

# First quarter 2023 financial results & operational highlights

Nasdaq: NVAX | May 9<sup>th</sup>, 2023

# Cautionary note regarding forward-looking statements

This presentation includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "may," "will," "believe," "estimate," "forecast," "goal," "project," and other words of similar meaning. These forward-looking statements address various matters including information relating to the future of Novavax, its key strategic priorities and commercial goals, its operating plans, objectives and prospects, including Novavax' ability to continue as a going concern within one year after the issuance date of the financial statements for the quarter ended March 31, 2023, its future financial or business performance, conditions, or strategy, including expectations regarding 2023 guidance, its future product demand trends, the amount, timing and impact of Novavax's global restructuring and cost reduction plan, which includes a reduction to our global workforce, as well as the consolidation of facilities and infrastructure; the expected timing and impact of cost savings from our global restructuring and cost reduction plan, its partnerships, the ongoing development of our vaccine candidates, including strain selection, anticipated timing of clinical trials and expected results, the ongoing development of NVX-CoV2373, a bivalent vaccine candidate, a COVID-Influenza combination vaccine candidate and other vaccine candidates, the timing of anticipated results and our efforts for the Fall 2023 vaccination season, the scope, timing and outcome of future regulatory filings and actions, including expected U.S. Biologics License Application filing in the second half of 2023, the efficacy, safety and intended utilization of NVX-CoV2373 and Novavax' other vaccine candidates and key upcoming milestones.

Each forward-looking statement contained in this presentation is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; unanticipated challenges or delays in conducting clinical trials; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; manufacturing delays or challenges, including as a result of the timing of the anticipated regulatory requirements for the fall 2023 vaccination season; the loss of future funding from the U.S. government; the potential for an unfavorable outcome in disputes, including the pending arbitration with Gavi and the risks identified under the heading "Risk Factors" in Novavax' most recent Annual Report on Form 10-K and subsequent Form 10-Qs, as well as subsequent filings with the Securities and Exchange Commission. Novavax cautions investors not to place considerable reliance on the forward-looking statements contained in this presentation. Investors are encouraged to read Novavax' filings with the Securities and Exchange Commission, available at www.sec.gov and on our website at www.novavax.com, for a discussion of these and other risks and uncertainties.

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# Non-GAAP financial measures

The Company has used a non-GAAP financial measure in this presentation, which is R&D and SG&A expense, excluding one-time restructuring charges including a restructuring charge related to employee severance and benefit costs of \$10 million to \$15 million and additional anticipated costs related to the consolidation of facilities and infrastructure. 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 excluding 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. The Company is unable to reconcile this forward-looking non-GAAP financial measure to the most directly comparable GAAP measure without unreasonable efforts because the company is currently unable to predict with a reasonable degree of certainty the type and extent of the anticipated costs related to the consolidation of facilities and infrastructure that would be expected to impact GAAP financial measure for the period but would not impact the non-GAAP financial measure.



# Q1 2023 Earnings call

**Agenda** 

Welcome



Erika Schultz
Senior Director, Investor Relations

Introduction



John C. Jacobs

President and Chief Executive Officer

COVID Variant Strain Development & Pipeline

Filip Dubovsky, MD President, Research and Development

**Commercial Updates** 

**John Trizzino** 

EVP, Chief Commercial Officer and Chief Business Officer

**Financial Results** 



Jim P. Kelly
EVP, Chief Financial Officer and Treasurer

**Closing Remarks** 



John C. Jacobs

President and Chief Executive Officer





# Recent progress across near-term priorities

# Priority #1

Deliver a competitive product for the upcoming 2023 fall vaccination season

# **Priority #2**

Reduce our rate of spend, manage our cash flow, and evolve our scale & structure

# Priority #3

Leverage our technology platform, our capabilities, and our portfolio of assets to drive additional value beyond

