Novavax Reports First Quarter 2024 Financial Results and Operational Highlights

May 10, 2024

- *Announces co-exclusive licensing agreement with Sanofi to co-commercialize COVID-19 vaccine, develop novel COVID-19-Influenza combination vaccines and develop multiple new vaccines utilizing Novavax's Matrix-M™ adjuvant*
- *This agreement represents a potential multi-billion dollar revenue opportunity for Novavax including:*
  - *$500 million upfront payment*
  - *Approximately $70 million equity investment in Novavax*
  - *Up to $700 million in COVID-19 and combination product near-term milestones, plus ongoing tiered royalties on product sales*
  - *Up to $200 million in milestones plus royalties for each new vaccine developed utilizing Novavax's Matrix-M™ adjuvant*
- *Announces addition of standalone influenza vaccine to Phase 3 COVID-19-Influenza Combination vaccine trial, which is on-track to initiate second half of 2024, with potential 2026 launch for both candidates*
- *Reduced current liabilities by an additional $831 million during Q1 2024*
- *Achieved total revenue in Q1 2024 of $94 million*
- *Novavax removes going concern notice*
- *Company to host conference call today at 8:30 a.m. ET*

GAITHERSBURG, Md., May 10, 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 first quarter ended March 31, 2024.

Earlier today, Novavax and Sanofi (NASDAQ: SNY) announced that they have entered into a co-exclusive licensing agreement. The terms of the agreement include: a co-exclusive license to co-commercialize Novavax's current stand-alone adjuvanted COVID-19 vaccine worldwide (except in countries with existing Advance Purchase Agreements [APAs] and in India, Japan and South Korea where Novavax has existing partnership agreements); a sole license to Novavax's adjuvanted COVID-19 vaccine for use in combination with Sanofi's flu vaccines while Novavax retains the right to and is developing its own COVID-19-Influenza Combination (CIC) vaccine candidate; a non-exclusive license to use Novavax's adjuvanted COVID-19 vaccine for use in combination with non-flu vaccines; and a non-exclusive license to use the Matrix-M adjuvant in vaccine products. In addition, Sanofi will take a minority (<5%) equity investment in Novavax.

"Today we announce the beginning of an exciting new chapter for Novavax with the launch of a strategically important partnership with one of the world's leading vaccine companies. We believe the combined strength of Novavax and Sanofi will enable us to better fulfill our mission of developing and improving access to life-saving vaccines," said John C. Jacobs, President and Chief Executive Officer, Novavax. "I am proud of the progress our Company has made this quarter as we continue to advance our COVID-19 vaccine for the upcoming 2024-2025 vaccination season and plan for the launch of our Phase 3 CIC and standalone influenza program in the second half of this year."

The agreement is further validation of Novavax's technology platform and provides significant opportunity to drive value creation and benefit global public health. It strengthens Novavax's balance sheet and cash flow position, providing the opportunity to focus more on research and development and pipeline expansion to accelerate growth and generate long-term value for shareholders.

Sanofi Agreement Highlights

Financial Highlights

- This agreement represents a potential multi-billion dollar revenue opportunity for Novavax.
- The total value of near-term upfront payments, Sanofi's equity investment and potential milestones associated with Nuvaxovid™ sales and the development of Sanofi's flu-COVID-19 combination vaccine equate to approximately $1.3 billion.
  - Novavax will receive an upfront payment of $500 million within 10 days.
  - Novavax will receive today an equity investment of approximately $70 million in Novavax common stock for a 4.9% minority interest.

    - Novavax is eligible to receive up to $350 million in milestones for activities related to Nuvaxovid.
    - Novavax is eligible to receive up to $350 million in additional milestones for Sanofi's flu-COVID-19 combination vaccine.
- In addition, Novavax is eligible to receive royalties associated with the ongoing sales of Nuvaxovid and Sanofi's flu-COVID-19 combination vaccine and any other combination vaccines Sanofi may develop including Nuvaxovid.
- And finally, 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 $200 million per product plus ongoing product royalties.

