

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2024

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission File No. 000-26770

NOVAVAX, INC.

(Exact name of registrant as specified in its charter)

Delaware

22-2816046

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification No.)

700 Quince Orchard Road, Gaithersburg, MD

20878

(Address of principal executive offices)

(Zip code)

(240) 268-2000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.01 per share	NVAX	The Nasdaq Global Select Market

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated Filer	o
Non-accelerated filer	o	Smaller reporting company	o
Emerging growth company	o		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No x

The number of shares outstanding of the Registrant's Common Stock, \$0.01 par value, was 140,403,554 as of April 30, 2024.

NOVAVAX, INC.
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	For the Three Months Ended March 31,	
	2024	2023
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)
Other income (expense):		
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

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2024	2023
Net loss	\$ (147,550)	\$ (293,905)
Other comprehensive loss:		
Foreign currency translation adjustment	(13,547)	3,211
Other comprehensive income (loss)	(13,547)	3,211
Comprehensive loss	\$ (161,097)	\$ (290,694)

The accompanying notes are an integral part of these financial statements.

NOVAVAX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share information)

	March 31, 2024	December 31, 2023		
	(unaudited)			
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 480,586	\$ 568,505		
Restricted cash	10,455	10,424		
Accounts receivable	21,380	297,240		
Inventory	15,778	41,696		
Prepaid expenses and other current assets	198,921	226,023		
Total current assets	727,120	1,143,888		
Property and equipment, net	291,093	305,771		
Right of use asset, net	181,175	185,218		
Goodwill	123,179	127,454		
Other non-current assets	30,967	35,159		
Total assets	\$ 1,353,534	\$ 1,797,490		
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 57,724	\$ 132,610		
Accrued expenses	257,365	394,668		
Deferred revenue	240,900	241,310		
Current portion of finance lease liabilities	6,291	5,142		
Other current liabilities	242,102	861,408		
Total current liabilities	804,382	1,635,138		
Deferred revenue	841,473	622,210		
Convertible notes payable	168,432	168,016		
Non-current finance lease liabilities	54,609	55,923		
Other non-current liabilities	351,722	33,130		
Total liabilities	2,220,618	2,514,417		
Commitments and contingencies (Note 13)				
Preferred stock, \$ 0.01 par value, 2,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023				
Stockholders' deficit:				
Common stock, \$ 0.01 par value, 600,000,000 shares authorized at March 31, 2024 and December 31, 2023; 141,700,972 shares issued and 140,373,255 shares outstanding at March 31, 2024 and 140,506,093 shares issued and 139,505,770 shares outstanding at December 31, 2023	1,417	1,405		
Additional paid-in capital	4,204,775	4,192,164		
Accumulated deficit	(4,968,501)	(4,820,951)		
Treasury stock, cost basis, 1,327,717 shares at March 31, 2024 and 1,000,323 shares at December 31, 2023	(93,950)	(92,267)		
Accumulated other comprehensive income (loss)	(10,825)	2,722		
Total stockholders' deficit	(867,084)	(716,927)		
Total liabilities and stockholders' deficit	\$ 1,353,534	\$ 1,797,490		

The accompanying notes are an integral part of these financial statements.

NOVAVAX, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
Three Months Ended March 31, 2024 and 2023
(in thousands, except share information)
(unaudited)

	Common Stock		Additional		Accumulated Deficit	Treasury Stock	Accumulated Other		Total Stockholders' Deficit
	Shares	Amount	Paid-in Capital	Accumulated Deficit			Comprehensive Income (Loss)		
Balance at December 31, 2023	140,506,093	\$ 1,405	\$ 4,192,164	\$ (4,820,951)	\$ (92,267)	\$ 2,722	\$ (716,927)		
Stock-based compensation	—	—	11,556	—	—	—	—	11,556	
Stock issued under incentive programs	1,194,879	12	1,055	—	(1,683)	—	—	(616)	
Foreign currency translation adjustment	—	—	—	—	—	—	(13,547)	(13,547)	
Net loss	—	—	—	(147,550)	—	—	—	(147,550)	
Balance at March 31, 2024	141,700,972	\$ 1,417	\$ 4,204,775	\$ (4,968,501)	\$ (93,950)	\$ (10,825)	\$ (867,084)		
Balance at December 31, 2022	86,806,554	\$ 868	\$ 3,737,979	\$ (4,275,889)	\$ (90,659)	\$ (6,377)	\$ (634,078)		
Stock-based compensation	—	—	28,647	—	—	—	—	28,647	
Stock issued under incentive programs	333,277	3	1,107	—	(567)	—	—	543	
Foreign currency translation adjustment	—	—	—	—	—	—	3,211	3,211	
Net loss	—	—	—	(293,905)	—	—	—	(293,905)	
Balance at March 31, 2023	87,139,831	\$ 871	\$ 3,767,733	\$ (4,569,794)	\$ (91,226)	\$ (3,166)	\$ (895,582)		

The accompanying notes are an integral part of these financial statements.

NOVAVAX, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating Activities:		
Net loss	\$ (147,550)	\$ (293,905)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	12,147	9,043
Non-cash stock-based compensation	11,556	28,647
Provision for excess and obsolete inventory	8,807	12,490
Impairment of long-lived assets	1,669	—
Other items, net	(4,449)	(1,252)
Changes in operating assets and liabilities:		
Inventory	16,819	(9,222)
Accounts receivable, prepaid expenses, and other assets	296,054	18,430
Accounts payable, accrued expenses, and other liabilities	(272,461)	(230,099)
Deferred revenue	(6,147)	140,275
Net cash used in operating activities	<u>(83,555)</u>	<u>(325,593)</u>
Investing Activities:		
Capital expenditures	(6,878)	(19,801)
Internal-use software	(372)	(3,757)
Net cash used in investing activities	<u>(7,250)</u>	<u>(23,558)</u>
Financing Activities:		
Net proceeds from sales of common stock	6,862	—
Net proceeds from the exercise of stock-based awards	(616)	543
Finance lease payments	(360)	(26,331)
Repayment of 2023 Convertible notes	—	(325,000)
Payments of costs related to issuance of 2027 Convertible notes	—	(3,591)
Net cash provided by (used in) financing activities	<u>5,886</u>	<u>(354,379)</u>
Effect of exchange rate on cash, cash equivalents, and restricted cash	(2,955)	(8,372)
Net decrease in cash, cash equivalents, and restricted cash	(87,874)	(711,902)
Cash, cash equivalents, and restricted cash at beginning of period	<u>583,810</u>	<u>1,348,845</u>
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 495,936</u>	<u>\$ 636,943</u>
Supplemental disclosure of non-cash activities:		
Capital expenditures included in accounts payable and accrued expenses	\$ 1,208	\$ 10,847
Internal-use software included in accounts payable and accrued expenses	\$ 250	\$ —
Supplemental disclosure of cash flow information:		
Cash interest payments, net of amounts capitalized	\$ 1,206	\$ 6,566
Cash paid for income taxes, net of refunds	\$ (71)	\$ —

The accompanying notes are an integral part of these financial statements.

NOVAVAX, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2024
(unaudited)

Note 1 – Organization and Business

Novavax, Inc. ("Novavax," and together with its wholly owned subsidiaries, the "Company") is a biotechnology company that promotes improved health by discovering, developing, and commercializing innovative vaccines to prevent serious infectious diseases. Novavax offers a differentiated vaccine platform that combines a recombinant protein approach, innovative nanoparticle technology and patented Matrix-M™ adjuvant to enhance the immune response. Novavax currently has one commercial program, for vaccines to prevent COVID-19, which includes Nuvaxovid™ prototype COVID-19 vaccine ("NVX-CoV2373," or "prototype vaccine") and Nuvaxovid™ updated COVID-19 vaccine ("NVX-CoV2601," or "updated vaccine") (collectively, "COVID-19 Vaccine"). Local regulatory authorities have also specified nomenclature for the labeling of the prototype and updated vaccines within their territories (e.g., "Novavax COVID-19 Vaccine, Adjuvanted" and "Novavax COVID-19, Adjuvanted (2023-2024 Formula)," respectively, for the U.S.). The Company's partner, Serum Institute of India Pvt. Ltd. ("SIIPL"), markets NVX-CoV2373 as "Covovax™."

Beginning in 2022, the Company received approval, interim authorization, provisional approval, conditional marketing authorization, and emergency use authorization ("EUA") from multiple regulatory authorities globally for its prototype vaccine for both adult and adolescent populations as a primary series and for both homologous and heterologous booster indications in select territories. In October 2023, the U.S. Food and Drug Administration amended the EUA for its prototype vaccine to include its updated vaccine. The amended EUA authorizes use of the Company's updated vaccine in individuals 12 years and older. In October 2023, the European Commission ("EC") granted approval for the Company's updated vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged 12 and older. Currently, the Company significantly depends on its supply agreement with SIIPL and its subsidiary, Serum Life Sciences Limited ("SLS"), for co-formulation, filling and finishing (other than in Europe) and on its service agreement with PCI Pharma Services for finishing in Europe.

Novavax is advancing development of other vaccine candidates, including its COVID-19-Influenza Combination ("CIC") vaccine candidate and additional vaccine candidates. The Company's COVID-19 Vaccine and its other vaccine candidates incorporate the Company's proprietary Matrix-M™ adjuvant to enhance the immune response and stimulate higher levels of functional antibodies and induce a cellular immune response.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. The consolidated financial statements are unaudited but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the financial position, operating results, comprehensive loss, changes in stockholders' deficit, and cash flows for the periods presented. Although the Company believes that the disclosures in these unaudited consolidated financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted as permitted under the rules and regulations of the United States Securities and Exchange Commission ("SEC").

The unaudited consolidated financial statements include the accounts of Novavax, Inc. and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. The aggregate foreign currency transaction gains and losses resulting from the conversion of the transaction currency to functional currency were a \$ 5.1 million loss and a \$ 16.3 million gain for the three months ended March 31, 2024 and 2023, respectively, which are reflected in Other income (expense).

The accompanying unaudited consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. Results for this or any interim period are not necessarily indicative of results for any future interim period or for the entire year. The Company operates in one business segment.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern within one year after the date that the financial statements are issued and contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainty described below.

Management's plans discussed below, including specifically the execution of the collaboration and license agreement (the "Collaboration and License Agreement") and securities subscription agreement (the "Subscription Agreement") effective May 10, 2024, with Sanofi Pasteur Inc. ("Sanofi") which will result in cash proceeds to the Company of \$ 568.8 million during the second quarter of 2024, has alleviated the substantial doubt outlined below regarding the Company's ability to continue as a going concern for the one year period from the date that these financial statements were issued.

As of March 31, 2024, the Company had \$ 480.6 million in cash and cash equivalents and had a working capital deficiency. During the three months ended March 31, 2024, the Company incurred a net loss of \$ 147.6 million and had net cash flows used in operating activities of \$ 83.6 million.

In accordance with Accounting Standards Codification ("ASC") Topic 205-40, Presentation of Financial Statements - Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. While the Company's current cash flow forecast for the one-year going concern look forward period estimates that there will be sufficient capital available to fund operations, this forecast is subject to significant uncertainty, including as it relates to revenue for the next 12 months and the Company's ability to execute on certain cost-reduction initiatives. The Company's revenue projections depend on its ability to successfully develop, manufacture, distribute, and market its updated vaccine for the 2024-2025 vaccination season, which is inherently uncertain and subject to a number of risks, including the Company's ability to obtain regulatory authorizations, introduce a single-dose vial or pre-filled syringe product presentation for the U.S. commercial and certain other markets, the incidence of COVID-19 during the 2024-2025 vaccination season, and the Company's ability to timely deliver doses and achieve commercial adoption and market acceptance of its updated vaccine. Further, the Company's revenue projections also depend on its ability to achieve expected product sales and related cash flows under its advance purchase agreements ("APAs"), including APAs in Australia and Canada, which are subject to regulatory uncertainties as described in Note 3.

Failure to meet regulatory milestones or achieve product volume or delivery timing obligations under the Company's APAs may require the Company to refund portions of upfront and other payments or result in reduced future payments, which would adversely affect the Company's ability to continue as a going concern.

Management believes that, given the history of recurring losses, negative working capital, and accumulated deficit, conditions or events exist that raise substantial doubt about the Company's ability to continue as a going concern through one year from the date that these financial statements are issued. Management's plans to potentially alleviate such conditions or events include the execution effective May 10, 2024, of the Collaboration and License Agreement with Sanofi that grants a co-exclusive license to Sanofi of the Company's current COVID-19 and related vaccine products, which will provide the Company with an initial \$ 500 million nonrefundable upfront payment, as well as the execution effective May 10, 2024, of the Subscription Agreement with Sanofi, which will provide the Company with a \$ 68.8 million equity investment, both of which are expected to be received in the second quarter of 2024 and are described further below. Management's plans also include execution of its commercial plans and its ongoing restructuring and cost reduction measures.

On May 10, 2024, the Company entered into the Collaboration and License Agreement with Sanofi pursuant to which Sanofi received:

- i) A co-exclusive license to commercialize with the Company all of the Company's current stand-alone COVID-19 vaccine products, including the Company's Nuvaxovid™ prototype COVID-19 vaccine and Nuvaxovid™ updated COVID-19 vaccine, and updated versions that address seasonal variants throughout the world ("COVID Mono Products"),
- ii) A sole license to develop and commercialize combination products containing a potential combination of the Company's COVID-19 vaccine and Sanofi's seasonal influenza vaccine ("COVID and influenza Combination Products" or "CIC Products"),

- iii) A non-exclusive license to develop and commercialize combination products containing both the Company's COVID-19 vaccine and one or more non-influenza vaccines ("Other Combination Products" and together with the COVID Mono Products, CIC Products, and Other Combination Products ("Licensed COVID-19 Products")), and
- iv) A non-exclusive license to develop and commercialize other vaccine products selected by Sanofi that include the Company's Matrix-M™ adjuvant (as described below, the "Adjuvant Products").

Under the Collaboration and License Agreement, the Company will receive a non-refundable upfront payment of \$ 500 million. In addition, the Company will also be eligible to receive development, technology transfer, launch, and sales milestone payments totaling up to \$ 700 million in the aggregate with respect to the Licensed COVID-19 Products and royalty payments on Sanofi's sales of such licensed products. In addition, the Company is eligible to receive development, launch, and sales milestone payments of up to \$ 200 million for each of the first four Adjuvant Products and \$ 210 million for each Adjuvant Product thereafter, and royalty payments on Sanofi's sales of all such licensed products.

Commencing shortly after the Effective Date of the Collaboration and License Agreement, the Company will perform a technology transfer of its manufacturing process for the COVID Mono Products and Matrix-M™ components to Sanofi. Until the successful completion of such transfer, the Company will supply Sanofi with both COVID Mono Products and Matrix-M™ intermediary components for Sanofi's use and is eligible for reimbursement of such costs from Sanofi. Additionally, Sanofi will reimburse the Company for its research and development and medical affairs costs related to the COVID Mono Products in accordance with agreed upon plans and budgets.

Under the Collaboration and License Agreement, the Company will continue to commercialize the COVID Mono Products in 2024. Beginning in 2025 and continuing during the term of the Collaboration and License Agreement, Sanofi and the Company will commercialize the COVID Mono Products worldwide in accordance with a commercialization plan agreed by the Company and Sanofi, under which the Company will continue to supply its existing APA customers and strategic partners, including Takeda, SK Biosciences, and the Serum Institute of India. Upon completion of the existing advance purchase agreements, Novavax and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction.

Effective May 10, 2024, the Company also entered into the Subscription Agreement with Sanofi, pursuant to which the Company sold and issued to Sanofi, in a private placement, 6,880,481 shares of the Company's common stock, par value \$ 0.01 per share at a price of \$ 10.00 per share for aggregate gross proceeds to the Company of \$ 68.8 million.

In May 2023, the Company announced a global restructuring and cost reduction plan (the "2023 Restructuring Plan"), which includes a more focused investment in its COVID-19 Vaccine, reduction to its pipeline spending, the continued rationalization of its manufacturing network, a reduction to the Company's global workforce, as well as the consolidation of facilities, and infrastructure. In January 2024, as part of reducing combined research and development and selling, general and administrative expenses, the Company announced further reductions in its global workforce (the "2024 Cost Reduction Plan"). The Company intends to prioritize improvements to its long-term supply chain efficiency. The Company expects the full annual impact of the 2023 Restructuring Plan to be realized in 2024, the full annual impact of the 2024 Cost Reduction Plan to be realized in 2025, and approximately 85 % of the annual impact of the 2024 Cost Reduction Plan, excluding one-time charges, to be realized in 2024. The 2024 Cost Reduction Plan supplemented the 2023 Restructuring Plan and hereafter both are jointly referred to as the "Restructuring Plan." During the three months ended March 31, 2024, the Company recorded a charge of \$ 4.4 million related to one-time employee severance and benefit costs and recorded an impairment charge of \$ 1.7 million related to the impairment of capitalized internal-use software (see Note 14).

Management's plans may also include raising additional capital through a combination of additional equity and debt financing, additional collaborations, strategic alliances, asset sales, and marketing, distribution, or licensing arrangements. New financings may not be available to the Company on commercially acceptable terms, or at all. Also, any additional collaborations, strategic alliances, asset sales and marketing, distribution, or licensing arrangements may require the Company to give up some or all of its rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If the Company is unable to obtain additional capital, the Company will assess its capital resources and may be required to delay, reduce the scope of, or eliminate some or all of its operations, or further downsize its organization, any of which may have a material adverse effect on its business, financial condition, results of operations, and ability to operate as a going concern.

Management's plans discussed above, including specifically the execution of the Collaboration and License Agreement and the Subscription Agreement effective May 10, 2024, with Sanofi which will result in cash proceeds to the Company of \$ 568.8 million during the second quarter of 2024, has alleviated the substantial doubt outlined below regarding the Company's ability to continue as a going concern for the one year period from the date that these financial statements were

issued.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from those estimates.

Restructuring

The Company recognizes restructuring charges when such costs are incurred. The Company's restructuring charges consist of employee severance and other termination benefits related to the reduction of its workforce, the consolidation of facilities, and infrastructure and other costs. Termination benefits are expensed on the date the Company notifies the employee, unless the employee must provide future service, in which case the benefits are expensed ratably over the future service period. Ongoing benefits are expensed when restructuring activities are probable and the benefit estimable.

See Note 14 for additional information on the severance and employee benefit costs for terminated employees and impairment of assets in connection with the Company's Restructuring Plan.

Recent Accounting Pronouncements

Not Yet Adopted

In October 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-06, Disclosure Improvements ("ASU 2023-06"), to clarify or improve disclosure and presentation requirements of a variety of topics and align the requirements in the FASB ASC with the SEC's regulations. The Company is currently evaluating ASU 2023-06 to determine its impact on the Company's consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures ("ASU 2023-09"). The standard enhances transparency in income tax disclosures by requiring, on an annual basis, certain disaggregated information about a reporting entity's effective tax rate reconciliation and income taxes paid. The ASU also requires disaggregated disclosure related to pre-tax income (or loss) and income tax expense (or benefit) and eliminates certain disclosures related to the balance of an entity's unrecognized tax benefit and the cumulative amount of certain temporary differences. The ASU is effective for the Company beginning on January 1, 2025. The Company is currently evaluating ASU 2023-09 to determine its impact on the Company's disclosures.

Note 3 – Revenue

The Company's accounts receivable included \$ 21.2 million and \$ 286.4 million related to amounts that were billed to customers and \$ 0.2 million and \$ 10.8 million related to amounts which had not yet been billed to customers as of March 31, 2024 and December 31, 2023, respectively. During the three months ended March 31, 2024 and 2023, changes in the Company's accounts receivables, allowance for credit losses, and deferred revenue balances were as follows (in thousands):

	Balance, Beginning of Period		Additions		Deductions		Balance, End of Period	
Accounts receivable:								
Three Months Ended March 31, 2024	\$ 304,916	\$ 136,510	\$ (412,370)	\$ 29,056				
Three Months Ended March 31, 2023	96,210	146,424	(115,950)	126,684				
Allowance for credit losses⁽¹⁾:								
Three Months Ended March 31, 2024	\$ (7,676)	\$ —	\$ —	\$ (7,676)				
Three Months Ended March 31, 2023	(13,835)	—	—	(13,835)				
Deferred revenue:⁽²⁾								
Three Months Ended March 31, 2024	\$ 863,521	\$ 225,000	\$ (6,148)	\$ 1,082,373				
Three Months Ended March 31, 2023	549,551	140,324	(49)	689,826				

(1) There was no allowance for credit losses recorded during the three months ended March 31, 2024 or 2023. To estimate the allowance for credit losses, the Company evaluates the credit risk related to its customers based on historical loss experience, economic conditions, the aging of receivables, and customer-specific risks.