Nuvaxovid<sup>TM,1</sup> alone



# SECTION

# COVID Variant Strain Development



# Vaccine candidates in variant development platform

	Pre-clinical Immunogenicity	Master Virus Seed Production	Large Scale GMP Manufacture	Clinical Studies	
Wuhan	✓	✓	✓	✓	
BA.1	✓	✓	✓	✓	
BA.2	✓				
BA.2.12.1	✓				
BA.5	✓	✓	✓	In Process	
BQ.1	✓				
BQ.1.1	✓	✓			
BF.7	✓				
CH.1.1	✓	✓			
BN.1	✓				
XBB	✓				
XBB.1	✓				
XBB.1.16	In Process	In Process			
XBB.1.5 (Lead Candidate)	✓	✓	In Process		



# Study 311: Part 2 Confirms strain change approach for future vaccine approvals



## Study 311: Part 1

Results announced November 2022



Evaluated NVX-CoV2373, BA.1 vaccine candidate, and bivalent BA.1 + Prototype vaccine candidate



BA.1 vaccine candidate met primary strainchange endpoint, demonstrating ability to develop variant vaccines



NVX-CoV2373 induced broad immune response against original Prototype, BA.1 and BA.5 strains



## Study 311: Part 2

Ongoing

- Evaluating NVX-CoV2373, BA.5 vaccine candidate, and bivalent BA.5 + Prototype vaccine candidate
- Completed enrollment in Q2 2023
- Topline results expected mid-2023
- Data to support regulatory filing for updated vaccine composition for 2023 fall vaccination season





COVID-Influenza Combination and Stand-alone Influenza Vaccines



# COVID-Influenza Combination (CIC) and stand-alone influenza vaccine candidates

#### Stand-alone Influenza Vaccine

Quadrivalent vaccine with four influenza Hemagglutinin (HA) genes





Matrix-M™ adjuvant



Phase 3 Immunogenicity Trial

Results announced March 2020



Previous influenza candidate met all primary endpoints

### COVID-Influenza Combination (CIC) Vaccine

Combines stand-alone influenza vaccine and NVX-CoV2373 in single formulation





Matrix-M™ adjuvant



Phase 1/2
Trial
Results announced
April 2022



Demonstrated feasibility, safety and immunogenicity of combination vaccine



# CIC Phase 2, Part 1: Design



Matrix-M.

#### **OBJECTIVES**

- Assess safety and reactogenicity of various COVID-Influenza combination (CIC) and aNIV formulations.
- Assess immunogenicity of various CIC and qNIV formulations.
- Assess CMI responses of various CIC and aNIV formulations.

#### DESIGN

- 1500 adults aged 50 80 years, seropositive by infection or vaccination ≥ 8 weeks prior
- 1 dose of various CIC or aNIV
  - rs dose range 15-35 µg/strain/dose
  - ► HA dose range 30-60 µg/strain/dose
  - Matrix-M adjuvant dose: 50-75 µg/dose
- ► Key reactogenicity and safety: Day 7, 21, 84, 182
- Key Immunogenicity (IgG, HAI, MN): Day 0, 7, 21, 84, 182
- Key CMI assessments (subset): Day 0, 7, 182



**Study Design** 

HA per

Strain, µg

**Vaccine Group** 

Ν

Day 0

rS, µg



# **Summary of safety**

## Data collected through Day 21

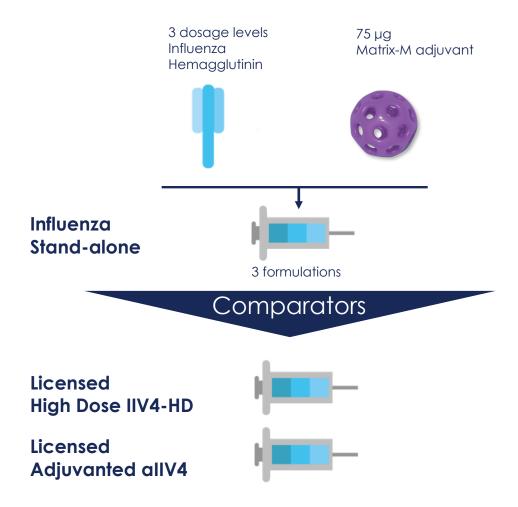
Both the stand-alone influenza vaccine and the combination vaccine had reassuring preliminary safety profiles that were clinically indistinguishable from the comparators