Additional Highlights

- Novavax is eligible for cost reimbursement by Sanofi of certain R&D and medical affairs costs, select technology transfer costs and supply of COVID-19 and Matrix-M adjuvant.
- Sanofi will be solely responsible for the development and commercialization of any novel flu-COVID-19 combination product containing a Sanofi flu vaccine, and any other combination products they may develop utilizing Nuvaxovid and any other new vaccines they develop utilizing the Matrix-M adjuvant.
- Outside of the collaboration, each party may develop and commercialize their own COVID-19-Influenza combination vaccines and adjuvanted products at their own cost.

First Quarter 2024 and Recent Highlights

During the first quarter, Novavax continued executing against its three key priorities for 2024.

Priority #1: Deliver an Updated COVID-19 Vaccine for the 2024-2025 Vaccination Season

U.S. Market:

- Updated protein-based COVID-19 vaccine to JN.1 with anticipated pre-filled syringe presentation.
- Completed the submission of the Biologics License Application for Novavax's COVID-19 vaccine with the U.S. Food and Drug Administration (FDA).
- Aligned with the FDA on pathway for Emergency Use Authorization for updated COVID-19 vaccine for the 2024-2025 vaccination season, with the intent of facilitating product availability at the beginning of the season.
- Advanced retail pharmacy contract negotiations for the 2024-2025 vaccination season.

Global Markets:

- Delivered doses of Nuvaxovid XBB.1.5 vaccine to Europe and for distribution by the Taiwan Centers for Disease Control.
- Received marketing authorization from the United Kingdom's (U.K.) Medicines and Healthcare products Regulatory Agency for Nuvaxovid XBB.1.5 in individuals aged 12 and older in January and progressed preparations for participation in the U.K. spring campaign for private healthcare providers.
- Granted full approval from Singapore's Health Sciences Authority for Nuvaxovid XBB.1.5 for active immunization to prevent COVID-19 in individuals aged 12 and older.

Priority #2: Launch Phase 3 trial of CIC and Stand-alone Influenza Program

Novavax remained focused on leveraging its technology platform, including its proprietary Matrix-M adjuvant, to expand its pipeline with CIC and stand-alone influenza vaccine candidates.

- Made strategic decision to add a stand-alone influenza arm to the Phase 3 trial and to focus on individuals at higher risk by enrolling adults aged 60 and older for both the stand-alone influenza and CIC arms of the trial.
- On track to submit an investigational new drug application and initiate the pivotal Phase 3 trial for both CIC and stand-alone influenza vaccine candidates in the second half of 2024, with potential for accelerated approval and launch in 2026.
- Continued to optimize preclinical candidates, including a new approach to H5N1 pandemic bird flu vaccination, and expanded core technology for novel applications including mucosal vaccination and high-density nanoparticles.

Priority #3: Continue Evolution of Novavax, Further Reducing Operating Expenses

Novavax has made significant progress on its commitment to improve its financial position while maintaining the capabilities that support long-term value creation.

- On track with global restructuring and cost reduction plan, continued to transform the Company into a more lean and agile organization, with an approximately 50% reduction in combined R&D and SG&A expenses in the first quarter of 2024 compared to 2023.
- Since December 31, 2022, reduced current liabilities by $1.7 billion, including an additional $831 million reduction in the first quarter of 2024, primarily driven by the settlements with Gavi, the Vaccine Alliance and Fujifilm Diosynth Biotechnologies.

First Quarter 2024 Financial Results

- **Total revenue** for the first quarter of 2024 was $94 million, compared to $81 million in the same period in 2023.
- **Cost of sales** for the first quarter of 2024 was $59 million, compared to $34 million in the same period in 2023. These quarters included $15 million and $25 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 first quarter of 2024 were $93 million, compared to $247 million in the same period in 2023. The decrease was primarily due to reductions in manufacturing and clinical research-related spend as well as a $27 million benefit associated with the favorable settlement of manufacturing liabilities recorded in the first quarter of 2024.
- **SG&A expenses** for the first quarter of 2024 were $87 million, compared to $113 million for the same period in 2023. The decrease was primarily due to the Company's continued cost containment measures to reduce operating spend.
- **Net loss** for the first quarter 2024 was $148 million, compared to a net loss of $294 million in the same period in 2023.
- **Cash, cash equivalents and restricted cash** were $496 million as of March 31, 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 February 28, 2024)	**Updated** (as of May 10, 2024)
Combined Revenue and Sanofi Agreement Payments	$800 - $1,000	$970 - $1,170
Total Revenue[1,2]	$800 - $1,000	$400 - $600
Initial Sanofi Agreement Payments[3]		~$570
Combined R&D and SG&A	$700 - $800	$700 - $750