(2) Deductions from Deferred revenue generally related to the recognition of revenue once performance obligations on a contract with a customer are met. During the three months ended March 31, 2024, deductions included a \$ 2.2 million reclassification of refundable upfront payments previously included in Deferred revenue to Other current liabilities. During the three months ended March 31, 2024, additions included a \$ 225.0 million reclassification of refundable upfront payment from Other current liabilities to Deferred revenue related to the settlement with Gavi as discussed below. There were no such reclassifications during the three months ended March 31, 2023.

As of March 31, 2024, the aggregate amount of the transaction price allocated to performance obligations that were unsatisfied (or partially unsatisfied), excluding amounts related to sales-based royalties, was approximately \$ 2 billion of which \$ 1.1 billion was included in Deferred revenue. Failure to meet regulatory milestones, obtain timely supportive recommendations from governmental advisory committees, or achieve product volume or delivery timing obligations under the Company's APAs may require the Company to refund portions of upfront and other payments or result in reduced future payments, which could adversely impact the Company's ability to realize revenue from its unsatisfied performance obligations. The timing to fulfill performance obligations related to APAs will depend on the timing of product manufacturing, receipt of marketing authorizations for additional indications, delivery of doses based on customer demand, and the ability of the customer to request the Company's updated vaccine under certain of the Company's APAs.

Under an APA with Gavi, the Vaccine Alliance ("Gavi"), entered into in May 2021 (the "Gavi APA"), the Company received upfront payments of \$ 700 million from Gavi (the "Advance Payment Amount") to be applied against purchases of the Company's prototype vaccine by certain countries participating in the COVAX Facility. As of December 31, 2023, the remaining Gavi Advance Payment Amount was \$ 696.4 million. On February 16, 2024, the Company entered into a Termination and Settlement Agreement with Gavi (the "Gavi Settlement Agreement") terminating the Gavi APA, settling the arbitration proceedings, and releasing both parties of all claims arising from, under, or otherwise in connection with the Gavi APA. On February 22, 2024, the claims and counterclaims were dismissed with prejudice. Pursuant to the Gavi Settlement Agreement, the Company is responsible for payment to Gavi of (i) an initial settlement payment of \$ 75 million, which the Company paid in February 2024, and (ii) deferred payments, in equal annual amounts of \$ 80 million payable each calendar year through a deferred payment term ending December 31, 2028. The deferred payments are due in variable quarterly installments beginning in the second quarter of 2024 and total \$ 400 million during the deferred payment term. Such deferred payments may be reduced through Gavi's use of an annual vaccine credit equivalent to the unpaid balance of such deferred payments each year, which may be applied to qualifying sales of any of the Company's vaccines for supply to certain low-income and lower-middle income countries. The Company has the right to price the vaccines offered to such low-income and lower-middle income countries in its discretion, and, when utilized by Gavi, the Company will credit the actual price per vaccine paid against the applicable credit. The Company intends to price vaccines offered via the tender process, consistent with its shared goal with Gavi to provide equitable access to those countries. Also, pursuant to the Gavi Settlement Agreement,

the Company granted Gavi an additional credit of up to \$ 225 million that may be applied against qualifying sales of any of the Company's vaccines for supply to such low-income and lower-middle income countries that exceed the \$ 80 million deferred payment amount in any calendar year during the deferred payment term. In total, the Gavi settlement agreement is comprised of \$ 700 million of potential consideration, consisting of the \$ 75 million initial settlement payment, deferred payments of up to \$ 400 million that may be reduced through annual vaccine credits, and the additional credit of up to \$ 225 million that may be applied for certain qualifying sales.

The Company recorded the \$ 3.6 million difference between the refund liability recorded as of December 31, 2023 of \$ 696.4 million and the \$ 700 million of total consideration under the arrangement as a reduction to revenue during the three months ended March 31, 2024. As of March 31, 2024, the remaining amounts included on the Company's consolidated balance sheet are classified as \$ 225 million in non-current Deferred revenue for the additional credit that may be applied against future qualifying sales, \$ 80 million in Other current liabilities, and \$ 320 million in Other non-current liabilities. In addition, the Company and Gavi entered into a security agreement pursuant to which Novavax granted Gavi a security interest in accounts receivable from SIIPL under the SIIPL R21 Agreement (see Note 4), which will continue for the deferred payment term of the Gavi Settlement Agreement.

Product Sales

Product sales by the Company's customer's geographic location was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
North America	\$ (6,361)	\$ —
Europe	90,416	57,267
Rest of the world	(1,731)	(64,724)
Total product sales revenue	\$ 82,324	\$ (7,457)

Product sales in the U.S. are primarily made through large pharmaceutical wholesale distributors at the wholesale acquisition cost ("WAC"). Product sales in the U.S. are recorded net of gross-to-net deductions. During the three months ended March 31, 2024, product sales in North America includes \$ 6.4 million of gross-to-net deductions in excess of the WAC, primarily due to wholesale distributor fees for shipments expected to be returned and adjustments made to estimated returns of prior period product sales. Product sales for the rest of the world includes a \$ 3.6 million reduction to revenue recognized pursuant to the Gavi Settlement Agreement as discussed above.

As of March 31, 2024, changes in the Company's gross-to-net deductions balances were as follows (in thousands):

	Wholesale Distributor Fees, Discounts, and Chargebacks			Product Returns	Total
Balance as of December 31, 2023	\$ 21,072	\$ 84,616	\$ 105,688		
Amounts charged against product sales ⁽¹⁾	16,076	19,296	35,372		
Payments	(26,979)	(10,999)	(37,978)		
Balance as of March 31, 2024	\$ 10,169	\$ 92,913	\$ 103,082		

(1) Amounts charged against product sales include \$ 3.4 million of adjustments made to prior period product sales due primarily to changes in the estimate of product returns.

As of March 31, 2024 and December 31, 2023, \$ 5.4 million and \$ 2.6 million of gross-to-net deductions were included in Accounts receivable, respectively, and \$ 97.7 million and \$ 103.1 million were included in Accrued expenses, respectively.

The Company has an APA with the Commonwealth of Australia ("Australia") for the purchase of doses of COVID-19 Vaccine (the "Australia APA"). In November 2023, the Company filed with the Therapeutic Goods Administration ("TGA") for authorization for its updated vaccine. Based on subsequent communication from the TGA that it will not recommend

approval of the filing as submitted and new data and information generated since that filing, the Company is evaluating the regulatory path for approval, including the potential to update the filing with new data and information, and resubmit in the coming months. In March 2024, the Company and Australia agreed to cancel the COVID-19 Vaccine doses previously scheduled for delivery in the fourth quarter of 2023. As a result of the cancellation, the total contract value was reduced by \$ 54.0 million, including \$ 6.0 million of deferred revenue related to the cancelled doses that will be applied as a credit towards future deliveries of doses. Under the Australia APA, Australia is not required to purchase the updated COVID-19 Vaccine doses until the Company receives authorization from TGA. The Company plans to seek an amendment to the Australia APA to address performance obligations and future delivery schedule, which may not be achievable on acceptable terms or at all.

The Company had an APA with the EC acting on behalf of various European Union member states to supply a minimum of 20 million and up to 100 million initial doses of prototype vaccine, with the option for the EC to purchase an additional 100 million doses up to a maximum aggregate of 200 million doses in one or more tranches, through 2023. In January 2023, the Company finalized a revised delivery schedule for the remaining committed doses under the APA that were originally scheduled for delivery during the first and second quarters of 2022. The APA expired in August 2023 and required that any open and outstanding orders from European Union member states be satisfied by February 2024. All outstanding orders were delivered to European Union Member states by February 2024.

The Company has an APA with His Majesty the King in Right of Canada as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (the "Canadian government"), for the purchase of doses of COVID-19 Vaccine (the "Canada APA"). The Canadian government may terminate the Canada APA, as amended, if the Company fails to receive regulatory approval for its COVID-19 Vaccine using bulk antigen produced at Biologics Manufacturing Centre ("BMC") Inc. on or before December 31, 2024. The Company does not anticipate achieving regulatory approval of its COVID-19 Vaccine using bulk antigen produced at BMC on or before December 31, 2024. Therefore, the Company plans to seek an amendment to the Canada APA to address possible alternatives, which may not be achievable on acceptable terms or at all. As of March 31, 2024, \$ 110.6 million was classified as current Deferred revenue and \$ 477.6 million was classified as non-current Deferred revenue with respect to the Canadian APA in the Company's consolidated balance sheet. If the Canadian government terminates the Canada APA, \$ 28.0 million of the deferred revenue would become refundable and approximately \$ 224 million of the contract value related to future deliverables would no longer be available.

Grants

The Company's U.S. government agreement consisted of a Project Agreement (the "Project Agreement") and a Base Agreement with Advanced Technology International, the Consortium Management Firm acting on behalf of the Medical CBRN Defense Consortium in connection with the partnership formerly known as Operation Warp Speed (the Base Agreement together with the Project Agreement the "USG Agreement"). As of December 31, 2023, the Company recognized the full \$ 1.8 billion funding in revenue.

Royalties and Other

Royalties and other includes royalty milestone payments, sales-based royalties, and Matrix-M™ adjuvant sales.

During the three months ended March 31, 2024, the Company recognized \$ 4.0 million in revenue related to license fees and \$ 7.5 million in revenue related to a Matrix-M™ adjuvant sales. During the three months ended March 31, 2024, the Company did not recognize revenue related to milestone payments.

During the three months ended March 31, 2023, the Company recognized \$ 1.0 million in revenue related to a Matrix-M™ adjuvant sales. During the three months ended March 31, 2023, the Company did not recognize revenue related to license fees or milestone payments.

Note 4 – Collaboration, License, and Supply Agreements

SIIPL

The Company previously granted SIIPL exclusive and non-exclusive licenses for the development, co-formulation, filling and finishing, registration, and commercialization of its prototype vaccine, its proprietary COVID-19 variant antigen candidate(s), and its CIC vaccine candidate. SIIPL agreed to purchase the Company's Matrix-M™ adjuvant and the Company granted SIIPL a non-exclusive license to manufacture the antigen drug substance component of the Company's COVID-19 Vaccine in SIIPL's licensed territory solely for use in the manufacture of COVID-19 Vaccine. The Company and SIIPL equally split the revenue from SIIPL's sale of COVID-19 Vaccine in its licensed territory, net of agreed costs. The Company also has a supply agreement with SIIPL and SLS under which SIIPL and SLS supply the Company with prototype vaccine, its proprietary COVID-19 variant antigen candidate(s), and its CIC vaccine candidate for commercialization and sale in certain territories, as well as a contract development manufacture agreement with SLS, under which SLS manufactures and supplies finished vaccine product to the Company using antigen drug substance and Matrix-M™ adjuvant supplied by the Company. In March 2020, the Company entered into an agreement with SIIPL that granted SIIPL a non-exclusive license for the use of Matrix-M™ adjuvant supplied by the Company to develop, manufacture, and commercialize R21/Matrix-M™ adjuvant ("SIIPL R21 Agreement"), a malaria vaccine created by the Jenner Institute, University of Oxford ("R21/Matrix-M™"). In December 2023, R21/Matrix-M™ received prequalification by the World Health Organization ("WHO"). Under the SIIPL R21 Agreement, SIIPL purchases the Company's Matrix-M™ adjuvant for use in development activities at cost and for commercial purposes at a tiered commercial supply price, and pays a royalty in the single-to low- double-digit range based on vaccine sales for a period of 15 years after the first commercial sale of the vaccine in each country.

Takeda Pharmaceutical Company Limited

The Company has a collaboration and license agreement with Takeda Pharmaceutical Company Limited ("Takeda") under which the Company granted Takeda an exclusive license to develop, manufacture, and commercialize the Company's COVID-19 Vaccine in Japan. Under the agreement, Takeda purchases Matrix-M™ adjuvant from the Company to manufacture doses of COVID-19 Vaccine, and the Company is entitled to receive milestone and sales-based royalty payments from Takeda based on the achievement of certain development and commercial milestones, as well as a portion of net profits from the sale of COVID-19 Vaccine. In September 2021, Takeda finalized an agreement with the Government of Japan's Ministry of Health, Labour and Welfare ("MHLW") for the purchase of 150 million doses of its prototype vaccine. In February 2023, MHLW canceled the remainder of doses under its agreement with Takeda. As a result, it is uncertain whether the Company will receive future sales-based royalty payments from Takeda under the terms and conditions of their current collaboration and licensing agreement.

Sanofi

Effective May 10, 2024, the Company entered into the Collaboration and License Agreement with Sanofi pursuant to which Sanofi received:

- i) A co-exclusive license to commercialize with the Company all of the COVID Mono Products,
- ii) A sole license to develop and commercialize combination COVID and influenza Combination Products,
- iii) A non-exclusive license to develop and commercialize Other Combination Products, and
- iv) A non-exclusive license to develop and commercialize Adjuvant Products.

Under the Collaboration and License Agreement, the Company will receive a non-refundable upfront payment of \$ 500 million. In addition, the Company will also be eligible to receive development, technology transfer, launch, and sales milestone payments totaling up to \$ 700 million in the aggregate with respect to the Licensed COVID-19 Products and royalty payments on Sanofi's sales of such licensed products. In addition, the Company is eligible to receive development, launch, and sales milestone payments of up to \$ 200 million for each of the first four Adjuvant Products and \$ 210 million for each Adjuvant Product thereafter, and royalty payments on Sanofi's sales of all such licensed products.

Commencing shortly after the Effective Date of the Collaboration and License Agreement, the Company will perform a technology transfer of its manufacturing process for the COVID Mono Products and Matrix-M™ components to Sanofi. Until the successful completion of such transfer, the Company will supply Sanofi with both COVID Mono Products and Matrix-M™ intermediary components for Sanofi's use and is eligible for reimbursement of such costs from Sanofi. Additionally, Sanofi will reimburse the Company for its research and development and medical affairs costs related to the COVID Mono Products in accordance with agreed upon plans and budgets.

Under the Collaboration and License Agreement, the Company will continue to commercialize the COVID Mono Products in 2024. Beginning in 2025 and continuing during the term of the Collaboration and License Agreement, Sanofi and the Company will commercialize the COVID Mono Products worldwide in accordance with a commercialization plan agreed by the Company and Sanofi, under which the Company will continue to supply its existing APA customers and strategic partners, including Takeda, SK Biosciences, and the Serum Institute of India. Upon completion of the existing advance purchase agreements, Novavax and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction.

Bill & Melinda Gates Medical Research Institute

In May 2023, the Company entered into a three-year agreement with the Bill & Melinda Gates Medical Research Institute to provide the Company's Matrix-M™ adjuvant for use in preclinical vaccine research.

Other Supply Agreements

In March 2024, the Company, FUJIFILM Diosynth Biotechnologies UK Limited ("FDBK"), FUJIFILM Diosynth Biotechnologies Texas, LLC ("FDBT") and FUJIFILM Diosynth Biotechnologies USA, Inc. ("FDBU" and together with FDBK and FDBT, "Fujifilm") entered into a Confidential Settlement Agreement and Release (the "Settlement Agreement") to resolve disputes regarding amounts that Fujifilm claimed were due under a prior Confidential Settlement Agreement and Release effective September 30, 2022 (the "CSAR") by and between the Company and Fujifilm.

Under the CSAR, the Company agreed to pay up to \$ 185.0 million to Fujifilm in connection with the cancellation of manufacturing activity at FDBT. The final two quarterly installments due to Fujifilm in 2023 under the CSAR, totaling \$ 68.6 million, were subject to Fujifilm's obligation to use commercially reasonable efforts to mitigate losses associated with the vacant manufacturing capacity caused by the termination of manufacturing activities at FDBT. In October 2023, the Company sent Fujifilm a notice of breach and refused to pay the final two installments based on its contention that Fujifilm had not used commercially reasonable efforts to mitigate losses and should have offset some portion of the final two payments. In October 2023, Fujifilm filed a demand for arbitration with Judicial Arbitration and Mediation Services ("JAMS") seeking payment of the full amount (the "Fujifilm Arbitration").

Pursuant to the Settlement Agreement, in March 2024 the Company paid \$ 42.0 million to Fujifilm, the parties agreed to a mutual release of claims arising from, under or otherwise in connection with the CSAR, and Fujifilm agreed to dismiss the Fujifilm Arbitration. This payment is less than amounts previously accrued for and reflected in Research and development expense, and accordingly, the Company recorded a benefit of \$ 26.6 million as Research and development expense during the three months ended March 31, 2024 upon the execution of the Settlement Agreement.

The Company continues to assess its manufacturing needs and intends to modify its global manufacturing footprint consistent with its contractual obligations to supply, and anticipated demand for, its COVID-19 Program, and in doing so, recognizes that significant costs may be incurred.

Note 5 – Cash, Cash Equivalents, and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported in the consolidated

balance sheets that sums to the total of such amounts shown in the consolidated statements of cash flows (in thousands):

	March 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 480,586	\$ 568,505
Restricted cash, current	10,455	10,424
Restricted cash, non-current ⁽¹⁾	4,895	4,881
Cash, cash equivalents, and restricted cash	<u><u>\$ 495,936</u></u>	<u><u>\$ 583,810</u></u>

(1) Classified as Other non-current assets as of March 31, 2024 and December 31, 2023, on the consolidated balance sheets.

Note 6 – Fair Value Measurements

The following table represents the Company's fair value hierarchy for its financial assets and liabilities (in thousands):

Assets	Fair Value at March 31, 2024			Fair Value at December 31, 2023		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Money market funds ⁽¹⁾	\$ 118,470	\$ —	\$ —	\$ 171,824	\$ —	\$ —
Government-backed securities ⁽¹⁾	—	200,000	—	—	200,000	—
Treasury securities ⁽¹⁾	—	46,875	—	—	45,622	—
Corporate debt securities ⁽¹⁾	—	61,428	—	—	—	—
Total cash equivalents	<u><u>\$ 118,470</u></u>	<u><u>\$ 308,303</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 171,824</u></u>	<u><u>\$ 245,622</u></u>	<u><u>\$ —</u></u>
Liabilities						
5.00 % Convertible notes due 2027	\$ —	\$ 109,088	\$ —	\$ —	\$ 100,909	\$ —

(1) All investments are classified as Cash and cash equivalents as of March 31, 2024 and December 31, 2023, on the consolidated balance sheets.

Fixed-income investments categorized as Level 2 are valued at the custodian bank by a third-party pricing vendor's valuation models that use verifiable observable market data, such as interest rates and yield curves observable at commonly quoted intervals and credit spreads, bids provided by brokers or dealers, or quoted prices of securities with similar characteristics. Pricing of the Company's convertible notes has been estimated using observable inputs, including the price of the Company's common stock, implied volatility, interest rates, and credit spreads.

During the three months ended March 31, 2024 and 2023, the Company did not have any transfers between levels.

The amount in the Company's consolidated balance sheets for accounts payable and accrued expenses approximates its fair value due to its short-term nature.

Note 7 – Inventory

Inventory consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	\$ 5,295	\$ 6,614
Semi-finished goods	8,984	7,392
Finished goods	1,499	27,690
Total inventory	<u><u>\$ 15,778</u></u>	<u><u>\$ 41,696</u></u>

Inventory write-downs as a result of excess, obsolescence, expiry, or other reasons, and losses on firm purchase commitments, offset by recoveries of such commitments, are recorded as a component of cost of sales in the Company's consolidated statements of operations. For the three months ended March 31, 2024, inventory write-downs were \$ 8.8 million. For the three months ended March 31, 2023, inventory write-downs were \$ 12.5 million and losses on firm purchase commitments were \$ 7.7 million. In addition, for the three months ended March 31, 2023 the Company recorded recoveries on

firm purchase commitments of \$ 0.8 million related primarily to negotiated reductions to previously recognized firm purchase commitments .

Note 8 – Goodwill

The Company has one reporting unit, which has a negative carrying amount as of March 31, 2024 and December 31, 2023. The change in the carrying amounts of goodwill for the three months ended March 31, 2024 was as follows (in thousands):

	Amount
Balance at December 31, 2023	\$ 127,454
Currency translation adjustments	(4,275)
Balance at March 31, 2024	\$ 123,179

Note 9 – Long-Term Debt

Total convertible notes payable consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
5.00 % Convertible notes due 2027	\$ 175,250	\$ 175,250
Unamortized debt issuance costs	(6,818)	(7,234)
Total convertible notes payable	\$ 168,432	\$ 168,016

The effective interest rate of the 2027 Convertible notes is 6.2 %. During the three months ended March 31, 2023, the Company repaid the outstanding principal amount of \$ 325.0 million on its 3.75 % Convertible notes due in 2023, together with accrued but unpaid interest on the maturity date.