- No AESI or PIMMC in any vaccine arm
- Few SAEs, none treatment-related
- Unsolicited adverse events occurred in ≤25%, none severe + treatment-related
- Solicited local and systemic adverse events were mostly mild to moderate and rates were comparable to the comparator influenza vaccines
  - Injection site pain, tenderness, and swelling, and fatigue, muscle pain, headache, and malaise were the most common
  - o <3% of subjects had grade 3 or higher solicited AEs
    </p>
- No consistent pattern of increase in event rates or severity with higher antigen/adjuvant doses



# Novavax stand-alone influenza vaccine compared to licensed influenza vaccine

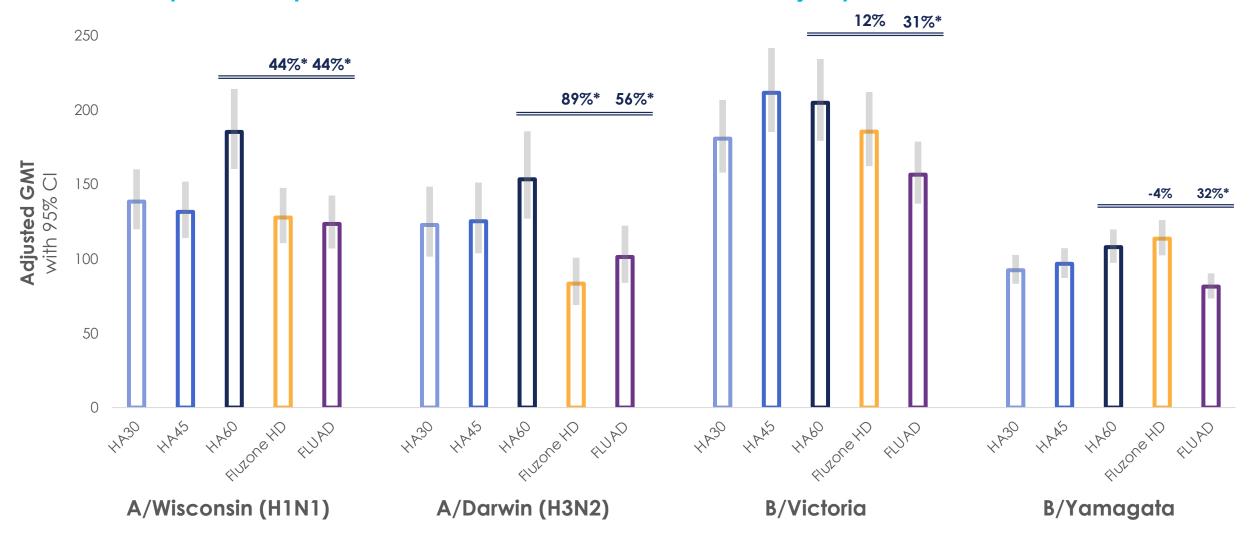
Key comparators to inform advanced development





# Stand-alone influenza GMT non-inferior for all strains for Fluzone HD and FLUAD

Baseline adjusted wild type HAI for qNIV compared to licensed influenza vaccines 44-89%\* improved responses for H1N1 and H3N2 which cause majority of disease

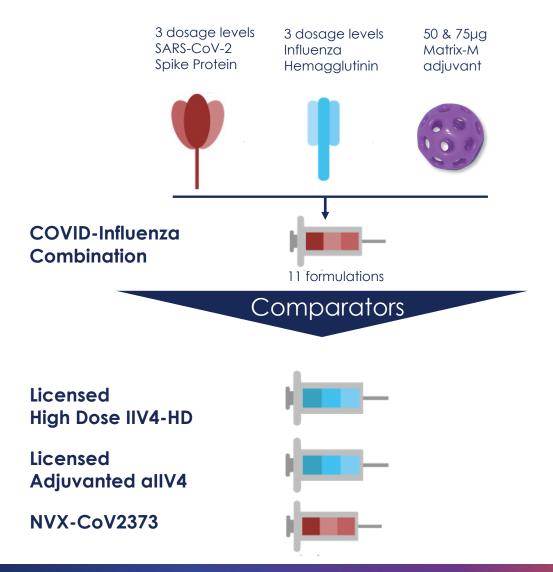




FLUAD® is a registered trademark of Seqirus UK Limited; Fluzone High-Dose Quadrivalent® is a registered trademark of Sanofi Pasteur Inc.