1. *Total Revenue includes product sales and royalties and other revenue.*
2. *Full year 2024 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 activity. The update to the expected 2024 APA dose delivery schedules reflects the anticipated shift of approximately $250 million in contracted doses from 2024 to future periods.*
3. *Sanofi agreement initial payments include a non-refundable $500 million upfront payment to be received within 10 days and an immediate $69 million equity investment in Novavax.*

Total potential contract value for APAs outstanding, as of March 31, 2024, was over $600 million related to expected dose deliveries for the second quarter of 2024 through 2026. This amount excludes deferred revenue associated with the 2023 Canada amendments to forfeit doses.

Novavax is prepared to initiate an additional cost reduction program to reduce 2025 R&D plus SG&A expenses to below $500 million, a portion of which it expects to be reimbursed by Sanofi under the agreement. This reflects a greater than $225 million reduction beyond prior stated targets.

Intends to further reshape the size and scope of global business operations to prioritize enabling Sanofi to successfully execute its commercial and development plans under the agreement, deliver on existing Novavax APAs and focus on creating value from R&D and business development.

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/3VNP8J5 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 (888) 664-6383 (Domestic) or (+1) (416) 764-8650 (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. EST on May 10, 2024, until 11:59 p.m. ET on May 17, 2024. To access the replay by telephone, dial (888) 390-0541 (Domestic) or (+1) (416) 764-8677 (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 June 10, 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.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its mission, its near-term priorities including delivering an updated 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 second half of 2024, with possible combination vaccine and stand-alone influenza vaccine launch in 2026, and reducing operations expenses, including by initiating an additional cost reduction program, the anticipated timing of potential BLA approval for Novavax's prototype vaccine and EUA for Novavax's updated 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 future financial or business performance, conditions or strategies, and its ability to attain contract value under existing APAs 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 COVID-19 vaccine including as a single dose vial or pre-filled syringe product presentation for the 2024-2025 vaccination season; 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; 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; Novavax's ability to timely deliver doses; challenges in obtaining commercial adoption and market acceptance of its updated 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; challenges related to the seasonality of 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 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

	Three Months Ended March 31,	
	2024	2023
	(unaudited)	
Revenue:		
Product sales	**$ 82,324**	$ (7,457)
Grants	**--**	87,379
Royalties and other	**11,531**	1,029
Total revenue	**93,855**	80,951
Expenses:		
Cost of sales	**59,209**	34,086
Research and development	**92,679**	247,101
Selling, general and administrative	**86,798**	112,532
Total expenses	**238,686**	393,719
Loss from operations	**(144,831)**	(312,768)
Interest expense	**(4,111)**	(4,316)
Other income	**3,654**	24,362
Loss before income taxes	**(145,288)**	(292,722)
Income tax expense	**2,262**	1,183
Net loss	**$ (147,550)**	$ (293,905)
Net loss per share		
Basic and Diluted	**$ (1.05)**	$ (3.41)
Weighted average number of common shares outstanding Basic and Diluted	**139,916**	86,158

SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	March 31, 2024	**December 31, 2023**
	(unaudited)	
Cash and cash equivalents	**$ 480,586**	**$ 568,505**
Total restricted cash	**15,350**	**15,305**
Total current assets	**727,120**	**1,143,888**
Working capital	**(77,262)**	**(491,250)**
Total assets	**1,353,534**	**1,794,490**
Convertible notes payable	**168,432**	**168,016**
Total stockholders' deficit	**(867,084)**	**(716,927)**

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