The interest expense incurred in connection with the convertible notes payable consisted of the following (in thousands):

	Three Months Ended March 31,	
	2024	2023
Coupon interest	\$ 2,192	\$ 3,206
Amortization of debt issuance costs	416	510
Total interest expense on convertible notes payable	\$ 2,608	\$ 3,716

Note 10 – Stockholders' Deficit

In August 2023, the Company entered into an At Market Issuance Sales Agreement (the “August 2023 Sales Agreement”), which allows it to issue and sell up to \$ 500 million in gross proceeds of shares of its common stock, and terminated its then-existing At Market Issuance Sales agreement entered in June 2021 (the “June 2021 Sales Agreement”). During the three months ended March 31, 2024, there were no sales recorded under the August 2023 Sales Agreement. As of March 31, 2024, the remaining balance available under the August 2023 Sales Agreement was approximately \$ 242 million.

During the three months ended March 31, 2023, there were no sales recorded under the June 2021 Sales Agreement.

Note 11 – Stock-Based Compensation

Equity Plans

In January 2023, the Company established the 2023 Inducement Plan (the “2023 Inducement Plan”), which provides for the granting of share-based awards to individuals who were not previously employees, or following a bona fide period of non-employment, as an inducement material to such individuals entering into employment with the Company. The Company reserved 1.0 million shares of common stock for grants under the 2023 Inducement Plan. As of March 31, 2024, there were 0.2 million shares available for issuance under the 2023 Inducement Plan.

The 2015 Stock Incentive Plan, as amended ("2015 Plan"), was approved at the Company's annual meeting of stockholders in June 2015. Under the 2015 Plan, equity awards may be granted to officers, directors, employees, and consultants of and advisors to the Company and any present or future subsidiary.

The 2015 Plan authorizes the issuance of up to 21.0 million shares of common stock under equity awards granted under the 2015 Plan. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 30, 2033. As of March 31, 2024, there were 2.6 million shares available for issuance under the 2015 Plan.

The Amended and Restated 2005 Stock Incentive Plan ("2005 Plan") expired in February 2015 and no new awards may be made under such plan, although awards will continue to be outstanding in accordance with their terms.

The 2023 Inducement Plan and the 2015 Plan permit, and the 2005 Plan permitted, the grant of stock options (including incentive stock options), restricted stock, stock appreciation rights ("SARs"), and restricted stock units ("RSUs"). In addition, under the 2023 Inducement Plan and the 2015 Plan, unrestricted stock, stock units, and performance awards may be granted. Stock options and SARs generally have a maximum term of ten years and may be or were granted with an exercise price that is no less than 100 % of the fair market value of the Company's common stock at the time of grant. Grants of share-based awards are generally subject to vesting over periods ranging from one to four years .

The Company recorded stock-based compensation expense in the consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Cost of sales	\$ 594	\$ 519
Research and development	5,505	13,858
Selling, general, and administrative	5,457	14,270
Total stock-based compensation expense	<u><u>\$ 11,556</u></u>	<u><u>\$ 28,647</u></u>

During the three months ended March 31, 2024, and March 31, 2023, there was no stock-based compensation capitalized in inventory.

As of March 31, 2024, there was approximately \$ 87 million of total unrecognized compensation expense related to unvested stock options, SARs, RSUs, and the ESPP. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of approximately two years and will be allocated between cost of sales, research and development, and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money stock options and SARs) that would have been received by the holders had all stock option and SAR holders exercised their stock options and SARs on March 31, 2024. This amount is subject to change based on changes to the closing price of the Company's common stock. The aggregate intrinsic value of stock options and SARs exercises and vesting of RSUs for the three months ended March 31, 2024 and 2023 was approximately \$ 4.5 million and \$ 1.5 million, respectively.

Stock Options and Stock Appreciation Rights

The following is a summary of stock options and SARs activity under the 2023 Inducement Plan, 2015 Plan, and 2005

Plan for the three months ended March 31, 2024:

	2023 Inducement Plan		2015 Plan		2005 Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at December 31, 2023	422,800	\$ 10.67	4,787,042	\$ 38.10	58,275	\$ 119.79
Granted	—	—	594,367	5.39	—	—
Exercised	—	—	(142)	5.22	—	—
Canceled	—	—	(284,823)	37.60	(57,569)	120.01
Outstanding at March 31, 2024	422,800	\$ 10.67	5,096,444	\$ 34.31	706	\$ 102.11
Shares exercisable at March 31, 2024	101,762	\$ 11.08	3,411,898	\$ 41.21	706	\$ 102.11

The fair value of stock options granted under the 2023 Inducement Plan and the 2015 Plan was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2024	2023
Weighted average Black-Scholes fair value of stock options granted	\$ 4.34	\$ 7.19
Risk-free interest rate	4.3 %	3.6 % - 4.0 %
Dividend yield	— %	— %
Volatility	114.3 % - 121.1 %	127.7 % - 140.3 %
Expected term (in years)	3.9 - 4.4	3.9 - 5.1

The total aggregate intrinsic value and weighted-average remaining contractual term of stock options and SARs outstanding under the 2023 Inducement Plan, 2015 Plan and 2005 Plan as of March 31, 2024 was less than \$ 0.1 million and 7.1 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options and SARs exercisable under the 2023 Inducement Plan, 2015 Plan and 2005 Plan as of March 31, 2024 was less than \$ 0.1 million and 6.0 years, respectively.

Restricted Stock Units

The following is a summary of RSU activity for the three months ended March 31, 2024:

	2023 Inducement Plan		2015 Plan	
	Number of Shares	Per Share Weighted-Average Fair Value	Number of Shares	Per Share Weighted-Average Fair Value
Outstanding and unvested at December 31, 2023	363,990	\$ 10.66	3,714,870	\$ 19.43
Granted	—	—	4,358,623	5.38
Vested	(102,797)	10.96	(778,278)	23.96
Forfeited	—	—	(359,910)	20.66
Outstanding and unvested at March 31, 2024	261,193	\$ 10.55	6,935,305	\$ 10.03

Employee Stock Purchase Plan

The ESPP was approved at the Company's annual meeting of stockholders in June 2013. The ESPP currently authorized an aggregate of 1.2 million shares of common stock to be purchased, and the aggregate number of shares will continue to increase 5 % on each anniversary of its adoption up to a maximum of 1.6 million shares. The ESPP allows

employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15 % of their compensation, at 85 % of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period (or, if later, the date during the option period when the employee was first eligible to participate). As of March 31, 2024, there were 0.2 million shares available for issuance under the ESPP.

Note 12 – Income Taxes

The Company evaluates the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. Significant pieces of objective evidence evaluated by the Company were the cumulative loss incurred over the three-year period ended March 31, 2024 and that the Company has historically generated pretax losses. Such objective evidence limits the ability to consider other subjective evidence, such as projections for future growth. On the basis of this evaluation, as of March 31, 2024, the Company continued to maintain a full valuation allowance against its deferred tax assets, except to the extent Net Operating Losses ("NOLs") have been used to reduce taxable income. As of March 31, 2024, the Company has \$ 2.4 billion of U.S. Federal NOLs carryforward, and all but \$ 11.3 million are subject to limitation in accordance with the 2017 Tax Cuts and Jobs Act ("TCJA"), which limits allowable NOL deductions to 80% of federal taxable income.

For the three months ended March 31, 2024 and March 31, 2023, the Company recognized \$ 2.3 million and \$ 1.2 million of federal, state, and foreign income tax expense, respectively.

Note 13 – Commitments and Contingencies

Legal Matters

Stockholder Litigation

On November 12, 2021, Sothiathan Sinnathurai filed a purported securities class action in the U.S. District Court for the District of Maryland (the "Maryland Court") against the Company and certain members of senior management, captioned Sothiathan Sinnathurai v. Novavax, Inc., et al., No. 8:21-cv-02910-TDC (the "Sinnathurai Action"). On January 26, 2022, the Maryland Court entered an order designating David Truong, Nuggehalli Balmukund Nandkumar, and Jeffrey Gabbert as co-lead plaintiffs in the Sinnathurai Action. The co-lead plaintiffs filed a consolidated amended complaint on March 11, 2022, alleging that the defendants made certain purportedly false and misleading statements concerning the Company's ability to manufacture prototype vaccine on a commercial scale and to secure the prototype vaccine's regulatory approval. The amended complaint defines the purported class as those stockholders who purchased the Company's securities between February 24, 2021 and October 19, 2021. On April 25, 2022, the defendants filed a motion to dismiss the consolidated amended complaint. On December 12, 2022, the Maryland Court issued a ruling granting in part and denying in part defendants' motion to dismiss. The Maryland Court dismissed all claims against two individual defendants and claims based on certain public statements challenged in the consolidated amended complaint. The Maryland Court denied the motion to dismiss as to the remaining claims and defendants, and directed the Company and other remaining defendants to answer within fourteen days. On December 27, 2022, the Company filed its answer and affirmative defenses. On March 16, 2023, the plaintiffs filed a motion for class certification and to appoint class representatives and counsel. The Company filed its opposition to the plaintiffs' motion on September 22, 2023. On December 4, 2023, the parties agreed to a binding settlement in principle (the "Proposed Settlement") to fully resolve the surviving claims in the Sinnathurai Action. Under the Proposed Settlement's terms, the Company agreed to pay \$ 47 million into a settlement fund, which will be funded by the Company's directors and officers' liability insurance and paid to members of a putative settlement class. On January 12, 2024, after the parties negotiated and executed a written agreement governing the Proposed Settlement, plaintiffs filed an unopposed motion for the Proposed Settlement's preliminary approval. On January 23, 2024, the Maryland Court granted the motion for preliminary approval and, as requested by the parties, preliminarily certified, for the purposes of settlement only, the settlement class. The court also scheduled a settlement hearing to consider final approval of the settlement for May 23, 2024. Ahead of the May 23 settlement hearing, on April 11, 2024, Plaintiffs filed a motion seeking the Maryland Court's final approval of the settlement. The Company determined that the settlement is probable and the insurance funding is realizable and, as such, recorded the \$ 47 million estimated settlement liability within Accrued expenses and the \$ 47 million estimated insurance recovery within Prepaid expenses and other current assets on the consolidated balance sheet as of December 31, 2023 and March 31, 2024.

After the Sinnathurai Action was filed, eight derivative lawsuits were filed: (i) Robert E. Meyer v. Stanley C. Erck, et al., No. 8:21-cv-02996-TDC (the "Meyer Action"), (ii) Shui Shing Yung v. Stanley C. Erck, et al., No. 8:21-cv-03248-TDC (the "Yung Action"), (iii) William Kirst, et al. v. Stanley C. Erck, et al., No. C-15-CV-21-000618 (the "Kirst Action"), (iv) Amy Snyder v. Stanley C. Erck, et al., No. 8:22-cv-01415-TDC (the "Snyder Action"), (v) Charles R. Blackburn, et al. v. Stanley C. Erck, et al., No. 1:22-cv-01417-TDC (the "Blackburn Action"), (vi) Diego J. Mesa v. Stanley C. Erck, et al., No. 2022-0770-NAC (the "Mesa Action"), (vii) Sean Acosta v. Stanley C. Erck, et al., No. 2022-1133-NAC (the "Acosta Action"), and (viii) Jared Needelman v. Stanley C. Erck, et al., No. C-15-CV-23-001550 (the "Needelman Action"). The Meyer, Yung, Snyder, and Blackburn Actions were filed in the Maryland Court. The Kirst Action was filed in the Circuit Court for Montgomery County, Maryland, and shortly thereafter removed to the Maryland Court by the defendants. The Needelman Action was also filed in the Circuit Court for Montgomery County, Maryland. The Mesa and Acosta Actions were filed in the Delaware Court of Chancery (the "Delaware Court"). The derivative lawsuits name members of the Company's board of directors and certain members of senior management as defendants. The Company is deemed a nominal defendant. The plaintiffs assert derivative claims arising out of substantially the same alleged facts and circumstances as the Sinnathurai Action. Collectively, the derivative complaints assert claims for breach of fiduciary duty, insider selling, unjust enrichment, violation of federal securities law, abuse of control, waste, and mismanagement. Plaintiffs seek declaratory and injunctive relief, as well as an award of monetary damages and attorneys' fees.

On February 7, 2022, the Maryland Court entered an order consolidating the Meyer and Yung Actions (the "First Consolidated Derivative Action"). The plaintiffs in the First Consolidated Derivative Action filed their consolidated derivative complaint on April 25, 2022. On May 10, 2022, the Maryland Court entered an order granting the parties' request to stay all proceedings and deadlines pending the earlier of dismissal or the filing of an answer in the Sinnathurai Action. On June 10, 2022, the Snyder and Blackburn Actions were filed. On October 5, 2022, the Maryland Court entered an order granting a request by the plaintiffs in the First Consolidated Derivative Action and the Snyder and Blackburn Actions to consolidate all three actions and appoint co-lead plaintiffs and co-lead and liaison counsel (the "Second Consolidated Derivative Action"). The co-lead plaintiffs in the Second Consolidated Derivative Action filed a consolidated amended complaint on November 21, 2022. On February 10, 2023, defendants filed a motion to dismiss the Second Consolidated Derivative Action. The plaintiffs filed their opposition to the motion to dismiss on April 11, 2023. Defendants filed their reply brief in further support of their motion to dismiss on May 11, 2023. On August 21, 2023, the court entered an order granting in part and denying in part the motion to dismiss. On September 5, 2023, the Company filed an Answer to the consolidated amended complaint. On September 6, 2023, the court entered an order granting the individual defendants an extension of time to file their answer until November 6, 2023. On October 6, 2023, the Board of Directors of the Company formed a Special Litigation Committee ("SLC") with full and exclusive power and authority of the Board to, among other things, investigate, review, and analyze the facts and circumstances surrounding the claims asserted in the pending derivative actions, including the claims that remain following the court's order on the motion to dismiss in the Second Consolidated Derivative Action. On November 7, 2023, the court entered an order granting the parties' request to stay the Second Consolidated Derivative Action for up to six months from the date of entry of the order, and, on April 15, 2024, the court entered a further order extending the stay by an additional month, and, on April 15, 2024, the court entered a further order extending the stay by an additional month. This includes staying the deadline for the individual defendants to respond to the consolidated amended complaint.

The Kirst Action was filed on December 28, 2021, and the defendants immediately removed the case to the Maryland Court. On July 21, 2022, the Maryland Court issued a memorandum opinion and order remanding the Kirst Action to state court. The plaintiffs filed an amended complaint on December 30, 2022. On January 23, 2023, defendants filed a motion to stay the Kirst action. On February 22, 2023, the parties in the Kirst Action filed for the Court's approval of a stipulation staying the Kirst Action pending the resolution of defendants' motion to dismiss in the Second Consolidated Derivative Action. On March 22, 2023, the Court entered the parties' stipulated stay of the Kirst Action pending resolution of the motion to dismiss in the Second Consolidated Derivative Action.

On August 30, 2022, the Mesa Action was filed. On October 3, 2022, the Delaware Court entered an order granting the parties' request to stay all proceedings and deadlines in the Mesa Action pending the earlier of dismissal of the Sinnathurai Action or the filing of an answer to the operative complaint in the Sinnathurai Action. On January 9, 2023, following the ruling on the motion to dismiss the Sinnathurai Action, the Delaware Court entered an order granting the Mesa Action parties' request to set a briefing schedule in connection with a motion to stay by defendants. On February 28, 2023, the court granted the defendants' motion and stayed the Mesa Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On August 31, 2023, the Mesa plaintiffs filed a motion to lift the stay in the Mesa Action. On October 6, 2023, the Company filed an opposition to plaintiff's motion to lift the stay. Plaintiff filed his reply on October 17, 2023. On December 27, 2023, the parties filed a letter informing the Court that the Second Consolidated Derivative Action had been stayed for a period of six months and asked the Court to stay further proceedings in the Mesa Action until expiration of that stay.

On December 7, 2022, the Acosta Action was filed. On February 6, 2023, defendants accepted service of the complaint and summons in the Acosta Action. On March 9, 2023, the court entered an order granting the parties' request to stay the Acosta Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On October 13, 2023, the parties filed, and the Delaware Court entered, a stipulated order providing that (i) if the Delaware Court declines to lift the stay in the Mesa Action, the Acosta Action will also remain stayed, and (ii) if the Delaware Court lifts the stay in the Mesa Action, the stay in the Acosta Action will also be lifted.

On April 17, 2023, the Needelman Action was filed. On July 12, 2023, the parties filed a stipulation and proposed order to stay the Needelman Action pending the Maryland Court's decision on the motion to dismiss in the Second Consolidated Derivative Action. The court entered that order on July 17, 2023.

On November 30, 2023, the court entered an order consolidating the Kirst and Needelman Actions. On December 14, 2023, the parties filed a stipulation (i) extending the plaintiffs' deadline to file a consolidated complaint until January 29, 2024, and (ii) otherwise staying all other proceedings in the case (including the defendants' deadline to respond to the consolidated complaint) until February 12, 2024. The stipulation entered by the court instructs the parties to discuss whether the stay should be further extended in light of the then-current status of the SLC's investigation. On May 3, 2024, the plaintiffs filed a consolidated complaint. The parties are discussing whether to extend defendants' deadline to respond to the consolidated complaint through early June.

The financial impact of the above derivative claims is not estimable.

On November 18, 2022, the Company delivered written notice to Gavi to terminate the Gavi APA based on Gavi's failure to procure the purchase of 350 million doses of prototype vaccine from the Company as required by the Gavi APA. As of November 18, 2022, the Company had only received orders under the Gavi APA for approximately 2 million doses. On December 2, 2022, Gavi issued a written notice purporting to terminate the Gavi APA based on Gavi's contention that the Company repudiated the agreement and, therefore, materially breached the Gavi APA. Gavi also contended that, based on its purported termination of the Gavi APA, it was entitled to a refund of the Advance Payment Amount less any amounts that have been credited against the purchase price for binding orders placed by a buyer participating in the COVAX Facility. Since December 31, 2022, the remaining Gavi Advance Payment Amount, which was \$ 696.4 million as of December 31, 2023, pending resolution of the dispute with Gavi related to a return of the remaining Advance Payment Amount, has been classified within Other current liabilities in the Company's consolidated balance sheet. On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on the claims described above. The Company filed its Answer and Counterclaims on March 2, 2023. On April 5, 2023, Gavi filed its Reply to the Company's Counterclaims.

On February 16, 2024, the Company entered into a Termination and Settlement Agreement with Gavi (the "Gavi Settlement Agreement") terminating the Gavi APA, settling the arbitration proceedings, and releasing both parties of all claims arising from, under, or otherwise in connection with the Gavi APA. Pursuant to the Gavi Settlement Agreement, the Company is responsible for payment to Gavi of (i) an initial settlement payment of \$ 75 million, which the Company paid in February 2024, and (ii) deferred payments, in equal annual amounts of \$ 80 million payable each calendar year through a deferred payment term ending December 31, 2028. The deferred payments are due in variable quarterly installments beginning in the second quarter of 2024 and total \$ 400 million during the deferred payment term. Such deferred payments may be reduced through Gavi's use of an annual vaccine credit equivalent to the unpaid balance of such deferred payments each year, which may be applied to qualifying sales of any of the Company's vaccines for supply to certain low-income and lower-middle income countries. The Company has the right to price the vaccines offered to such low-income and lower-middle income countries in its discretion, and, when utilized by Gavi, the Company will credit the actual price per vaccine paid against the applicable credit. The Company intends to price vaccines offered via the tender process, consistent with its shared goal with Gavi to provide equitable access to those countries. Also, pursuant to the Gavi Settlement Agreement, the Company granted Gavi an additional credit of up to \$ 225 million that may be applied against qualifying sales of any of the Company's vaccines for supply to such low-income and lower-middle income countries that exceed the \$ 80 million deferred payment amount in any calendar year during the deferred payment term. In total, the Gavi settlement agreement is comprised of \$ 700 million of potential consideration, consisting of the \$ 75 million initial settlement payment, deferred payments of up to \$ 400 million that may be reduced through annual vaccine credits, and the additional credit of up to \$ 225 million that may be applied for certain qualifying sales. In addition, the Company and Gavi entered into a security agreement pursuant to which Novavax granted Gavi a security interest in accounts receivable from SIIPL under the SIIPL R21 Agreement (see Note 4), which will continue for the deferred payment term of the Gavi Settlement Agreement. On February 22, 2024, the claims and counterclaims were dismissed with prejudice.