# COVID-Influenza Combination vaccine compared to Nuvaxovid and licensed influenza vaccines

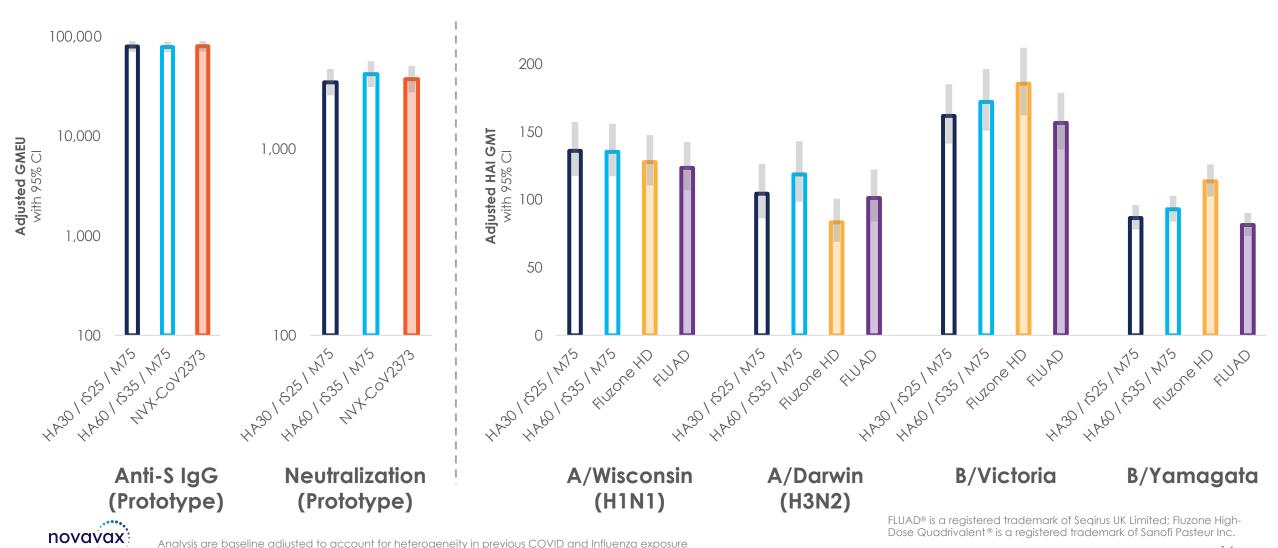
Key comparators to inform advanced development





# Combination vaccine immune responses are comparable to individual COVID and influenza vaccines

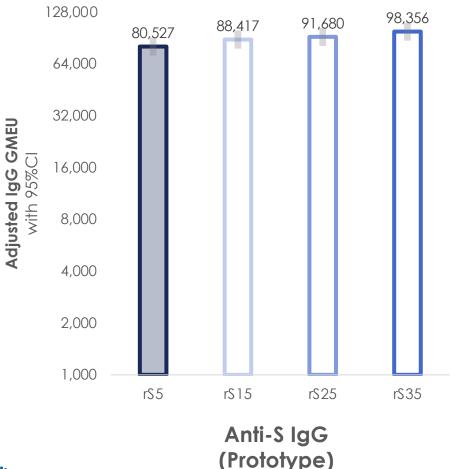
Select CIC formulations compared to authorized Nuvaxovid and licensed influenza vaccines

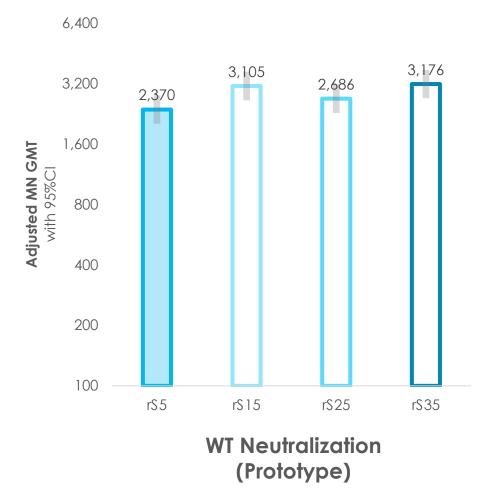


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# Approximately 30%\* increase observed with highest dose COVID vaccine compared to authorized Nuvaxovid

