial guidance, its commercial launch plans for the 2024-2025 vaccination season, its future financial or business performance, conditions or strategies, and the downsizing of commercial operations in Europe are forward-looking statements. 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 and Sanofi's ability to successfully implement its partnership, including the ability to transition key processes and effect technology transfers, Novavax's ability to successfully and timely manufacture, distribute, or market its updated 2024-2025 formula COVID-19 vaccine including as a single dose vial or pre-filled syringe product presentation for the 2024-2025 vaccination season and its ability to receive a BLA from the FDA for the 2024-2025 vaccination season; challenges related to Novavax's new partnership with Sanofi; 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; challenges or delays in obtaining regulatory authorization for its product candidates, including its updated COVID-19 vaccine in time for the 2024-2025 vaccination season or for future COVID-19 variant strain changes, its CIC and stand-alone influenza vaccine candidate; 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 and PCI Pharma Services for finishing Novavax's COVID-19 vaccine and the impact of any delays or disruptions in their operations on the delivery of customer orders; 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, in multiple jurisdictions simultaneously, leading to staggering of regulatory filings, and potential regulatory actions; challenges in implementing its global restructuring and cost reduction plan and additional cost reduction program; Novavax's ability to timely deliver doses; 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; 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; 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 June 30,		Six Months Ended June 30,	
	2024	2023	**2024**	2023
	(unaudited)		**(unaudited)**	

Revenue:				
Product sales	**$ 19,904**	$ 285,163	**$ 102,228**	$ 277,706
Licensing, royalties and other	**395,580**	2,184	**407,111**	3,213
Grants	--	137,079	--	224,458
Total revenue	**415,484**	424,426	**509,339**	505,377
Expenses:				
Cost of sales	**46,242**	55,777	**105,451**	89,863
Research and development	**106,946**	219,475	**199,625**	466,576
Selling, general and administrative	**101,298**	93,717	**188,096**	206,249
Total expenses	**254,486**	368,969	**493,172**	762,688
Income (loss) from operations	**160,998**	55,457	**16,167**	(257,311)
Interest expense	**(4,143)**	(3,124)	**(8,254)**	(7,440)
Other income, net	**7,731**	5,532	**11,385**	29,894
Income (loss) before income tax expense (benefit)	**164,586**	57,865	**19,298**	(234,857)
Income tax expense (benefit)	**2,205**	(143)	**4,467**	1,040
Net income (loss)	**$ 162,381**	$ 58,008	**$ 14,831**	$ (235,897)
Net income (loss) per share:				
Basic	**$ 1.09**	$ 0.65	**$ 0.10**	$ (2.69)
Diluted	**$ 0.99**	$ 0.58	**$ 0.10**	$ (2.69)
Weighted average number of common shares outstanding:				
Basic	**148,379**	89,362	144,147	87,769
Diluted	**165,855**	104,065	145,121	87,769

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	June 30, 2024	**December 31, 2023**
	(unaudited)	
Cash and cash equivalents	**$ 680,162**	**$ 568,505**
Marketable securities	**369,432**	**--**
Total restricted cash	**15,396**	**15,305**
Total current assets	**1,203,370**	**1,143,888**
Working capital	**45,559**	**(491,250)**
Total assets	**1,818,646**	**1,794,490**
Convertible notes payable	**168,848**	**168,016**
Total stockholders' deficit	**(431,706)**	**(716,927)**

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