On September 30, 2022, the Company and Fujifilm entered into the CSAR regarding amounts due to Fujifilm in

connection with the termination of manufacturing activity at FDBT under the Commercial Supply Agreement dated August 20, 2021 (the "CSA") and the Master Services Agreement dated June 30, 2020 and associated statements of work (the "MSA") by and between the Company and Fujifilm. The MSA and CSA established the general terms and conditions applicable to Fujifilm's manufacturing and supply activities related to the Company's prototype vaccine under the associated statements of work. Pursuant to the CSAR, the Company agreed to pay up to \$ 185.0 million (the "Settlement Payment") to Fujifilm in connection with cancellation of manufacturing activity at FDBT. Under the CSAR, the final two quarterly installments due to Fujifilm were subject to Fujifilm's obligation to use commercially reasonable efforts to mitigate losses associated with the vacant manufacturing capacity caused by the termination of manufacturing activities at FDBT under the CSA. Any replacement revenue achieved by Fujifilm's mitigation efforts between July 1, 2023 and December 31, 2023 would offset the final two settlement payments owed by the Company. On October 2, 2023, the Company sent a notice of breach under the Fujifilm Settlement Agreement to Fujifilm setting forth the Company's position that Fujifilm had not used commercially reasonable efforts to mitigate losses. The Company withheld the \$ 34.3 million installment payment due to Fujifilm on September 30, 2023, pending resolution of the issues identified in the notice of breach (see Note 4). On October 30, 2023, FDBT filed a demand for arbitration with JAMS seeking payment of the third quarter installment of the Settlement Payment. An arbitration hearing was scheduled for May 2024. As of December 31, 2023, the remaining payment of \$ 68.6 million was reflected in Accrued expenses. On March 21, 2024, the Company and Fujifilm entered into a Settlement Agreement to resolve disputes regarding amounts that Fujifilm claimed were due under the CSAR. Pursuant to the Settlement Agreement, in March 2024 the Company paid \$ 42.0 million to Fujifilm, the parties agreed to a mutual release of claims arising from, under or otherwise in connection with the CSAR, and Fujifilm agreed to dismiss the Fujifilm Arbitration. This payment is less than amounts previously accrued for and reflected in Research and development expense, and accordingly, the Company recorded a benefit of \$ 26.6 million as Research and development expense in the first quarter of 2024 upon the execution of the Settlement Agreement.

The Company is also involved in various other legal proceedings arising in the normal course of business. Although the outcomes of these other legal proceedings are inherently difficult to predict, the Company does not expect the resolution of these other legal proceedings to have a material adverse effect on its financial position, results of operations, or cash flows.

Note 14 – Restructuring

During the three months ended March 31, 2024, the restructuring charge recorded by the Company comprised (in thousands):

	Amount
Severance and employee benefit costs	\$ 4,401
Impairment of assets	1,669
Total Restructuring charge ⁽¹⁾	\$ 6,070

(1) Restructuring charges of \$ 1.6 million and \$ 4.5 million are included in Research and development and Selling, general, and administrative expenses, respectively, in the Consolidated Statements of Operations for the three months ended March 31, 2024.

During the three months ended March 31, 2023, the Company did not recognize any restructuring charges.

Severance and employee benefit costs

Employees affected by the reduction in force under the Restructuring Plan are entitled to receive severance payments and certain termination benefits. The Company recorded a severance and termination benefit cost in full for employees who were notified of their termination in the three months ended March 31, 2024 and had no requirements for future service. The Company paid a total of \$ 3.9 million for the severance and employee benefit costs during the three months ended March 31, 2024 and the remaining liability of \$ 0.5 million is included in Accrued expenses in the Company's consolidated balance sheet as of March 31, 2024.

Impairment of assets

In connection with the Restructuring Plan, the Company evaluated its long-lived assets for impairment including certain leased laboratory and office spaces located in Gaithersburg, Maryland. The Company performed an impairment evaluation for the applicable long-lived assets, which is subject to judgment and actual results may vary from the estimates, resulting in potential future adjustments to amounts recorded. During the three months ended March 31, 2024, the Company

recorded an impairment charge of \$ 1.7 million related to the impairment of capitalized internal-use software.

Note 15 – Subsequent Events

Effective May 10, 2024, the Company entered into the Collaboration and License Agreement with Sanofi pursuant to which Sanofi received:

- i) A co-exclusive license to commercialize with the Company all of the COVID Mono Products,
- ii) A sole license to develop and commercialize combination COVID and influenza Combination Products,
- iii) A non-exclusive license to develop and commercialize Other Combination Products, and
- iv) A non-exclusive license to develop and commercialize Adjuvant Products.

Under the Collaboration and License Agreement, the Company will receive a non-refundable upfront payment of \$ 500 million. In addition, the Company will also be eligible to receive development, technology transfer, launch, and sales milestone payments totaling up to \$ 700 million in the aggregate with respect to the Licensed COVID-19 Products and royalty payments on Sanofi's sales of such licensed products. In addition, the Company is eligible to receive development, launch, and sales milestone payments of up to \$ 200 million for each of the first four Adjuvant Products and \$ 210 million for each Adjuvant Product thereafter, and royalty payments on Sanofi's sales of all such licensed products.

Commencing shortly after the Effective Date of the Collaboration and License Agreement, the Company will perform a technology transfer of its manufacturing process for the COVID Mono Products and Matrix-M™ components to Sanofi. Until the successful completion of such transfer, the Company will supply Sanofi with both COVID Mono Products and Matrix-M™ intermediary components for Sanofi's use and is eligible for reimbursement of such costs from Sanofi. Additionally, Sanofi will reimburse the Company for its research and development and medical affairs costs related to the COVID Mono Products in accordance with agreed upon plans and budgets.

Under the Collaboration and License Agreement, the Company will continue to commercialize the COVID Mono Products in 2024. Beginning in 2025 and continuing during the term of the Collaboration and License Agreement, Sanofi and the Company will commercialize the COVID Mono Products worldwide in accordance with a commercialization plan agreed by the Company and Sanofi, under which the Company will continue to supply its existing APA customers and strategic partners, including Takeda, SK Biosciences, and the Serum Institute of India. Upon completion of the existing advance purchase agreements, Novavax and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction.

Effective May 10, 2024, the Company also entered into the Subscription Agreement with Sanofi, pursuant to which the Company sold and issued to Sanofi, in a private placement, 6,880,481 shares of the Company's common stock, par value \$ 0.01 per share at a price of \$ 10.00 per share for aggregate gross proceeds to the Company of \$ 68.8 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Any statements in the discussion below and elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report") about expectations, beliefs, plans, objectives, assumptions, or future events or performance of Novavax, Inc. ("Novavax," together with its wholly owned subsidiaries, the "Company," "we," or "us") are not historical facts and are forward-looking statements. Such forward-looking statements include, without limitation, statements about our capabilities, goals, expectations regarding future revenue and expense levels, and capital raising activities; our operating plans and prospects, including our ability to continue as a going concern through one year from the date of our unaudited financial statements for the period ended March 31, 2024 are issued; our global restructuring and cost reduction plan ("Restructuring Plan"), which includes a more focused investment in our COVID-19 program (which currently includes Nuvaxovid™ prototype COVID-19 vaccine ("NVX-CoV2373" or "prototype vaccine") and Nuvaxovid™ updated COVID-19 vaccine ("NVX-CoV2601" or "updated vaccine") collectively referred to as our ("COVID-19 Program," or "COVID-19 Vaccine")); our cash flow forecast and projected revenue; potential market sizes and demand for our products and product candidates; the efficacy, safety, and intended utilization of our products and product candidates; the development of our clinical-stage product candidates and our recombinant vaccine and adjuvant technologies; the development of our preclinical product candidates; our expectations related to enrollment in our clinical trials; the conduct, timing, and potential results from clinical trials and other preclinical studies; plans for and potential timing of regulatory filings; our expectation of manufacturing capacity, timing, production, distribution, and delivery for our COVID-19 Vaccine by us and our partners; our expectations with respect to the anticipated ongoing development and commercialization or licensure of the COVID-19 Vaccine, ongoing development of COVID-19 variant strain-containing monovalent or bivalent formulations, including the Phase 2b/3 Hummingbird™ trial, and our COVID-19 Influenza Combination ("CIC") vaccine candidate and our stand-alone influenza vaccine candidate; efforts to expand the COVID-19 Vaccine label worldwide as a booster, and to various age groups and geographic locations; the expected timing, content, and outcomes of regulatory actions; funding under our advance purchase agreements ("APAs") and supply agreements and amendments to, termination of, discussion regarding, or legal disputes relating to any such agreement; our available cash resources and usage and the availability of financing generally; plans regarding partnering activities and business development initiatives; our plans regarding APA amendments; and other matters referenced herein. Generally, forward-looking statements can be identified through the use of words or phrases such as "believe," "may," "could," "will," "would," "possible," "can," "estimate," "continue," "ongoing," "consider," "anticipate," "intend," "seek," "plan," "project," "expect," "should," "would," "aim," or "assume," the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs and expectations about the future of our business, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. Forward-looking statements involve estimates, assumptions, risks, and uncertainties that could cause actual results or outcomes to differ materially from those expressed or implied in any forward-looking statements, and, therefore, you should not place considerable reliance on any such forward-looking statements. Such risks and uncertainties include, without limitation, our ability to successfully and timely manufacture, distribute, or market our updated COVID-19 vaccine including as a single dose vial or pre-filled syringe product presentation for the 2024-2025 vaccination season and our ability to receive a Biologics License Application ("BLA") from the U.S. Food and Drug Administration ("U.S. FDA") 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 our product candidates, including our updated COVID-19 vaccine in time for the 2024-2025 vaccination season or for future COVID-19 variant strain changes, our CIC vaccine candidate and our stand-alone influenza vaccine candidate; manufacturing, distribution or export delays or challenges; our 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 our 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 the ability of Novavax 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 the Restructuring Plan; our ability to timely deliver doses; challenges in obtaining commercial adoption and market acceptance of our 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 us 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 other risks and uncertainties identified in Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023 and this Quarterly Report on Form 10-Q, which may be detailed and modified or updated in other documents filed with the SEC from time to time, and are available at www.sec.gov and at www.novavax.com. You are encouraged to read these filings as they are made.

We cannot guarantee future results, events, level of activity, performance, or achievement. Any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate or materially different from actual results. Further, any forward-looking statement speaks only as of the date when it is made, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Information in this Quarterly Report includes a financial measure that was not prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), which we refer to as adjusted cost of sales. We are presenting this non-GAAP financial measure to assist an understanding of our business and its performance. Adjusted cost of sales includes an estimate of standard manufacturing costs that were previously expensed to research and development prior to regulatory approvals for our COVID-19 Vaccine that would otherwise have been capitalized to inventory. Any non-GAAP financial measures presented are not, and should not be viewed as, substitutes for financial measures required by GAAP, have no standardized meaning prescribed by GAAP, and may not be comparable to the calculation of similar measures of other companies.

Overview

We are a biotechnology company that promotes improved global health through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Our proprietary recombinant technology platform harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticle vaccines designed to address global health needs.

Our vaccine candidates are nanostructures of conformationally correct recombinant proteins that mimic those found on pathogens. This technology enables the immune system to recognize target proteins and develop protective immune responses. We believe that our vaccine technology may lead to the induction of a differentiated immune response that may be more efficacious than naturally occurring immunity or some other vaccine approaches. Our vaccine candidates also incorporate our proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response, stimulate higher levels of functional antibodies, and induce a cellular immune response.

We previously developed an updated COVID-19 vaccine for the 2023-2024 vaccination season, for which the U.S. FDA granted emergency use authorization ("EUA") in October 2023 for active immunization to prevent COVID-19. We are in the process of developing an updated COVID-19 vaccine for the 2024-2025 vaccination season and expect our updated COVID-19 vaccine to be available at U.S. pharmacy retailers in September 2024. During the first quarter of 2024, we completed the submission of the BLA for our prototype COVID-19 vaccine with the U.S. FDA. In addition, we aligned with the U.S. FDA on pathway for EUA for our updated COVID-19 vaccine for the 2024-2025 vaccination season.

Outside the U.S., in January 2024, our updated vaccine was granted marketing authorization by the United Kingdom's ("UK") Medicines and Healthcare products Regulatory Agency ("MHRA"). We are committed to meeting the full supply of our key target markets through APAs covering such markets. We continue to work closely with regulatory authorities globally for authorization of our updated vaccine. We previously developed a prototype COVID-19 vaccine, which has received full marketing authorization ("MA"), marketing approval, interim authorization, provisional approval, or conditional marketing authorization ("CMA"), from multiple regulatory authorities in over 40 countries globally. We continue to progress our regulatory authorizations for our prototype vaccine in select territories, as we believe these may facilitate authorization of our vaccine candidates for updated strains in the future.

Additionally, our near-term focus is on developing a CIC vaccine candidate as well as seasonal influenza vaccine candidate, and we are on track to initiate a Phase 3 trial in the second half of 2024 for both vaccines. Furthermore, we provide our Matrix-M™ adjuvant for collaborations, including in R21/Matrix-M™ adjuvant malaria vaccine, which recently received authorization in several countries, as well as other preclinical vaccine research with our Matrix-M™ adjuvant, including through a partnership with the Bill & Melinda Gates Medical Research Institute.

We intend to focus our organization to align our investments and activities with our top priority of delivering our updated COVID-19 vaccine for the 2024-2025 vaccination season. To maximize our opportunities and mitigate the significant risks and uncertainties of the COVID-19 market, we have progressed our cost restructuring measures to reduce spend, extend our cash runway, and operate efficiently to seek the best position for the Company to deliver longer-term growth. We discuss these cost restructuring strategies in greater detail in Note 2 to our consolidated financial statements.

Technology Overview

We believe our recombinant nanoparticle vaccine technology, together with our proprietary Matrix-M™ adjuvant, is well suited for the development and commercialization of vaccine candidates targeting a broad scope of respiratory and other endemic and emerging infectious diseases.

Recombinant Nanoparticle Vaccine Technology

Once a target of interest has been identified, the genetic sequence encoding an antigen is selected for developing the vaccine construct. The genetic sequence may be optimized to enhance protein stability or confer resistance to degradation. This genetic construct is inserted into the baculovirus *Spodoptera frugiperda* ("Sf-/BV") insect cell-expression system, which enables efficient, large-scale expression of the optimized protein. The Sf-/BV system produces protein-based antigens that are properly folded and modified, which can be critical for functional, protective immunity. Protein antigens are purified and organized around a polysorbate-based nanoparticle core in a configuration that resembles their native presentation. This results in a highly immunogenic nanoparticle that is ready to be formulated with Matrix-M™ adjuvant.

Matrix-M™ Adjuvant

Our proprietary Matrix-M™ adjuvant is a key differentiator within our platform. This adjuvant has enabled potent, well tolerated, and durable efficacy by stimulating the entry of antigen presenting cells ("APCs") into the injection site and enhancing antigen presentation in local lymph nodes. This in turn activates APCs, T-cell and B-cell populations, and plasma cells, which promote the production of high affinity antibodies, an immune boosting response. This potent mechanism of action enables a lower dose of antigen to achieve the desired immune response, thereby contributing to increased vaccine supply and manufacturing capacity. These immune-boosting and dose-sparing capabilities contribute to the adjuvant's highly unique profile.

We continue to evaluate commercial opportunities for the use of our Matrix-M™ adjuvant alongside vaccine antigens produced by other manufacturers. Matrix-M™ adjuvant is being evaluated in combination with several partner-led malaria vaccine candidates, including for R21/Matrix-M™ adjuvant, a malaria vaccine candidate created by the Jenner Institute, University of Oxford. The R21/Matrix-M™ adjuvant vaccine has been licensed to Serum Institute of India Pvt. Ltd. ("SIIPL") for commercialization and in December 2023 received prequalification by the World Health Organization ("WHO"), along with authorizations received earlier in the year in Burkino Faso, Ghana, and Nigeria. Additionally, in May 2023, we entered into a three-year agreement with the Bill & Melinda Gates Medical Research Institute to provide our Matrix-M™ adjuvant for use in preclinical vaccine research. In June 2023, we signed a material transfer agreement with SK bioscience Co., Ltd. ("SK") for use of our Matrix-M™ adjuvant in preclinical vaccine experiments for shingles, influenza, and pan-COVID-19. Our adjuvant technology is also being used by commercial partners as a key component in veterinary vaccines against equine influenza and Strangles, as well as the manufacture of black-widow anti-venom.

COVID-19 Vaccine Regulatory and Licensure

We continue to receive authorizations for our updated vaccine developed for the 2023-2024 COVID-19 vaccination season in accordance with the updated strain protocol guidance. We are also continuing to progress our regulatory authorizations for our prototype vaccine in select territories, as we believe these may facilitate authorization of our vaccine candidates for updated strains in the future. Additionally, we continue to progress our regulatory authorizations for our updated vaccine and plan to continue to do so for subsequent future variant strains for each annual respiratory season, including the upcoming 2024-2025 vaccination season.

Within the U.S. market, our updated vaccine received EUA in October 2023 from the U.S. FDA to prevent COVID-19 in individuals aged 12 and older and is marketed in the U.S. under the name Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula). The formulation for our updated vaccine aligns with global harmonized guidance from the U.S. FDA, the European Medicines Agency ("EMA"), and WHO recommendations for the 2023-2024 vaccination season.

Outside the U.S. market, we continue to progress regulatory authorizations for our updated vaccine globally. In January 2024, we were granted marketing authorization by the UK MHRA for our updated vaccine, marketed under the name Nuvaxovid™ XBB.1.5 Vaccine, in individuals aged 12 and older.

We have previously received authorizations for our prototype COVID-19 vaccine in over 40 countries globally, including from major regulatory agencies such as the U.S. FDA, WHO, EMA, and MHRA. To date, we have received full MA, approval, interim authorization, provisional approval, CMA, and EUA for the adult population, aged 18 and older, the adolescent population, aged 12 to 17 years, and the pediatric population, aged 7 to 11 years in select territories. The regulatory authorizations for our prototype vaccine include primary series and both homologous and heterologous booster indications within specific countries. For the territories in which our vaccine has received regulatory authorizations, our prototype vaccine is marketed under the names (i) Nuvaxovid™ (SARS-CoV-2 rS Recombinant, adjuvanted), (ii) Covovax™ (manufacturing and commercialization by SIPL), or (iii) Novavax COVID-19 Vaccine, Adjuvanted.

We are working to continue to expand our label for primary and re-vaccination in younger children, and to achieve supportive policy recommendations enabling broad market access. We continue to work closely with governments, regulatory authorities, and non-governmental organizations in our commitment to facilitate global access to our COVID-19 vaccine.

Product Pipeline

Our clinical pipeline encompasses vaccine candidates for infectious diseases, with our COVID-19 prototype vaccine (NVX-CoV2373) and our COVID-19 updated vaccine (NVX-CoV2601), as our lead products. Our updated vaccine has received authorization from the U.S. FDA, the EC, the WHO, and several other countries globally. Beyond our COVID-19 vaccine, our clinical pipeline includes a CIC vaccine candidate, and a seasonal influenza vaccine candidate in addition to our Matrix-M™ adjuvant being used for collaboration in R21/Matrix-M™ adjuvant malaria vaccine.

Disease	Product	Preclinical	Phase 1	Phase 2	Phase 3	Authorized
Novavax						
Coronavirus	Novavax COVID-19 Vaccine ¹	Matrix-M				
COVID / Influenza	Combination Vaccine (CIC)	Matrix-M				
Seasonal Influenza	Influenza (Older Adults)	Matrix-M				
Partnered						
Malaria	R21/Matrix-M™ adjuvant ²	Matrix-M				

Novavax continues to optimize preclinical candidates, including a new approach to H5N1 pandemic bird flu vaccination, and expand our core technology for novel applications including mucosal vaccination and high-density nanoparticles.

- (1) Authorized in select geographies under trade names Novavax COVID-19 Vaccine, Adjuvanted; Covovax™; and Nuvaxovid™, and authorized in the U.S. under trade name, Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula); Ongoing post-authorization Phase 3 strain change trial.
- (2) Authorized in Ghana, Nigeria, and Burkina Faso; Commercialized by Serum Institute of India; Granted prequalification by the WHO.

Coronavirus Vaccine Clinical Development

We remain focused on expanding our COVID-19 vaccine label within the booster, adolescent, and pediatric indications. We continue to evaluate vaccine safety, immunogenicity, and effectiveness through ongoing clinical trials and collaborative evidence-generating real-world studies. We expect to leverage these clinical insights to advance additional regulatory approvals of our COVID-19 vaccine globally, amidst the evolving COVID-19 landscape.

Phase 3 Strain-Change and Re-vaccination Studies

Study 311 Part 2: In August 2023, we announced primary endpoint topline results demonstrating immunologic superiority of our bivalent prototype and Omicron BA.5 vaccine compared to our prototype vaccine (NVX-CoV2373) for Omicron BA.5 specific responses. This study was designed to support our 2023-2024 strain change for our updated vaccine (NVX-CoV2601). In March 2024, interim results of this study were published in *The Lancet*.