Anti-S IgG and neutralization responses for High-Dose COVID vaccine







<sup>\*</sup> p=<0.05 In pairwise comparison of ratio of GMEU or GMT; Analysis are baseline adjusted to account for heterogeneity in previous COVID exposure

# CIC Phase 2: Preliminary observations

#### Stand-alone Influenza vaccine

- Preliminary safety profile reassuring with reactogenicity comparable to Fluzone HD and FLUAD
- HAI\* responses 31-56% higher for all four strains compared to FLUAD
- HAI\* responses 44-89% higher for A strains compared to Fluzone HD; B-strains non-inferior

#### COVID-Influenza Combination vaccine

- Preliminary safety profile reassuring with reactogenicity comparable to Fluzone HD and FLUAD
- Anti-S IgG and neutralization responses achieved levels seen in Nuvaxovid Phase 3 study
- HAI\* responses generally consistent with Fluzone HD and FLUAD

# High-Dose COVID vaccine

- Preliminary safety profile reassuring and comparable to Fluzone HD and FLUAD
- Anti-S IgG and neutralization response 20-30% higher compared to Nuvaxovid





# Commercial Updates



# Long-term market opportunity expected for COVID

Transition to more traditional commercial market underway in priority markets



# U.S. commercial readiness efforts for 2023 fall vaccination season

Preparing for commercial market utilizing existing influenza vaccine logistics and go-to-market infrastructure



Discussions with all major retail pharmacies nationwide



Educating healthcare providers (HCPs) and pharmacists about our COVID vaccine



Engaging with distributors, physician buying groups, doctors' offices, and integrated delivery networks



Coordinating with the U.S. government for **participation in national public health programs** 



Expect to file BLA with U.S. FDA in 2H 2023

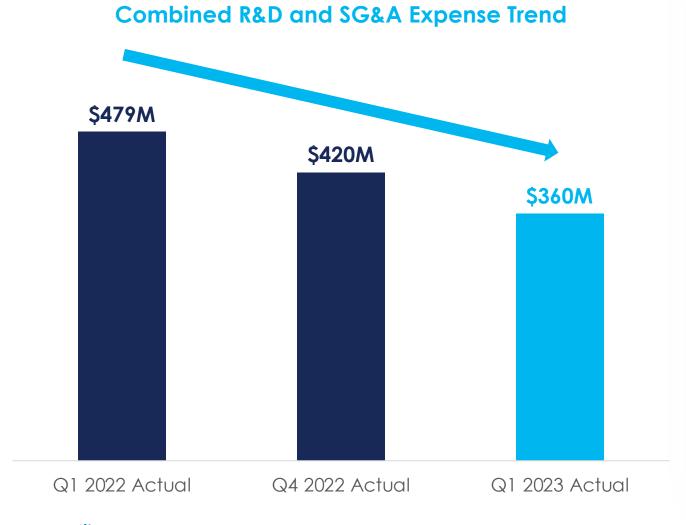




# Financial Results



# Q1 2023 Financial results



#### Q1 2023 Overview

- Reduction to combined R&D and SG&A expense to \$360 million
  - Decreased by \$120 million &
     25% compared to Q1 2022
  - Decreased by \$60 million &
     14% compared to Q4 2022
- Total revenue of \$81 million
- Reduction to current liabilities by \$541 million
- \$637 million in cash as of 3/31/2023<sup>1</sup>



# Q1 2023 Financial results

(\$ in millions, except per share amounts)	Q1 2023	Q1 2022		
Product sales 1	\$ (7)	\$ 586		
Grants Royalties & other	87 1	99 19		
Total revenue	81	704		
Cost of sales	34	15		
Research & development	247	383		
Selling, general & administrative	113	96		
Total expenses	394	495		
Income (loss) from operations	(313)	209		
Interest expense	(4)	(5)		
Other income (expense)	24	2		
Income (loss) before income tax expense	(293)	206		
Income tax expense (benefit)	1	3		
Net income (loss)	\$ (294)	\$ 203		
Net income (loss) per share				
Basic	\$ (3.41)	\$ 2.66		
Diluted	\$ (3.41)	\$ 2.56		



<sup>1.</sup> First quarter 2023 product sales include a \$65 million revenue reversal associated with doses delivered in 2022 that are scheduled for future replacement.