Study 313: In November 2023, we fully enrolled 338 adults aged 18 and older and in Part 2 of the study we will evaluate the immunogenicity of our updated vaccine (NVX-CoV2601) in previously unvaccinated individuals. Topline results are expected by the second quarter of 2024. Data from Study 313 are intended to support BLA supplements and similar

regulatory submissions in other territories for future variant strain formulations.

Phase 2b/3 Pediatric Hummingbird™ Study

In August 2023, we announced topline results from our Phase 2b/3 Hummingbird™ trial that met its primary endpoints in children aged 6 through 11 years demonstrating both tolerability and immunologic responses. This ongoing trial is evaluating the safety, effectiveness (immunogenicity), and efficacy of two doses of our prototype vaccine (NVX-CoV2373), followed by a booster 6 months after the primary vaccination series. The trial includes three age de-escalation cohorts of 1,200 children each. Cohorts aged 2 through 5 years and 6 to 23 months are fully enrolled. In consultation with regulatory bodies, the filing strategy includes filing a supplemental BLA for these cohorts once the initial BLA is approved. Therefore, we do not anticipate authorization for these age groups for the 2024-2025 vaccination season.

COVID-Influenza Combination and Stand-alone Influenza Program

For our CIC vaccine, we have previously received agreement with the U.S. FDA on a Phase 3 design, study endpoints, trivalent comparators, and size of licensure enabling safety database. We have recently decided to modify the study to focus on individuals at higher risk by enrolling adults aged 60 years and older and to include a stand-alone influenza vaccine comparative component. We remain on track to submit an investigational new drug application, inclusive of this new study design and initiate the study in the second half of 2024, with potential accelerated approval and launch of the CIC vaccine in the fall of 2026.

While our focus remains on the combination product, our development plans will maintain optionality to advance our stand-alone influenza vaccine, as described above, creating a pathway to potentially seek licensure. For our stand-alone influenza vaccine, we have generated positive data through our previous Phase 2 trial. We expect to confirm and expand on these findings in the planned Phase 3 trial. We continue to believe this asset may also be attractive from a pandemic preparedness perspective and that similar performance in terms of comparative immunogenicity may be expected for A/H5N1 pandemic strains.

High-dose COVID-19 Vaccine Study

Study 205: In October 2023, we completed enrollment in a Phase 2 trial to evaluate our high-dose COVID-19 vaccine for annual vaccination in 994 adults ages 50 years and older. The trial will compare immunogenicity levels of 5 micrograms of our prototype vaccine (NVX-CoV2373) against 5 micrograms, 35 micrograms, and 50 micrograms of our updated vaccine (NVX-CoV2601) that are matched with different levels of adjuvant. Data from this trial is intended to potentially support further development of a higher-dose formulation for older adults, similar to that of influenza vaccines. Analysis of the complete dataset is ongoing to determine the utility of pursuing a high dose formulation.

R21/Matrix-M™ Adjuvant Malaria Vaccine

R21/Matrix-M™ adjuvant malaria vaccine, formulated with our Matrix-M™ adjuvant is developed by our partner, the Jenner Institute, University of Oxford, and manufactured by SIIPL. We have an agreement with SIIPL related to its manufacture of R21/Matrix-M™ adjuvant malaria vaccine under which SIIPL purchases our Matrix-M™ adjuvant for use in development activities at cost and for commercial purposes at a tiered commercial supply price, and pays a royalty in the single- to low-double digit range based on vaccine sales for a period of 15 years after the first commercial sale of the vaccine in each country.

In February 2024, peer-reviewed results from the Phase 3 efficacy trial were published in *The Lancet* reporting R21/Matrix-M™ adjuvant malaria vaccine has a well-tolerated safety profile and offers high-level efficacy against clinical malaria in African children at sites of both seasonal and perennial transmission.

In December 2023, the WHO announced it prequalified the R21/Matrix-M™ adjuvant malaria vaccine to prevent malaria disease in children caused by the *P. falciparum* parasite in endemic areas. Prequalification status enables United Nations agencies to procure the vaccine for eligible countries and will enable rollout of the vaccine in mid-2024. The WHO recommended that the R21/Matrix-M™ adjuvant malaria vaccine be administered in a four-dose schedule beginning at five months of age. Previously, R21/Matrix-M™ adjuvant malaria vaccine received authorization in Burkina Faso, Ghana and Nigeria.

Business Highlights

First Quarter 2024 and Recent Highlights

We and Sanofi Pasteur Inc. ("Sanofi") announced that we entered into a co-exclusive licensing agreement. The terms of the agreement include: a co-exclusive license to co-commercialize our current stand-alone adjuvanted COVID-19 vaccine worldwide (except in countries with existing APAs and in India, Japan and South Korea where we have existing partnership agreements); a sole license to our adjuvanted COVID-19 vaccine for use in combination with Sanofi's influenza vaccines while we retain the right to and is developing its own COVID-19-Influenza Combination vaccine candidate; a non-exclusive license to use our adjuvanted COVID-19 vaccine for use in combination with non-influenza 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 our Company.

First Quarter 2024 and Recent Highlights

U.S. Market:

- Updated our protein-based non-mRNA COVID-19 vaccine to JN.1 with anticipated pre-filled syringe presentation.
- Completed the submission of the BLA for Novavax's COVID-19 vaccine with the U.S. FDA.
- Aligned with the U.S. FDA on pathway for EUA 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 UK's MHRA for Nuvaxovid™ XBB.1.5 in individuals aged 12 and older in [January](#) and progressed preparations for participation in the UK 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.

Clinical development and technology platform updates:

- Made strategic decision to add a stand-alone influenza vaccine comparative component 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 our core technology for novel applications including mucosal vaccination and high-density nanoparticles.

We are on track with our global restructuring and cost reduction plan, as we continue to transform the Company into a more lean and agile organization, with an approximately 50% reduction to combined research and development and Selling, general, and administrative expenses in the first quarter of 2024, compared to 2023.

Sales of Common Stock

In August 2023, we entered into an At Market Issuance Sales Agreement (the "August 2023 Sales Agreement"), which allows us to issue and sell up to \$500 million in gross proceeds of shares of our common stock, and terminated our then-existing At Market Issuance Sales agreement entered in June 2021 (the "June 2021 Sales Agreement"). There were no sales recorded under the August 2023 Sales Agreement during the three months ended March 31, 2024. As of March 31, 2024, the remaining balance available under the August 2023 Sales Agreement was approximately \$242 million. There were no sales recorded under the June 2021 Sales Agreement during the three months ended March 31, 2023.

Critical Accounting Policies and Use of Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements (unaudited) and the accompanying notes, which have been prepared in accordance with generally accepted accounting principles in the United States.

The preparation of our consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, and equity and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Our critical accounting policies and estimates are included under Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC.

Recent Accounting Pronouncements Not Yet Adopted

See "Note 2—Summary of Significant Accounting Policies" included in our Notes to Consolidated Financial Statements (under the caption "Recent Accounting Pronouncements").

Results of Operations

The following is a discussion of the historical financial condition and results of our operations that should be read in conjunction with the unaudited consolidated financial statements and notes set forth in this Quarterly Report.

Three Months Ended March 31, 2024 and 2023

Revenue

	Three Months Ended March 31,		
	2024	2023	Change
Revenue (in thousands):			
Product sales	\$ 82,324	\$ (7,457)	\$ 89,781
Grants	—	87,379	(87,379)
Royalties and other	11,531	1,029	10,502
Total revenue	\$ 93,855	\$ 80,951	\$ 12,904

Revenue for the three months ended March 31, 2024 was \$93.9 million as compared to \$81.0 million for the same period in 2023, an increase of \$12.9 million. Revenue for the three months ended March 31, 2024 was primarily comprised of revenue from product sales of COVID-19 Vaccine. Revenue for the three months ended March 31, 2023 was primarily comprised of services performed under our U.S. government agreement with Advanced Technology International ("USG Agreement"), the Consortium Management Firm acting on behalf of the Medical CBRN Defense Consortium in connection with the partnership formerly known as Operation Warp Speed. The increase in revenue is due to an increase in the quantity of dose sales of COVID-19 Vaccine, sales-based royalties, and Matrix-M™ adjuvant sales during the three months ended March 31, 2024, partially offset by a decrease in revenue under the USG Agreement.

Product sales

Product sales for the three months ended March 31, 2024 were \$82.3 million as compared to \$7.5 million during the three months ended March 31, 2023. Our product sales related to revenue from commercial sales of COVID-19 Vaccine, which commenced in 2022. Product sales in the three months ended March 31, 2023, included a credit of \$64.7 million for certain doses delivered in 2022 that qualified for replacement. The credit is the result of a single lot sold to the Australian government that upon pre-planned 6-month stability testing was found to have fallen below the defined specifications and the lot was

therefore removed from the market.

The geographic distribution of product sales was as follows:

	Three Months Ended March 31,		
	2024	2023	Change
North America	\$ (6,361)	\$ —	\$ (6,361)
Europe	90,416	57,267	33,149
Rest of the world	(1,731)	(64,724)	62,993
Total product sales	<u>\$ 82,324</u>	<u>\$ (7,457)</u>	<u>\$ 89,781</u>

During the three months ended March 31, 2024, product sales in North America includes \$6.4 million of gross-to-net deductions in excess of the wholesaler acquisition costs ("WAC"), primarily due to wholesale distributor fees for shipments expected to be returned and adjustments made to estimated returns of prior period product sales. Product sales for the rest of the world includes a \$3.6 million reduction to revenue recognized in prior periods due to the Gavi Settlement Agreement (see Note 3 to our consolidated financial statements).

Grants

We did not have any Grant revenue during the three months ended March 31, 2024, as compared to \$87.4 million during the same period in 2023, a decrease of \$87.4 million. Grant revenue comprised revenue for services performed under our USG Agreement. As of December 31, 2023, we had recognized the full contract funding under the USG Agreement in revenue.

Royalties and other

Royalties and other includes royalty milestone payments, sales-based royalties, and Matrix-M™ adjuvant sales. Royalties and other revenue during the three months ended March 31, 2024 was \$11.5 million as compared to \$1.0 million during the same period in 2023, an increase of \$10.5 million. The increase was primarily due to \$4.0 million in revenue related to license fees and \$7.5 million in revenue related to a Matrix-M™ adjuvant sales.

Expenses

	Three Months Ended March 31,		
	2024	2023	Change
Expenses (in thousands):			
Cost of sales	\$ 59,209	\$ 34,086	\$ 25,123
Research and development	92,679	247,101	(154,422)
Selling, general, and administrative	86,798	112,532	(25,734)
Total expenses	<u>\$ 238,686</u>	<u>\$ 393,719</u>	<u>\$ (155,033)</u>

Cost of Sales

Cost of sales was \$59.2 million for the three months ended March 31, 2024, including expenses of \$8.8 million related to excess, obsolete, or expired inventory, and \$6.0 million related to unutilized manufacturing capacity. Cost of sales was \$34.1 million for the three months ended March 31, 2023, including expense of \$19.4 million related to excess, obsolete, or expired inventory and losses on firm purchase commitments, partially offset by negotiated reductions to certain previously recognized firm purchase commitments, and \$4.6 million related to unutilized manufacturing capacity. Prior to receiving regulatory approval, we expensed manufacturing costs as research and development expenses. After receiving regulatory approval, we capitalize the costs of production for a particular supply chain when we determine that we have a present right to the economic benefit associated with the product. While we tracked the quantities of our manufactured vaccine product and components, we did not track pre-approval manufacturing costs and therefore the manufacturing cost of our pre-launch inventory produced prior to approval is not reasonably determinable. If inventory sold for the three months ended March 31, 2024 was valued at expected standard cost, including expenses related to excess and obsolete inventory, adjusted cost of sales for the period would have been approximately \$60.8 million, an adjustment of \$1.6 million as compared to cost of sales recognized. If inventory sold for the three months ended March 31, 2023 was valued at expected standard cost, adjusted cost of

sales for the period would have been approximately \$49.1 million, an adjustment of \$15.0 million. The cost of sales as a percentage of product sales may fluctuate in the future as a result of changes to our customer pricing mix or standard costs.

Research and Development Expenses

Research and development expenses were \$92.7 million for the three months ended March 31, 2024 as compared to \$247.1 million for the three months ended March 31, 2023, a decrease of \$154.4 million. The decrease was primarily due to a reduction in overall expenditures relating to development activities on coronavirus vaccines, including our COVID-19 Program, and CIC, as summarized in the table below (in thousands):

	Three Months Ended March 31,	
	2024	2023
Coronavirus vaccines	\$ 26,061	\$ 140,014
Other vaccine development programs	336	1,957
Total direct external research and development expense	26,397	141,971
Employee expenses	37,953	53,413
Stock-based compensation expense	5,505	13,858
Facility expenses	11,797	19,402
Other expenses	11,027	18,457
Total research and development expenses	\$ 92,679	\$ 247,101

Research and development expenses for coronavirus vaccines for the three months ended March 31, 2024 and 2023 decreased from \$140.0 million to \$26.1 million primarily as a result of a reduction in manufacturing and support costs due, in part, to a reduction in our global manufacturing footprint consistent with our contractual obligations to supply, and anticipated demand for, COVID-19 Vaccine, including embedded lease costs, under manufacturing supply agreements with Contract Manufacturing Organizations ("CMOs") and contract manufacturing and development organizations ("CDMOs"). The decrease was also due to a benefit of \$26.6 million for the three months ended March 31, 2024 resulting from the Confidential Settlement Agreement and Release agreement executed with Fujifilm resulting in a reduction to previously recorded expense (see Note 4 to our consolidated financial statements).

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses were \$86.8 million for the three months ended March 31, 2024 as compared to \$112.5 million for the same period in 2023, a decrease of \$25.7 million. The decrease in selling, general, and administrative expenses is primarily due to certain cost containment measures to reduce our operating spend.

For the remainder of 2024, we expect a reduction in our annual combined research and development, and selling, general, and administrative spend as a result of our Restructuring Plan announced during the three months ended March 31, 2024.

Other Income (Expense)

	Three Months Ended March 31,		
	2024	2023	Change
Other income (expense):			
Interest expense	\$ (4,111)	\$ (4,316)	\$ 205
Other income	3,654	24,362	(20,708)
Total other income (expense), net	\$ (457)	\$ 20,046	\$ (20,503)

Total other expense, net was \$0.5 million for the three months ended March 31, 2024 as compared to a total other income, net of \$20.0 million for the same period in 2023. The decrease in other income, net is due to the unfavorable impact in 2024 as compared to 2023 of exchange rates on foreign currency denominated balances, including an intercompany loan with Novavax CZ.

Income Tax Expense

During the three months ended March 31, 2024, we recognized an income tax expense of \$2.3 million related to foreign income taxes. During the three months ended March 31, 2023, we recognized an income tax expense of \$1.2 million related to federal, state, and foreign income taxes.

Net Income (Loss)

	Three Months Ended March 31,		
	2024	2023	Change
Net Loss (in thousands, except per share information):			
Net loss	\$ (147,550)	\$ (293,905)	\$ 146,355
Net loss per share, basic and diluted	\$ (1.05)	\$ (3.41)	\$ 2.36
Weighted average shares outstanding, basic and diluted	139,916	86,158	53,758

Net loss for the three months ended March 31, 2024 was \$147.6 million, or \$1.05 per share, as compared to net loss of \$293.9 million, or \$3.41 per share, for the same period in 2023. The decrease in net loss during the three months ended March 31, 2024, was primarily due to a decrease in research and development expenses.

The increase in weighted average shares outstanding for the three months ended March 31, 2024 was primarily a result of sales of our common stock.

Liquidity Matters and Capital Resources

Our future capital requirements depend on numerous factors including, but not limited to, revenue from our product sales, milestone payments, royalties and reimbursements under licensing arrangements with our strategic partners; our projected activities related to the development and commercial support of our COVID-19 Vaccine and our CIC vaccine candidate, including significant commitments under various clinical research organizations, CMO, and CDMO agreements; the progress of preclinical studies and clinical trials; the time and costs involved in obtaining regulatory approvals; the costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights; and other manufacturing, sales, and distribution costs. We plan to continue developing other vaccines and product candidates, such as our potential combination vaccines candidates, which are in various stages of development.

Effective May 10, 2024, we entered into a collaboration and license agreement (the "Collaboration and License Agreement") with Sanofi pursuant to which Sanofi received:

- i) A co-exclusive license to commercialize with us all of our current stand-alone COVID-19 vaccine products, including the our Nuvaxovid™ prototype COVID-19 vaccine and Nuvaxovid™ updated COVID-19 vaccine, and updated versions that address seasonal variants throughout the world ("COVID Mono Products"),
- ii) A sole license to develop and commercialize combination products containing a potential combination of our COVID-19 vaccine and Sanofi's seasonal influenza vaccine ("COVID and influenza Combination Products" or "CIC Products"),
- iii) A non-exclusive license to develop and commercialize combination products containing both our COVID-19 vaccine and one or more non-influenza vaccines ("Other Combination Products" and together with the COVID Mono Products, CIC Products, and Other Combination Products ("Licensed COVID-19 Products"), and
- iv) A non-exclusive license to develop and commercialize other vaccine products selected by Sanofi that include our Matrix-M™ adjuvant (as described below, the "Adjuvant Products").

Under the Collaboration and License Agreement, we will receive a non-refundable upfront payment of \$500 million. In addition, we will also be eligible to receive development, technology transfer, launch, and sales milestone payments totaling up to \$700 million in the aggregate with respect to the Licensed COVID-19 Products and royalty payments on Sanofi's sales of such licensed products. In addition, we are eligible to receive development, launch, and sales milestone payments of up to \$200 million for each of the first four Adjuvant Products and \$210 million for each Adjuvant Product thereafter, and royalty payments on Sanofi's sales of all such licensed products.

Commencing shortly after the Effective Date of the Collaboration and License Agreement, we will perform a technology transfer of our manufacturing process for the COVID Mono Products and Matrix-M™ components to Sanofi. Until the successful completion of such transfer, we will supply Sanofi with both COVID Mono Products and Matrix-M™ intermediary components for Sanofi's use and are eligible for reimbursement of such costs from Sanofi. Additionally, Sanofi will reimburse us for our research and development and medical affairs costs related to the COVID Mono Products in accordance with agreed upon plans and budgets.

Under the Collaboration and License Agreement, we will continue to commercialize the COVID Mono Products in 2024. Beginning in 2025 and continuing during the term of the Collaboration and License Agreement, Sanofi and we will commercialize the COVID Mono Products worldwide in accordance with a commercialization plan agreed by us and Sanofi, under which we will continue to supply our existing APA customers and strategic partners, including Takeda, SK Biosciences, and the Serum Institute of India. Upon completion of the existing advance purchase agreements, we and Sanofi will jointly agree on commercialization activities of each party in each jurisdiction.

Effective May 10, 2024, we also entered into a securities subscription agreement (the "Subscription Agreement") with Sanofi, pursuant to which we sold and issued to Sanofi, in a private placement, 6,880,481 shares of our common stock, par value \$0.01 per share at a price of \$10.00 per share for aggregate gross proceeds to us of \$68.8 million.

We have entered into supply agreements, sometimes referred to as APAs, with the EC and various countries globally. We also have license agreements. As of March 31, 2024, the aggregate amount of the transaction price allocated to performance obligations that were unsatisfied (or partially unsatisfied), excluding amounts related to sales-based royalties under the licensing agreements, was approximately \$2 billion, of which \$1.1 billion is included in Deferred revenue on our consolidated balance sheet. Failure to timely meet regulatory milestones, obtain timely supportive recommendations from governmental advisory committees, or achieve product volume or delivery timing obligations under our APAs may require us to refund portions of upfront or other payments or result in reduced future payments, which could adversely impact our ability to realize revenue from our unsatisfied performance obligations. The timing to fulfill performance obligations related to supply agreements will depend on timing of product manufacturing, receipt of marketing authorizations for additional indications, delivery of doses based on customer demand, and the ability of the customer to request variant vaccine under certain of our APAs. The supply agreements typically contain terms that include upfront payments intended to assist us in funding investments related to building out and operating our manufacturing and distribution network, among other expenses, in support of our global supply commitment, and are applied to billings upon delivery of COVID-19 Vaccine. Such upfront payments generally become non-refundable upon our achievement of certain development, regulatory, and commercial milestones.