# 2023 Liability management



## **Current Liabilities Progress**

- Reduced current liabilities outstanding as of 3/31/2023 by \$541 million
- In April 2023, addressed additional \$140 million including:
  - \$27 million payment to resolve the Par arbitration, and
  - \$113 million payment to the UK government per the terms of our APA

Current Liabilities	12/	31/2022	3/3	1/2023	Cł	nange
\$ in millions						
AP & Accrued	\$	808	\$	644	\$	(164)
Finance Lease		27		1		(26)
Convertible Notes		325				(325)
Deferred Revenue		370		416		46
Other Current 1		930		858		(72)
Total Current Liabilities	\$	2,460	\$	1,919	\$	(541)



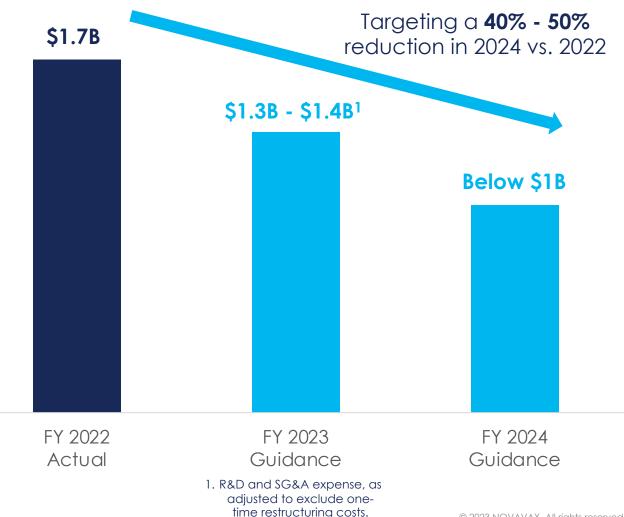
<sup>1.</sup> Other Current liabilities includes approximately \$700 million related to the GAVI arbitration and the \$113 million UK APA related payment made in April 2023.

# Global restructuring and cost reduction initiative

# **Cost Footprint Restructuring**

- An approximately 25% reduction to global workforce
- Focused investment in COVID program
- Reduction to pipeline investment
- Continued rationalization of manufacturing network
- Consolidation of facilities and infrastructure

## Combined Annual R&D and SG&A Expense





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# Full year 2023 financial guidance

Revenue			
Total Revenue <sup>1</sup>	Between \$1.4 billion and \$1.6 billion		
Grant Revenue	Between \$340 million and \$360 million		
Product Sales <sup>2</sup>	Between \$1.06 billion and \$1.24 billion		
Expenses			
Combined R&D and SG&A Expenses 3,4	Between \$1.3 billion and \$1.4 billion		

#### Other Financial Considerations

- Approximately \$800 million in APA orders secured for 2023 based on committed delivery schedules, subject to updated variant manufacturing and regulatory approvals
- Secured \$100 million payment in Q2 2023 related to a negotiated APA to reduce a portion of committed dose deliveries<sup>5</sup>

- 1. Total revenue includes Product Sales, Grants, and Royalties/Other.
- 2. APAs based on 2023 committed dose delivery schedules of approximately \$800 million and U.S. market sales, subject to updated variant manufacturing and regulatory approvals.
- 3. Combined R&D and SG&A expense, as adjusted to exclude one-time restructuring costs.
- 4. Novavax expects to record a restructuring charge of \$10 million to \$15 million related to employee severance and benefit costs, the majority of which are expected to be incurred in the second quarter of 2023 and is evaluating the anticipated cost related to the consolidation of facilities and infrastructure.
- 5. Payment excluded from full year 2023 sales guidance.



# Closing Remarks





# G&A