On October 3, 2023, our updated vaccine received EUA from the U.S. FDA for active immunization to prevent COVID-19 in individuals aged 12 and older. Immediately upon authorization, our updated vaccine has also been included in the recommendations issued by the CDC in September 2023. Doses became available within the U.S. at many major pharmacy retailers, following the Center for Biologics Evaluation and Research release of vaccine batches. We have established reserves for gross-to-net deductions for amounts that we expect to return to our customers. As of March 31, 2024, gross-to-net reserve balances were \$92.9 million related to product returns and \$10.2 million related to wholesale distributor fees, discounts, and chargebacks, of which \$5.4 million was included in Accounts receivable and \$97.7 million was included in Accrued expenses on our consolidated balance sheet.

Pursuant to the Settlement Agreement with Fujifilm (see Note 4 to our consolidated financial statements), in March 2024 we paid \$42.0 million to Fujifilm, the parties agreed to a mutual release of claims arising from, under or otherwise in connection with the prior confidential settlement agreement and release effective September 30, 2022, and Fujifilm agreed to dismiss its demand for arbitration with the Judicial Arbitration and Mediation Services ("JAMS"). This payment is less than amounts previously recognized as embedded lease expense and reflected in Research and development expenses from Fujifilm manufacturing activity and accordingly, during the three ended March 31, 2024, we recorded a benefit of \$26.6 million as Research and development expenses.

We have an APA with the Commonwealth of Australia ("Australia") for the purchase of doses of COVID-19 Vaccine (the "Australia APA"). In November 2023, we filed with the Therapeutic Goods Administration ("TGA") for authorization for our updated vaccine. Based on subsequent communication from the TGA that it will not recommend approval of the filing as submitted and new data and information generated since that filing, we are evaluating the regulatory path for approval, including the potential to withdraw the filing, update with new data and information, and resubmit in the coming months. In March 2024, we and Australia agreed to cancel the COVID-19 Vaccine doses previously scheduled for delivery in the fourth quarter of 2023. As a result of the cancellation, the total contract value was reduced by \$54.0 million, including \$6.0 million of deferred revenue related to the cancelled doses that will be applied as a credit towards future deliveries of doses. Australia is not required to purchase the updated COVID-19 Vaccine doses until we receive authorization from TGA. We plan to seek an

amendment to the Australia APA to address performance obligations and future delivery schedule, which may not be achievable on acceptable terms or at all.

We have an APA with His Majesty the King in Right of Canada as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (the "Canadian government"), for the purchase of doses of COVID-19 Vaccine (the "Canada APA"). The Canadian government may terminate the Canada APA, as amended, if we fail to receive regulatory approval for its COVID-19 Vaccine using bulk antigen produced at Biologics Manufacturing Centre ("BMC") Inc. on or before December 31, 2024. We do not anticipate achieving regulatory approval of our COVID-19 Vaccine using bulk antigen produced at BMC on or before December 31, 2024. Therefore, we plan to seek an amendment to the Canada APA to address possible alternatives, which may not be achievable on acceptable terms or at all. As of March 31, 2024, \$110.6 million was classified as current Deferred revenue and \$477.6 million was classified as non-current Deferred revenue with respect to the Canadian APA in our consolidated balance sheet. If the Canadian government terminates the Canada APA, \$28.0 million of the deferred revenue would become refundable and approximately \$224 million of the contract value related to future deliverables would no longer be available.

In September 2022, we entered into an Amended and Restated SARS-CoV-2 Vaccine Supply Agreement (the "Amended and Restated UK Supply Agreement") with The Secretary of State for Business, Energy and Industrial Strategy (as assigned to the UK Health Security Agency), acting on behalf of the government of the United Kingdom of Great Britain and Northern Ireland (the "Authority"), which amended and restated in its entirety the SARS-CoV-2 Vaccine Supply Agreement, dated October 22, 2020, between the parties (the "Original UK Supply Agreement"). Under the terms of the Amended and Restated UK Supply Agreement, the Authority agreed to purchase a minimum of 1 million doses and up to an additional 15 million doses (the "Conditional Doses") of our prototype vaccine, with the number of Conditional Doses contingent on, and subject to reduction based on, our timely achievement of supportive recommendations from the Joint Committee on Vaccination and Immunisation ("JCVI") that is approved by the UK Secretary of State for Health. If the Authority did not purchase the Conditional Doses or the number of such Conditional Doses was reduced below 15 million doses of our prototype vaccine, we would have to repay up to \$225.0 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. Under the Amended and Restated UK Supply Agreement, the Authority also has the option to purchase up to an additional 44 million doses, in one or more tranches, through 2024.

As of November 30, 2022, the JCVI had not made a supportive recommendation with respect to our prototype vaccine, thereby triggering, under the terms of the Amended and Restated UK Supply Agreement, (i) a reduction of the number of Conditional Doses from 15 million doses to 7.5 million doses, which reduced number of Conditional Doses are contingent on, and subject to further reduction based on, our timely achievement by November 30, 2023 of a supportive recommendation from JCVI that is approved by the UK Secretary of State for Health as described in the paragraph above, and (ii) an obligation for us to repay \$112.5 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. In April 2023, we repaid the \$112.5 million related to the November 30, 2022 triggering event. As of November 30, 2023, the JCVI had not made a supportive recommendation with respect to the prototype vaccine, thereby triggering a reduction in the number of Conditional Doses from 7.5 million doses to zero. As of May 2024, we are in discussions with the Authority regarding the treatment of the remaining upfront amount previously received of \$112.5 million, which is reflected in Other current liabilities on our consolidated balance sheet.

We entered into an APA with the Vaccine Alliance ("Gavi") in May 2021 (the "Gavi APA"), pursuant to which we received upfront payments of \$700 million from Gavi (the "Advance Payment Amount") to be applied against purchases of our prototype vaccine by certain countries participating in the COVAX Facility. As of December 31, 2023, the remaining Gavi Advance Payment Amount was \$696.4 million. On February 16, 2024, we and Gavi entered into a Termination and Settlement Agreement (the "Gavi Settlement Agreement") terminating the Gavi APA, settling the arbitration proceedings, and releasing both parties of all claims arising from, under, or otherwise in connection with the Gavi APA. Pursuant to the Gavi Settlement Agreement, we are responsible for payment to Gavi of (i) an initial settlement payment of \$75 million, which we paid in February 2024, and (ii) deferred payments, in equal annual amounts of \$80 million payable each calendar year through a deferred payment term ending December 31, 2028. The deferred payments are due in variable quarterly installments beginning in the second quarter of 2024 and total \$400 million during the deferred payment term. Such deferred payments may be reduced through Gavi's use of an annual vaccine credit equivalent to the unpaid balance of such deferred payments each year, which may be applied to qualifying sales of any of our vaccines funded by Gavi for supply to certain low-income and lower-middle income countries. We have the right to price the vaccines offered to such low-income and lower-middle income countries in our discretion, and, when utilized by Gavi, we will credit the actual price per vaccine paid against the applicable credit. We intend to price vaccines offered via the tender process, consistent with our shared goal with Gavi to provide equitable access to those countries. Also, pursuant to the Gavi Settlement Agreement, we granted Gavi an additional credit of up to \$225 million that may be applied against qualifying sales of any of our vaccines for supply to such low-income and lower-middle income

countries that exceed the \$80 million deferred payment amount in any calendar year during the deferred payment term. In total, the Gavi settlement agreement is comprised of \$700 million of potential consideration, consisting of the \$75 million initial settlement payment, deferred payments of up to \$400 million that may be reduced through annual vaccine credits, and the additional credit of up to \$225 million that may be applied for certain qualifying sales.

We recorded the \$3.6 million difference between the refund liability recorded as of December 31, 2023 of \$696.4 million and the \$700 million of total consideration under the arrangement as a revenue adjustment during the three months ended March 31, 2024. As of March 31, 2024, the remaining amounts included on our consolidated balance sheet are classified as \$225 million in non-current Deferred revenue for the additional credit that may be applied against future qualifying sales, \$80 million in Other current liabilities, and \$320 million in Other non-current liabilities. In addition, we and Gavi entered into a security agreement pursuant to which we granted Gavi a security interest in accounts receivable from SIIPL under the SIIPL R21 Agreement (see Note 4 to our consolidated financial statements), which will continue for the deferred payment term of the Gavi Settlement Agreement. On February 22, 2024, the claims and counterclaims were dismissed with prejudice.

Our funding agreements currently include funding from the Coalition for Epidemic Preparedness Innovations ("CEPI") in the form of one or more forgivable no interest term loans ("CEPI Forgivable Loan Funding"). Payments received under the CEPI Forgivable Loan Funding are only repayable if project vaccine, as defined under the CEPI funding agreement, manufactured by the CMO network funded by CEPI is sold to one or more third parties (which could include sales credited under the Gavi Settlement Agreement), and such sales cover our costs of manufacturing such vaccine, not including manufacturing costs funded by CEPI. The timing and amount of any loan repayments is currently uncertain.

We continue to assess our manufacturing needs and modify our global manufacturing footprint consistent with our contractual obligations to supply, and anticipated demand for, COVID-19 Vaccine, and in doing so recognize that significant costs may be incurred. For the 2023-2024 vaccination season, we have depended exclusively on SIIPL and SLS for co-formulation and filling (other than in Europe), and PCI Pharma Services for finishing COVID-19 Vaccine in Europe. For the 2024-2025 vaccination season, we are seeking to expand our supply chain network and introduce new single-dose vial or pre-filled syringe product presentations in certain markets. Any delays or disruptions in these suppliers' operations could prevent or delay the delivery of customer orders.

As of March 31, 2024, we had \$495.9 million in cash and cash equivalents and restricted cash as compared to \$583.8 million as of December 31, 2023.

We funded our operations for the three months ended March 31, 2024 primarily with cash and cash equivalents, upfront payments under APAs, revenue from product sales, and royalties under licensing arrangements with our strategic partners. In May 2023, we announced our plan to restructure our global footprint to reduce our planned expenditures and in January 2024, we announced further reductions in our global workforce. We anticipate our future operations to be funded primarily by milestone payments, royalties and reimbursements under our Collaboration and License Agreement and equity investment under the Subscription Agreement with Sanofi, revenue from product sales, our cash and cash equivalents, and other potential funding sources including equity financings, which may include at the market offerings under our August 2023 Sales Agreement, debt financings, collaborations, strategic alliances, asset sales, and marketing, distribution or licensing arrangements.

The following table summarizes cash flows for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,		
	2024	2023	Change
Net cash provided by (used in):			
Operating activities	\$ (83,555)	\$ (325,593)	\$ 242,038
Investing activities	(7,250)	(23,558)	16,308
Financing activities	5,886	(354,379)	360,265
Effect on exchange rate on cash, cash equivalents, and restricted cash	(2,955)	(8,372)	5,417
Net decrease in cash, cash equivalents, and restricted cash	(87,874)	(711,902)	624,028
Cash, cash equivalents, and restricted cash at beginning of period	583,810	1,348,845	(765,035)
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 495,936</u>	<u>\$ 636,943</u>	<u>\$ (141,007)</u>

Net cash used in operating activities was \$83.6 million for the three months ended March 31, 2024, as compared to

\$325.6 million for the same period in 2023. The decrease in cash used in operating activities is primarily due to an increase in amounts received under our APAs and an overall decrease in operating expenses period over period, partially offset by the timing of payments to vendors.

Net cash used in investing activities was \$7.3 million for the three months ended March 31, 2024, as compared to \$23.6 million for the same period in 2023. The decrease in cash used in investing activities is primarily due to lower expenditures on equipment and leasehold improvements.

Net cash provided by financing activities was \$5.9 million for the three months ended March 31, 2024, as compared to net cash used in financing activities of \$354.4 million for the same period in 2023. The decrease in cash used in financing activities is primarily due to the \$325 million repayment of our 3.75% Convertible notes and finance lease payments during 2023.

Going Concern

As described in Note 2 to our consolidated financial statements, conditions or events existed that raised substantial doubt about our ability to continue as a going concern for at least one year from the date that the financial statements were issued. However, management's plans, including specifically the execution of the Collaboration and License Agreement and Subscription Agreement with Sanofi effective May 10, 2024, which will result in cash proceeds to us of \$568.8 million during the second quarter of 2024, has alleviated the substantial doubt regarding our ability to continue as a going concern for the one-year period from the date these the financial statements were issued.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are subject to certain risks that may affect our results of operations, cash flows, and fair values of assets and liabilities, including volatility in foreign currency exchange rates and interest rate movements.

Foreign Currency Exchange Risk

Although we are headquartered in the U.S. our results of operations, including our foreign subsidiaries' operations, are subject to foreign currency exchange rate fluctuations, primarily the U.S. dollar against the Euro, Pound Sterling, Swedish Krona, and Czech Koruna. This exchange exposure may have a material effect on our cash and cash equivalents, cash flows, and results of operations, particularly in cases of revenue generated under APAs that include provisions that impact our and our counterparty's currency exchange exposure. To date, we have not entered into any foreign currency hedging contracts, although we may do so in the future.

We also face foreign currency exchange exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. While the financial results of our global activities are reported in U.S. dollars, the functional currency for our foreign subsidiaries is generally their respective local currency. Fluctuations in the foreign currency exchange rates of the countries in which we do business will affect our operating results, often in ways that are difficult to predict. A 10% decline in the foreign exchange rates (primarily against the U.S. dollar) relating to our foreign subsidiaries would result in a decline of stockholders' equity (deficit) of approximately \$54.1 million as of March 31, 2024.

Market and Interest Rate Risk

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income.

Our exposure to interest rate risk is primarily confined to our investment portfolio. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our marketable securities when they mature and the proceeds are reinvested into new marketable securities and, therefore, could impact our cash flows and results of operations.

Interest and dividend income is recorded when earned and included in investment income. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in investment income. The specific identification method is used in computing realized gains and losses on the sale of our securities.

Our convertible senior unsecured notes have a fixed interest rate, and we have no additional material debt. As such, we

do not believe that we are exposed to any material interest rate risk as a result of our borrowing activities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the assistance of our chief executive officer and chief financial officer, has reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of March 31, 2024. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving such control objectives. Based on the evaluation of our disclosure controls and procedures as of March 31, 2024, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

Our management, including our chief executive officer and chief financial officer, have evaluated changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2024, and have concluded that there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Stockholder Litigation

On November 12, 2021, Sothiathan Sinnathurai filed a purported securities class action in the U.S. District Court for the District of Maryland (the "Maryland Court") against the Company and certain members of senior management, captioned Sothiathan Sinnathurai v. Novavax, Inc., et al., No. 8:21-cv-02910-TDC (the "Sinnathurai Action"). On January 26, 2022, the Maryland Court entered an order designating David Truong, Nuggehalli Balmukund Nandkumar, and Jeffrey Gabbert as co-lead plaintiffs in the Sinnathurai Action. The co-lead plaintiffs filed a consolidated amended complaint on March 11, 2022, alleging that the defendants made certain purportedly false and misleading statements concerning the Company's ability to manufacture prototype vaccine on a commercial scale and to secure the prototype vaccine's regulatory approval. The amended complaint defines the purported class as those stockholders who purchased the Company's securities between February 24, 2021 and October 19, 2021. On April 25, 2022, the defendants filed a motion to dismiss the consolidated amended complaint. On December 12, 2022, the Maryland Court issued a ruling granting in part and denying in part defendants' motion to dismiss. The Maryland Court dismissed all claims against two individual defendants and claims based on certain public statements challenged in the consolidated amended complaint. The Maryland Court denied the motion to dismiss as to the remaining claims and defendants, and directed the Company and other remaining defendants to answer within fourteen days. On December 27, 2022, the Company filed its answer and affirmative defenses. On March 16, 2023, the plaintiffs filed a motion for class certification and to appoint class representatives and counsel. The Company filed its opposition to the plaintiffs' motion on September 22, 2023. On December 4, 2023, the parties agreed to a binding settlement in principle (the "Proposed Settlement") to fully resolve the surviving claims in the Sinnathurai Action. Under the Proposed Settlement's terms, the Company agreed to pay \$47 million into a settlement fund, which will be funded by the Company's directors and officers' liability insurance and paid to members of a putative settlement class. On January 12, 2024, after the parties negotiated and executed a written agreement governing the Proposed Settlement, plaintiffs filed an unopposed motion for the Proposed Settlement's preliminary approval. On January 23, 2024, the Maryland Court granted the motion for preliminary approval and, as requested by the parties, preliminarily certified, for the purposes of settlement only, the settlement class. The court also scheduled a settlement hearing to consider final approval of the settlement for May 23, 2024. Ahead of the May 23 settlement hearing, on April 11, 2024, Plaintiffs filed a motion seeking the Maryland Court's final approval of the settlement.

After the Sinnathurai Action was filed, eight derivative lawsuits were filed: (i) Robert E. Meyer v. Stanley C. Erck, et al., No. 8:21-cv-02996-TDC (the "Meyer Action"), (ii) Shui Shing Yung v. Stanley C. Erck, et al., No. 8:21-cv-03248-TDC (the "Yung Action"), (iii) William Kirst, et al. v. Stanley C. Erck, et al., No. C-15-CV-21-000618 (the "Kirst Action"), (iv) Amy Snyder v. Stanley C. Erck, et al., No. 8:22-cv-01415-TDC (the "Snyder Action"), (v) Charles R. Blackburn, et al. v. Stanley C. Erck, et al., No. 1:22-cv-01417-TDC (the "Blackburn Action"), (vi) Diego J. Mesa v. Stanley C. Erck, et al., No. 2022-0770-NAC (the "Mesa Action"), (vii) Sean Acosta v. Stanley C. Erck, et al., No. 2022-1133-NAC (the "Acosta Action"), and (viii) Jared Needelman v. Stanley C. Erck, et al., No. C-15-CV-23-001550 (the "Needelman Action"). The Meyer, Yung, Snyder, and Blackburn Actions were filed in the Maryland Court. The Kirst Action was filed in the Circuit Court for Montgomery County, Maryland, and shortly thereafter removed to the Maryland Court by the defendants. The Needelman Action was also filed in the Circuit Court for Montgomery County, Maryland. The Mesa and Acosta Actions were filed in the Delaware Court of Chancery (the "Delaware Court"). The derivative lawsuits name members of the Company's board of directors and certain members of senior management as defendants. The Company is deemed a nominal defendant. The plaintiffs assert derivative claims arising out of substantially the same alleged facts and circumstances as the Sinnathurai Action. Collectively, the derivative complaints assert claims for breach of fiduciary duty, insider selling, unjust enrichment, violation of federal securities law, abuse of control, waste, and mismanagement. Plaintiffs seek declaratory and injunctive relief, as well as an award of monetary damages and attorneys' fees.

On February 7, 2022, the Maryland Court entered an order consolidating the Meyer and Yung Actions (the "First Consolidated Derivative Action"). The plaintiffs in the First Consolidated Derivative Action filed their consolidated derivative complaint on April 25, 2022. On May 10, 2022, the Maryland Court entered an order granting the parties' request to stay all proceedings and deadlines pending the earlier of dismissal or the filing of an answer in the Sinnathurai Action. On June 10, 2022, the Snyder and Blackburn Actions were filed. On October 5, 2022, the Maryland Court entered an order granting a request by the plaintiffs in the First Consolidated Derivative Action and the Snyder and Blackburn Actions to consolidate all three actions and appoint co-lead plaintiffs and co-lead and liaison counsel (the "Second Consolidated Derivative Action"). The co-lead plaintiffs in the Second Consolidated Derivative Action filed a consolidated amended complaint on November 21, 2022. On February 10, 2023, defendants filed a motion to dismiss the Second Consolidated Derivative Action. The plaintiffs filed their opposition to the motion to dismiss on April 11, 2023. Defendants filed their reply brief in further support of their motion to dismiss on May 11, 2023. On August 21, 2023, the court entered an order granting in part and denying in part the motion to dismiss. On September 5, 2023, the Company filed an Answer to the consolidated amended complaint. On September 6, 2023, the court entered an order granting the individual defendants an extension of time to file their answer until November 6, 2023. On October 6, 2023, the Board of Directors of the Company formed a Special Litigation Committee ("SLC") with full and exclusive power and authority of the Board to, among other things, investigate, review, and analyze the facts and circumstances surrounding the claims asserted in the pending derivative actions, including the claims that remain following the court's order on the motion to dismiss in the Second Consolidated Derivative Action. On November 7, 2023, the court entered an order granting the parties' request to stay the Second Consolidated Derivative Action for up to six months from the date of entry of the order, and, on April 15, 2024, the court entered a further order extending the stay by an additional month, and, on April 15, 2024, the court entered a further order extending the stay by an additional month. This includes staying the deadline for the individual defendants to respond to the consolidated amended complaint.

The Kirst Action was filed on December 28, 2021, and the defendants immediately removed the case to the Maryland Court. On July 21, 2022, the Maryland Court issued a memorandum opinion and order remanding the Kirst Action to state court. The plaintiffs filed an amended complaint on December 30, 2022. On January 23, 2023, defendants filed a motion to stay the Kirst action. On February 22, 2023, the parties in the Kirst Action filed for the Court's approval of a stipulation staying the Kirst Action pending the resolution of defendants' motion to dismiss in the Second Consolidated Derivative Action. On March 22, 2023, the Court entered the parties' stipulated stay of the Kirst Action pending resolution of the motion to dismiss in the Second Consolidated Derivative Action.

On August 30, 2022, the Mesa Action was filed. On October 3, 2022, the Delaware Court entered an order granting the parties' request to stay all proceedings and deadlines in the Mesa Action pending the earlier of dismissal of the Sinnathurai Action or the filing of an answer to the operative complaint in the Sinnathurai Action. On January 9, 2023, following the ruling on the motion to dismiss the Sinnathurai Action, the Delaware Court entered an order granting the Mesa Action parties' request to set a briefing schedule in connection with a motion to stay by defendants. On February 28, 2023, the court granted the defendants' motion and stayed the Mesa Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On August 31, 2023, the Mesa plaintiffs filed a motion to lift the stay in the Mesa Action. On October 6, 2023, the Company filed an opposition to plaintiff's motion to lift the stay. Plaintiff filed his reply on October 17, 2023. On December 27, 2023, the parties filed a letter informing the Court that the Second Consolidated Derivative Action had been stayed for a period of six months and asked the Court to stay further proceedings in the Mesa Action until expiration of that stay.

On December 7, 2022, the Acosta Action was filed. On February 6, 2023, defendants accepted service of the complaint and summons in the Acosta Action. On March 9, 2023, the court entered an order granting the parties' request to stay the Acosta Action pending the entry of a final, non-appealable judgment in the Second Consolidated Derivative Action. On October 13, 2023, the parties filed, and the Delaware Court entered, a stipulated order providing that (i) if the Delaware Court declines to lift the stay in the Mesa Action, the Acosta Action will also remain stayed, and (ii) if the Delaware Court lifts the stay in the Mesa Action, the stay in the Acosta Action will also be lifted.

On April 17, 2023, the Needelman Action was filed. On July 12, 2023, the parties filed a stipulation and proposed order to stay the Needelman Action pending the Maryland Court's decision on the motion to dismiss in the Second Consolidated Derivative Action. The court entered that order on July 17, 2023.

On November 30, 2023, the court entered an order consolidating the Kirst and Needelman Actions. On December 14, 2023, the parties filed a stipulation (i) extending the plaintiffs' deadline to file a consolidated complaint until January 29, 2024, and (ii) otherwise staying all other proceedings in the case (including the defendants' deadline to respond to the consolidated complaint) until February 12, 2024. The stipulation entered by the court instructs the parties to discuss whether the stay should be further extended in light of the then-current status of the SLC's investigation. On May 3, 2024, the plaintiffs filed a consolidated complaint. The parties are discussing whether to extend defendants' deadline to respond to the consolidated complaint through early June.

On November 18, 2022, the Company delivered written notice to Gavi to terminate the Gavi APA based on Gavi's failure to procure the purchase of 350 million doses of prototype vaccine from the Company as required by the Gavi APA. As of November 18, 2022, the Company had only received orders under the Gavi APA for approximately 2 million doses. On December 2, 2022, Gavi issued a written notice purporting to terminate the Gavi APA based on Gavi's contention that the Company repudiated the agreement and, therefore, materially breached the Gavi APA. Gavi also contended that, based on its purported termination of the Gavi APA, it was entitled to a refund of the Advance Payment Amount less any amounts that have been credited against the purchase price for binding orders placed by a buyer participating in the COVAX Facility. Since December 31, 2022, the remaining Gavi Advance Payment Amount, which was \$696.4 million as of December 31, 2023, pending resolution of the dispute with Gavi related to a return of the remaining Advance Payment Amount, has been classified within Other current liabilities in the Company's consolidated balance sheet. On January 24, 2023, Gavi filed a demand for arbitration with the International Court of Arbitration based on the claims described above. The Company filed its Answer and Counterclaims on March 2, 2023. On April 5, 2023, Gavi filed its Reply to the Company's Counterclaims. On February 16, 2024, the Company and Gavi entered into a Termination and Settlement Agreement (the "Gavi Settlement Agreement") terminating the Gavi APA, settling the arbitration proceedings and releasing both parties of all claims arising from, under or otherwise in connection with the Gavi APA. Pursuant to the Gavi Settlement Agreement, the Company is responsible for payment to Gavi of (i) an initial settlement payment of \$75 million, which the Company paid in February 2024, and (ii) deferred payments, in equal annual amounts of \$80 million payable each calendar year through a deferred payment term ending December 31, 2028. The deferred payments are due in variable quarterly installments beginning in the second quarter of 2024 and total \$400 million during the deferred payment term. Such deferred payments may be reduced through Gavi's use of an annual vaccine credit equivalent to the unpaid balance of such deferred payments each year, which may be applied to qualifying sales of any of the Company's vaccines funded by Gavi for supply to certain low-income and lower-middle income countries. The Company has the right to price the vaccines offered to such low-income and lower-middle income countries at its discretion, and, when utilized by Gavi, the Company will credit the actual price per vaccine paid against the applicable credit. The Company intends to price vaccines offered via the tender process, consistent with its shared goal with Gavi to provide equitable access to those countries. Also, pursuant to the Gavi Settlement Agreement, we granted Gavi an additional credit of up to \$225 million that may be applied against qualifying sales of any of the Company's vaccines for supply to such low-income and lower-middle income countries that exceed the \$80 million deferred payment amount in any calendar year during the deferred payment term. In total, the Gavi settlement agreement is comprised of \$700 million of potential consideration, consisting of the \$75 million initial settlement payment, deferred payments of up to \$400 million that may be reduced through annual vaccine credits, and the additional credit of up to \$225 million that may be applied for certain qualifying sales. In addition, we and Gavi entered into a security agreement pursuant to which Novavax granted Gavi a security interest in accounts receivable from SIIPL under the SIIPL R21 Agreement (see Note 4 to our consolidated financial statements), which will continue for the deferred payment term of the Gavi Settlement Agreement. On February 22, 2024, the claims and counterclaims were dismissed with prejudice.

On September 30, 2022, the Company, FUJIFILM Diosynth Biotechnologies UK Limited ("FDBK"), FUJIFILM Diosynth Biotechnologies Texas, LLC ("FDBT"), and FUJIFILM Diosynth Biotechnologies USA, Inc. ("FDBU" and together with FDBK and FDBT, "Fujifilm") entered into a Confidential Settlement Agreement and Release (the "Fujifilm Settlement Agreement") regarding amounts due to Fujifilm in connection with the termination of manufacturing activity at FDBT under the Commercial Supply Agreement (the "CSA") dated August 20, 2021 and Master Services Agreement dated June 30, 2020 and associated statements of work (the "MSA") by and between the Company and Fujifilm. The MSA and CSA established the general terms and conditions applicable to Fujifilm's manufacturing and supply activities related to the Company's prototype vaccine under the associated statements of work. Pursuant to the Fujifilm Settlement Agreement, the Company agreed to pay up to \$185.0 million (the "Settlement Payment") to Fujifilm in connection with cancellation of manufacturing activity at FDBT. Under the Fujifilm Settlement Agreement, the final two quarterly installments due to Fujifilm were subject to Fujifilm's obligation to use commercially reasonable efforts to mitigate losses associated with the vacant manufacturing capacity caused by the termination of manufacturing activities at FDBT under the CSA. Any replacement revenue achieved by Fujifilm's mitigation efforts between July 1, 2023 and December 31, 2023 would offset the final two settlement payments owed by the Company. On October 2, 2023, the Company sent a notice of breach under the Fujifilm Settlement Agreement to Fujifilm setting forth the Company's position that Fujifilm had not used commercially reasonable efforts to mitigate losses. The Company withheld the \$34.3 million installment payment due to Fujifilm on September 30, 2023, pending resolution of the issues identified in the notice of breach. On October 30, 2023, FDBT filed a demand for arbitration with Judicial Arbitration and Mediation Services seeking payment of the third quarter installment of the Settlement Payment. On March 21, 2024, the Company and Fujifilm entered into a Confidential Settlement Agreement and Release ("Second Fujifilm Settlement Agreement") to resolve the disputes in the pending arbitration. Pursuant to the Second Fujifilm Settlement Agreement, the Company paid \$42.0 million to Fujifilm in March 2024 in exchange for a full release of claims and dismissal of the arbitration.

We are also involved in various other legal proceedings arising in the normal course of business. Although the outcomes of these other legal proceedings are inherently difficult to predict, we do not expect the resolution of these other legal proceedings to have a material adverse effect on our financial position, results of operations, or cash flows.

Item 1A. Risk Factors

Information regarding risk and uncertainties related to our business appears in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on February 28, 2024. There have been no material changes from the risk factors previously disclosed in the Annual Report on Form 10-K, for the fiscal year ended December 31, 2023, other than as described below.

Risks Related to Regulatory and Compliance Matters

We may not succeed in obtaining full U.S. FDA licensure or foreign regulatory approvals necessary to sell our vaccine candidates.

The development, manufacture and marketing of our pharmaceutical and biological products are subject to government regulation by the U.S. FDA and regulatory authorities in other jurisdictions, including the EMA, the Czech Republic's State Institute for Drug Control ("SUKL") with respect to our manufacturing facility in the Czech Republic and the Swedish Medical Products Agency (Läkemedelsverket, LV) with respect to our adjuvant product being developed in Sweden, as well as other country authorities into which active pharmaceutical ingredients and excipients are imported and/or manufactured by us or our sub-contracted manufacturers. In the U.S. and most foreign countries, we must complete rigorous preclinical testing and extensive clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. For example, while we have completed the submission of the BLA for our COVID-19 Vaccine, we have decided, based on discussions with U.S. FDA, to also seek EUA for our updated COVID-19 Vaccine for the 2024-2025 vaccination season. Operating under an EUA for the 2024-2025 vaccination season, rather than an approved BLA, could have a negative impact on our ability to successfully market and commercialize our updated COVID-19 Vaccine and therefore our financial condition and results of operation.

Additionally, we must demonstrate that our manufacturing facilities, processes and controls are adequate with respect to such product to assure safety, purity and potency and comply with applicable good manufacturing practice requirements. None of our vaccine candidates has yet gained full regulatory approval in the U.S., although our COVID-19 Vaccine has received provisional registration, conditional marketing authorization, emergency use authorization, or full approval in the various jurisdictions. We also have vaccine candidates in clinical trials and preclinical laboratory or animal studies.

Risks Related to Our Financial Condition and Capital Requirements

Our existing funding and supply agreements or our advance purchase agreements do not assure success of our vaccine candidates or vaccines or that we will be able to fully fund our vaccine candidates or vaccines or our company operations, and if we are unable to satisfy the performance obligations under such agreements the agreements may be terminated, the purchase commitments may be reduced or we may be required to refund advance payments.

Our funding agreements with the U.S. government ("USG") and CEPI each reimburse a portion of the expenses associated with the development and commercialization of our COVID-19 Vaccine. To the extent funding commitments in such agreements are conditioned on our meeting certain milestones or conditions, we may not ultimately receive the full amount of committed funds and may require additional funding to support our COVID-19 Vaccine development and commercialization activities, and we may be unable to timely obtain additional funding. For example, in July 2021, in connection with funding from the USG partnership formerly known as Operation Warp Speed, the USG instructed us to prioritize alignment with the U.S. FDA on our analytic methods before conducting additional U.S. manufacturing, and the USG indicated that it would not fund additional U.S. manufacturing until such alignment was reached, which did not occur until June 2022. In February 2023, in connection with the execution of Modification 17 to the USG Agreement, the U.S. government indicated to us that the award may not be extended past its current period of performance. The USG Agreement also includes provisions giving the USG termination rights based on a determination that the funded project will not produce beneficial results commensurate with the expenditure of resources and that termination would be in the USG's interest. Such a determination would result in the loss of funding under that agreement and could result in other actions by the USG. The CEPI funding agreement, meanwhile, provides CEPI certain "march-in" rights in the event of certain breaches of that agreement.

Additionally, we have entered into, and plan to continue entering into, supply agreements (also sometimes referred to as advance purchase agreements) for our COVID-19 Vaccine that include prepayments from the purchasers to help fund our development and manufacture of the vaccine. Under certain supply agreements, if we do not timely achieve requisite regulatory milestones for our COVID-19 Vaccine in the relevant jurisdictions, obtain supportive recommendations from governmental advisory committees, and/or achieve product volume or delivery timing obligations, purchasers may seek to terminate such agreements, reduce their purchase commitments, require us to refund all or some prepayments we have received, or renegotiate such agreements, each of which could have a material and adverse effect on our financial condition. The timing to fulfill performance obligations related to supply agreements will depend on timing of product manufacturing, receipt of marketing authorizations for additional indications, delivery of doses based on customer demand, and the ability of the customer to request variant vaccine in place of prototype vaccine under certain of our supply agreements. The supply agreements typically contain terms that include upfront payments intended to assist us in funding investments related to building out and operating our manufacturing and distribution network, among other expenses, in support of our global supply commitment, and are applied to billings upon delivery of COVID-19 Vaccine. Such upfront payments generally become non-refundable upon our achievement of certain development, regulatory and commercial milestones. We may not achieve such milestones, which could have a material and adverse effect on our financial condition.

For example, in September 2022, following a delay in obtaining regulatory approval in the United Kingdom, we entered into the Amended and Restated UK Supply Agreement, which amended and restated in its entirety the Original UK Supply Agreement, which reduced the volume of vaccine doses that the Authority is committed to purchase as compared to the Original UK Supply Agreement. Under the terms of the Amended and Restated UK Supply Agreement, the Authority agreed to purchase a minimum of 1 million doses and up to an additional 15 million doses (the "Conditional Doses") of our prototype vaccine, with the number of Conditional Doses contingent on, and subject to reduction based on, our timely achievement of supportive recommendations from the JCVI that is approved by the UK Secretary of State for Health. If the Authority did not purchase the Conditional Doses or the number of such Conditional Doses was reduced below 15 million doses of our prototype vaccine, we would have to repay up to \$225.0 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. Under the Amended and Restated UK Supply Agreement, the Authority also has the option to purchase up to an additional 44 million doses, in one or more tranches, through 2024. As of November 30, 2022, the JCVI had not made a supportive recommendation with respect to our prototype vaccine, thereby triggering, under the terms of the Amended and Restated UK Supply Agreement, (i) a reduction of the number of Conditional Doses from 15 million doses to 7.5 million doses, which reduced number of Conditional Doses are contingent on, and subject to further reduction based on, our timely achievement by November 30, 2023 of a supportive recommendation from JCVI that is approved by the UK Secretary of State for Health as described in the paragraph above, and (ii) an obligation for us to repay \$112.5 million related to the upfront payment previously received from the Authority under the Original UK Supply Agreement. In April 2023, we repaid the \$112.5 million related to the November 30, 2022 triggering event. As of November 30, 2023, the JCVI had not made a supportive recommendation with respect to the prototype vaccine, thereby triggering a reduction in the number of Conditional Doses from 7.5 million doses to zero. As of May 2024, we are in discussions with the Authority regarding the treatment of the remaining upfront amount previously received of \$112.5 million, which is reflected in Other current liabilities on our consolidated balance sheet.

We have an APA with the Commonwealth of Australia ("Australia") for the purchase of doses of COVID-19 Vaccine (the "Australia APA"). In November 2023, we filed with the Therapeutic Goods Administration ("TGA") for authorization for our updated vaccine. Based on subsequent communication from the TGA that it will not recommend approval of the filing as submitted and new data and information generated since that filing, we are evaluating the regulatory path for approval, including the potential to withdraw the filing for authorization, update with new data and information, and resubmit in the coming months. In March 2024, we and Australia agreed to cancel the COVID-19 Vaccine doses previously scheduled for delivery in the fourth quarter of 2023. As a result of the cancellation, the total contract value was reduced by \$54.0 million, including \$6.0 million of deferred revenue related to the cancelled doses that will be applied as a credit towards future deliveries of doses. We are working with Australia on an amendment to the APA that addresses performance obligations and future delivery schedules.

We have an APA with His Majesty the King in Right of Canada as represented by the Minister of Public Works and Government Services, as successor in interest to Her Majesty the Queen in Right of Canada, as represented by the Minister of Public Works and Government Services (the "Canadian government"), for the purchase of doses of COVID-19 Vaccine (the "Canada APA"). The Canadian government may terminate the Canada APA, as amended, if we fail to receive regulatory approval for its COVID-19 Vaccine using bulk antigen produced at Biologics Manufacturing Centre ("BMC") Inc. on or before December 31, 2024. We do not currently anticipate achieving regulatory approval of our COVID-19 Vaccine using bulk antigen produced at BMC on or before December 31, 2024. Therefore, in parallel, we plan to work with the Canadian government on an amendment that addresses possible alternatives, which may not be achievable on acceptable terms or at all. As of March 31, 2024, \$110.6 million was classified as current Deferred revenue and \$477.6 million was classified as non-current Deferred revenue with respect to the Canadian APA in our consolidated balance sheet. If the Canadian government terminates the Canada APA, \$28.0 million of the deferred revenue would become refundable and approximately \$224.0 million of the contract value related to future deliverables would no longer be available.

Item 5. Other Information

During the three months ended March 31, 2024, no director or "officer" (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

3.1	Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
3.2	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 9, 2019 (File No. 000-26770))
3.3	Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 22, 2024 (File No. 000-26770))
3.4	Certificate of Designation of Series A Convertible Preferred Stock of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed June 19, 2020 (File No. 000- 26770))
10.1*±	Confidential Settlement Agreement and Release, dated March 21, 2024, between the Company and FUJIFILM Diosynth Biotechnologies UK Limited, FUJIFILM Diosynth Biotechnologies Texas, LLC, and FUJIFILM Diosynth Biotechnologies USA, Inc.
10.2*±	Modification No. 19 to Undefinitized Project Agreement No. 1, dated September 19, 2023, between the Company and Advanced Technology International
10.3*±	Modification No. 20 to Undefinitized Project Agreement No. 1, dated December 1, 2023, between the Company and Advanced Technology International
10.4*±	Modification No. 21 to Undefinitized Project Agreement No. 1, dated February 6, 2024, between the Company and Advanced Technology International
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, formatted in Inline Extensible Business Reporting Language (Inline XBRL): (i) the Consolidated Statements of Operations for the three-month periods ended March 31, 2024 and 2023, (ii) the Consolidated Statements of Comprehensive Loss for the three-month periods ended March 31, 2024 and 2023, (iii) the Consolidated Balance Sheets as of March 31, 2024 and December 31, 2023, (iv) the Consolidated Statements of Changes in Stockholders' Deficit for the three-month periods ended March 31, 2024 and 2023, (v) the Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2024 and 2023, and (vi) the Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed or furnished herewith.

± Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NOVAVAX, INC.

Date: May 10, 2024

By: /s/ John C. Jacobs

John C. Jacobs
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2024

By: /s/ James P. Kelly

James P. Kelly
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS OF THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

CONFIDENTIAL SETTLEMENT AGREEMENT AND RELEASE

This **CONFIDENTIAL SETTLEMENT AGREEMENT AND RELEASE** (the “**Agreement**”), effective as of March 21, 2024 (the “**Effective Date**”), is made by and between Novavax, Inc. (“**Novavax**”) on the one hand, and FUJIFILM Diosynth Biotechnologies UK Limited (“**FDBK**”), FUJIFILM Diosynth Biotechnologies Texas, LLC (“**FDBT**”), and FUJIFILM Diosynth Biotechnologies USA, Inc. (“**FDBU**”), on the other. FDBK, FDBT and FDBU shall individually and/or collectively, as the context requires, be referred to herein as “**Fujifilm**”. Novavax and Fujifilm are referred to herein together, as the **Parties**, and each, as a “**Party**.”

RECITALS

WHEREAS, Novavax and Fujifilm are parties to a Confidential Settlement Agreement and Release effective September 30, 2022 (“**SAR**”);

WHEREAS, the Parties disagree about the amount due to Fujifilm under the SAR in connection with the mitigation terms and the final two payments that amount to \$68,593,750;

WHEREAS, the Parties are engaged in arbitration initiated by Fujifilm on October 30, 2023. The arbitration is captioned Fujifilm Diosynth Biotechnologies Texas, LLC v. Novavax, Inc. and bears JAMS Ref. No. 1425041173 (“**Arbitration**”);

WHEREAS, this Agreement is intended to resolve the disagreements of the Parties regarding the amounts due under the SAR and the Arbitration proceeding;

NOW, THEREFORE, in consideration of the promises and the mutual covenants of the Parties herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Recitations.** The above recitals are true and correct and are incorporated herein by reference and the Parties are entitled to rely upon them.

2. **Non-Admission of Liability.** The Parties understand and agree that this is a compromise and settlement of disputed claims. Each of the Parties specifically denies any liability or wrongdoing whatsoever on their part. Nothing in this Agreement shall constitute or be construed as an admission of liability on behalf of the Parties or their agents, affiliates, assigns, parents, subsidiaries, and/or successors, or an admission as to the validity of the claims.

3. **Attorney Representation.** This Agreement is entered into voluntarily by the Parties who stipulate and agree that they are under no duress or undue influence. The Parties represent that in the execution of this Agreement, they had the opportunity to consult legal

counsel of their own selection and that the said attorneys have reviewed this Agreement, made any desired changes, and advised their respective clients with respect to the advisability of making the settlement and releases provided herein and of executing this Agreement.

4. **Terms.** As full and final settlement of the Released Claims (defined herein), the Parties agree as follows:

(a) Novavax must pay to Fujifilm \$42,000,000.00, subject to the following terms (**Settlement Payment**):

- The Settlement Payment must be received on or before March 25, 2024.
- The Settlement Payment shall be made according to the following wire payment information:

[***]

(b) Within five (5) business days of bank clearance of the Settlement Payment, Fujifilm shall cause its counsel to voluntarily dismiss the Arbitration, with prejudice. Each Party shall remain liable for its portion of any outstanding Arbitration costs or fees.

(c) The Parties agree that time is of the essence in the performance of the obligations in this Paragraph 4.

5. **Releases.** In consideration of Paragraph 4 herein, the Parties agree as follows:

(a) Subject to and contingent upon bank clearance of the Settlement Payment, Fujifilm, on behalf of itself and its successors and assigns, agrees to remise, release, acquit, satisfy, and forever discharge Novavax and its past, present and future officers, directors, heirs, agents, servants, employees, legal representatives, assigns, successors, affiliates, shareholders, beneficiaries, predecessors, insurers, administrators, and successors in interest; their parent, holding, subsidiary, affiliated, and related entities; any business entity or division owning or controlling Novavax in whole or in part; any business entity or division owned or controlled in whole or in part by Novavax (all of the foregoing persons and entities are hereinafter collectively referred to as the **“Novavax Released Parties”**), of and from all claims, liabilities, obligations, promises, agreements, damages, actions, demands, costs, losses, fees and expenses as of the Effective Date relating to the SAR and the Arbitration (“**Released Claims**”). For the avoidance of doubt, Fujifilm has no obligation to release the Novavax Released

Parties unless and until the Settlement Payment is received and cleared by the bank.

- (b) Upon execution of this Agreement, Novavax, on behalf of itself and its successors and assignees, agrees to remise, release, acquit, satisfy, and forever discharge Fujifilm and its past, present and future officers, directors, heirs, agents, servants, employees, legal representatives, assigns, successors, affiliates, shareholders, beneficiaries, predecessors, insurers, administrators, and successors in interest; their parent, holding, subsidiary, affiliated, and related entities; any business entity or division owning or controlling Fujifilm in whole or in part; any business entity or division owned or controlled in whole or in part by Fujifilm (all of the foregoing persons and entities are hereinafter collectively referred to as the "**Fujifilm Released Parties**"), of and from all Released Claims.
- (c) For the avoidance of doubt, nothing in this Paragraph shall release the Parties' obligations under this Agreement.

6. **Revival and Reinstatement of Claims in the Event of Bankruptcy.** In consideration of the promises and mutual undertakings called for herein, the Parties acknowledge and agree that if any payments or any part of any payment made to Fujifilm under this Agreement are required to be rescinded or must otherwise be repaid, transferred, restored or surrendered by Fujifilm or its affiliates in the event of the bankruptcy, insolvency, reorganization or similar event involving any of the Novavax Released Parties, then the releases by Fujifilm and Novavax described in Paragraph 5 shall not be effective and shall be null and void as to those amounts repaid, rescinded, restored, transferred or surrendered by Fujifilm or its affiliates, and that all claims of Fujifilm and Novavax shall be fully effective, revived and reinstated, as the case may be. If any settlement, compromise, adjudication, proceeding or disposition of such claim is made by or against Fujifilm or its affiliates for repayment or recovery of any funds received under this Agreement, Novavax agrees that such proceeding, settlement, compromise, adjudication, or disposition of such claim shall be binding upon Novavax, and that Novavax shall be liable to Fujifilm or its affiliates for the entire amount so repaid or recovered.

7. **Representations and Warranties.** Each Party hereby represents and warrants to the other Party that:

- (a) It has the full right, power, and authority to enter into this Agreement, to grant the release contained herein and to perform its obligations hereunder;
- (b) The execution of this Agreement by the individual whose signature is set out at the end of this Agreement on behalf of such Party, and the delivery of this Agreement by such Party, have been duly authorized by all necessary corporate action on the part of such Party;

- (c) This Agreement has been executed and delivered by each Party and constitutes the legal, valid, and binding obligation of each Party, enforceable against each Party in accordance with its terms; and
- (d) Neither Party has assigned nor transferred any of the Released Claims herein to any person or entity and no person or entity has subrogated to or has any interest, liens, or rights in any Released Claims.

8. **Confidentiality.** Each Party acknowledges the confidential nature of the terms and conditions of this Agreement, as well as the Confidentiality terms that remain in full force and effect in the SAR, the Master Services Agreement dated June 20, 2022 and associated statements of work (“MSA”) and the Commercial Supply Agreement dated August 20, 2020 (“CSA,” and together with the SAR and the MSA, the “**Confidential Information**”) and, except as set forth below or in Section 9(a) of this Agreement, each Party agrees that it shall not (a) disclose any Confidential Information to any person or entity, except to such Party’s and its affiliates’ employees, advisors, and other representatives who need to know the Confidential Information to assist such Party, or act on its behalf, to exercise its rights or perform its obligations under this Agreement, or (b) use the Confidential Information, or permit it to be accessed or used, for any purpose other than to exercise its rights or perform its obligations under this Agreement. Each Party shall be responsible for any breach of this Section 8 caused by any of its and its affiliates’ employees, advisors, or other representatives. Notwithstanding the foregoing, if any Confidential Information is permissibly disclosed under Section 9(a), such information will no longer be deemed “Confidential Information” for the purposes of this Section 8.

In the event that either Party receives a request to produce Confidential Information of the other Party pursuant to an order of a court of competent jurisdiction or a facially valid administrative, Congressional, state or local legislative or other subpoena or believes that such Party is otherwise required by law to disclose Confidential Information, then such Party shall [***] notify the other Party prior to making such disclosure, unless prior notification is precluded by law or regulation or where enforcement action by applicable authority precludes prior notification, in which case the Party will notify the other Party [***], and shall provide the other Party the opportunity to challenge or otherwise lawfully seek limits upon such disclosure of Confidential Information.

9. **Publicity and Announcements.**

- (a) Neither Party shall (orally or in writing) publicly disclose or issue any press release, make any other public statement, or otherwise communicate with the media, concerning any Confidential Information, without the prior written approval of the other Party, except to the extent that such Party is required to make any public disclosure or filing regarding the subject matter of this Agreement by applicable laws or regulations, or in connection with enforcing its rights under this Agreement.

(b) Neither Party shall make, publish, or communicate to any person or entity or in any public forum any comments or statements (written or oral) that denigrate or disparage, or are detrimental to, the reputation or stature of the other Party or its businesses, or any of its employees, officers, directors, and existing and prospective customers, suppliers, investors, and other associated third parties.

10. **Entire Agreement.** This Agreement is the sole and entire agreement of the Parties regarding the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, regarding such subject matter.

11. **Amendments.** This Agreement may not be amended, modified, or altered at any time without the approval of the Parties; however, any such amendment must be in writing and signed by all Parties for such amendment to be of any force and effect.

12. **Survival.** All representations and warranties contained herein shall survive the execution and delivery of this Agreement, and the execution and delivery of any other document or instrument referred to herein.

13. **Governing Law and Dispute Resolution.** The laws of [***] (without giving effect to its conflict of law principles) govern all matters arising out of or relating to this Agreement, including, without limitation, its validity, interpretation, construction, performance, and enforcement.

14. **Costs.** The Parties have agreed to bear their own attorneys' fees and costs with respect to the preparation of any and all documents necessary to enter into this Agreement.

15. **Counterparts.** This Agreement may be signed and executed in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one Agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or email shall be effective as delivery of an originally executed counterpart of this Agreement.

16. **No Adverse Construction.** The Parties acknowledge that this Agreement has been prepared by each of them through counsel. In the event any part of this Agreement is found to be ambiguous, such ambiguity shall not be construed against any Party.

[INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date set forth below.

On behalf of **Novavax, Inc.**

By: /s/ Mark J. Casey

Printed Name: Mark J. Casey

Title: EVP, Chief Legal Officer & Corporate
Secretary

Date: March 21, 2024

On behalf of **FUJIFILM Diosynth Biotechnologies Texas, LLC**

By: /s/ [***]

Printed Name: [***]

Title: [***]

Date: March 21, 2024

On behalf of **FUJIFILM Diosynth Biotechnologies U.S.A., Inc.**

By: /s/ [***]

Printed Name: [***]

Title: [***]

Date: March 21, 2024

On behalf of **FUJIFILM Diosynth Biotechnologies UK Limited**

By: /s/ [***]

Printed Name: [***]

Title: [***]

Date: March 21, 2024

Exhibit [10.2]



CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS OF THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

September 19, 2023

Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

Attention: [***], Vice President, Government Alliance Management
and Contracting

Subject: Modification No. 19 to Project Agreement No. 01; MCDC2011-001

Reference: MCDC Base Agreement No. 2020-530

Dear [***]:

In accordance with the terms and conditions of the referenced MCDC Base Agreement, Modification No. 19 hereby amends Project Agreement No. 01 as follows:

DESCRIPTION OF MODIFICATION

1) The Technical and Administratives Representatives clause of the Project Agreement is hereby amended as indicated in bold below:

10. TECHNICAL AND ADMINISTRATIVE REPRESENTATIVES

The following technical and contractual representatives of the Parties are hereby designated for this Project Agreement. Either party may change their designated representatives by written notification to the other.

MCDC CMF Contractual Representative:

[***]
Advanced Technology International
315 Sigma Drive
Summerville, SC 29486
Email: [***]
Phone: [***]

Project Agreement Holder's Representatives:

Technical Representative:
[***]
21 Firstfield Road
Gaithersburg, MD 20878
Email: [***]
Phone: [***]

Contractual Representative:
[***]
21 Firstfield Road
Gaithersburg, MD 20878
Email: [***]
Phone: [***]

MCDC Representatives:

Agreements Officer Representative (AOR) and Alternate AOR are identified in Section 14 of Attachment A, Statement of Work.

2) Attachment A, Statement of Work, of the Project Agreement is hereby amended as attached herein.

Except as provided herein, all Terms and Conditions of the referenced MCDC Base Agreement, Project Agreement, and preceding modifications remain unchanged and in full force and effect.

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Novavax, Inc.

Advanced Technology International

By: /s/ [***] __

Name: [***] __

Title: VP Government Contracting __

Date: 9/22/2023 __

By: /s/ [***] __

Name: [***] __

Title: Sr. Subcontracts Administrator __

Date: 9/25/2023 __

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Attachment A
Statement of Work
(Incorporated as of as of Modification No. 19)

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Attachment A
Statement of Work

(Incorporated as of Modification No. 19; Changes to Section 14 are indicated below)

For

Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

29 August 2023

RPP #: 20-11

Project Identifier: MCDC2011-001

Consortium Member: Novavax, Inc.

Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

Requiring Activity: Joint Mission between the Department of Health and Human Services and Department of Defense to Combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the ability to manufacture and deliver up to 100M doses of a SARS-CoV-2 vaccine, NVX-CoV-2373, which is suitable for use in humans under a sufficiently informed deployment

strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the “prototype project” will effectively demonstrate Novavax’s ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial ([**]) and is stored at refrigerated temperature (2-8°C).

Successful development of the prototype will demonstrate Novavax’s ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

Successful completion of the prototype will require three coordinated and integrated lines of effort:

- a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
- b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.
- c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG’s deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are “positive” or “negative” is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10 U.S.C. 4022(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to

production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population (~560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above.

One lot will be manufactured initially, with approximately 3M doses delivered in support of this agreement. In addition, the following lots will also be delivered under this agreement:

1. A second partial lot of approximately [***] doses with expiry of [***].
2. A third partial lot of approximately [***] (Up to [***]) doses with expiry no earlier than [***]. Actual requirements will depend on jurisdiction/pharmacy and federal entity orders.

Delivery of doses to the USG is contingent on the following:

1. Timing of EUA approval by FDA.
2. Timing of label language and artwork approval by FDA.
3. Timing of Advisory Committee on Immunization Practices (ACIP) recommendation.

Any additional manufacturing and deliveries will be contingent on 1) USG demand, 2) FDA guidance on strain changes, and 3) agreement on price.

The scope includes the following activities:

- o **Manufacturing**

Manufacturing of up to 100M doses of NVX-CoV-2373 vaccine (or a variant construct if terms, including price, can be agreed upon) for distribution to the USG upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.

Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.

Comparability among clinical vaccine lots and commercial lots using a comparability protocol.

Validation of manufacturing processes will be performed to cGMP standards.

o Clinical

Phase 3 pivotal clinical trial harmonized with USG clinical strategies.

A Phase 3 clinical trial in pediatric populations (<18 years).

Phase 2 studies in at-risk subpopulations (e.g., co-morbidities, [***], immunocompromised), as well as studies to support manufacturing site comparability.

o Non-clinical

Studies to support EUA and regulatory approval (BLA).

o Regulatory

EUA submission when data supports it, while maintaining progress toward eventual BLA submission.

BLA submission when appropriate.

Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.

Meetings as needed with regulators.

o Project Management

Mandatory reporting requirements, as described in the Base Agreement.

Submission of Quarterly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.

Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.

Final prototype project report and applicable patents report(s).

Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).

All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials ([**]) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – [**] Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant

[**] to supply large-scale manufacturing of vaccine doses will be manufactured at [**] and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supplyup to 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supplyup to 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply up to 100M Vaccine Doses

Antigen will be manufactured to supply up to 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of up to 100M Vaccine Doses

Up to 100M doses of finished vaccine in [***] vials will be manufactured. This will include secondary packaging. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system to enable shipment of product to the Biomedical Advanced Research and Development Authority (BARDA)-managed inventory system (McKesson depots). Novavax will perform activities to establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.1.8 Subtask: Manufacture of 3M Doses and Subsequent Manufacturing

Initially, approximately 3M doses will be manufactured at Serum Institute of India (Pune, India) or other FDA-approved location, for delivery as soon as feasible after receipt of EUA from the FDA, at an agreed-upon price per dose. In addition, the following lots will also be delivered under this agreement:

1. Novavax will deliver approximately [***] doses within [***] business days of fully executed Modification #17, from a lot that has [***] expiry and is acceptable for use under EUA.
2. Novavax will deliver approximately [***] (Up to [***]) doses within [***] business days of FDA release of the new lot or [***], whichever comes later, but no later than [***], unless agreed to by both parties. The lot will have expiry no earlier than [***]. Actual requirements will depend on jurisdiction/pharmacy and federal entity orders.

The manufacture and delivery of any doses beyond this quantity is dependent upon USG demand, FDA guidance on strain selection, and agreement between the parties on price, to be incorporated via a mutually agreed upon modification.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 US/Mexico Efficacy Study, Adults \geq 18 and $<$ 75 years

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a “crossover” component where patients that received placebo were offered the vaccine after [***].

Population: Adults \geq 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: US/Mexico.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M – dose determined by Phase 2 dose confirmation study, Placebo; \sim 0.5 mL dose Intramuscular (IM) injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL N: \sim 30,000 (adjusted for expected endpoint incidence). [***].

3.2.1.1 Subtask: Phase 3 US/Mexico Efficacy Study, Adults \geq 18, Booster Study

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a booster component where patients will receive a booster dose of vaccine approximately [***] after completion of the dose regimen, and a second booster dose no less than [***] after the previous booster.

Enrollment: TOTAL N: \sim 25,000 (adjusted for expected enrollment).

3.2.1.2 Subtask: Phase 3 US/Mexico Efficacy Study, Adolescents \geq 12 and $<$ 18 years, Adolescent/Adolescent Booster Study

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a booster component where patients will receive a booster dose of vaccine approximately [***] after completion of the dose regimen. A subgroup of patients (approximately 200) will receive a second booster dose no less than [***] after the previous booster.

Enrollment: TOTAL N: \sim 2500 (adjusted for expected enrollment).

3.2.2 Reserved

3.2.3 Reserved

3.2.4 Reserved

3.2.5 Subtask: Lot-to-Lot Consistency/Comparability Study (US or other)

Study: Phase 2 lot-to-lot consistency/comparability study (US or other), 2019nCoV-307.

Population: Adults \geq 18 to $<$ 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded.

Test Product(s); Dose Regimen; Route of Administration Vaccine + Matrix-M; [***].

Enrollment: ~300 per cohort, each cohort having [***]. Study size may be adjusted to allow non-inferiority testing.

3.2.6 Reserved

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: Phase 3 Pediatric Study

Study: Phase 2/3 pediatric study, 2019nCoV-503.

Population: Children \geq 6 months to < 12 years (3 age cohorts).

Locations: [***]

Primary Objectives: Safety, immunogenicity, effectiveness (determined by immunogenicity).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration Vaccine + Matrix-M [***].

Enrollment: N = 1,200 ([***]); N = 1,200 ([***]); N = 1,200 ([***]); TOTAL: N = 3,600; [***].

3.2.9 Subtask: Heterologous Boosting Study with Prototype Vaccine (formerly Novavax 307b, now 312)

A study (N=300) will be performed to measure the immune response of heterologous boosting (after mRNA vaccine priming). Previous participants of this study who received 2 or 3 doses of mRNA vaccine + 1 Novavax boost, will receive a second Novavax boost.

Outcomes/Measures: Compare immune responses following second NVX boost in mRNA primed participants to responses seen in initial part of study for NVX primed and mRNA primed and boosted individuals. Reactogenicity for [***] following second NVX boost and additional safety data through end of study. Magnitude and breadth of immune response as measured by IgG and pseudoneutants to vaccine and forward drift variants, will be assessed.

3.2.10 Subtask: Adult and Adolescent Heterologous Booster Study with BA.5 Vaccine and/or Other Variants, as Recommended by FDA (formerly Novavax 311, now as denoted below)

Additional cohorts will be added to this study, to include a boost with a BA.5 (Omicron) specific Novavax vaccine (different than the prototype vaccine). These cohorts will consist of:

- 1) 12-17 year olds previously vaccinated with 2 or 3 doses of mRNA vaccines [***] prior to enrollment (now Study 314).

- 2) Adults previously vaccinated with 3 doses of mRNA vaccines [***] prior to enrollment (now Study 311, Part 2).
- 3) Novel variant adults previously vaccinated with 3 doses of mRNA vaccines [***] prior to enrollment (now Study 313).

3.2.11 Subtask: Higher Dose Booster Safety and Immunogenicity Study (Novavax 205)

A new study will be conducted in adults to evaluate whether higher antigen doses of monovalent and bivalent vaccines produce better immune responses than the current [***] µg dose.

Population: Adults over the age of 50 with >2 prior doses of mRNA vaccine [***] prior to enrollment.

Intervention: Randomized into one of 8 study arms.

- Prototype at [***]ug.
- XBB.1.5 at [***]ug or [***]ug or [***]ug of antigen.
- Bivalent at [***]+[***]ug or [***]+[***]ug or [***]+[***]ug of antigen.
- mRNA arm (if available).

Outcomes/Measures: Comparing low, medium, and high dose groups.

- Reactogenicity for [***] following vaccination and additional safety data through end of study.
- Magnitude and breadth of immune response by IgG and pseudoneutants to vaccine (prototype and BA.5) and forward drift variants.

3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Subtask: Mouse Study, Immunogenicity

Study 702-100. [***] in mice for vaccine efficacy profile to comply with FDA guidelines.

3.3.2 Subtask: Rhesus Study, Immunogenicity

Study 702-099. [***] in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Subtask: Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Subtask: Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Subtask: Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Subtask: Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Subtask: Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Subtask: Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (Cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Subtask: Neutralizing Assay Histopathology for On-going [*]**

Histopathology readings for current neutralization studies in [***]. This will support the safety profile of the vaccine for FDA approval.

3.3.10 Subtask: Mouse Study, Immunogenicity [*] Studies**

Individual immunogenicity studies [***] in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.3.11 Subtask: Durability of NVX-CoV-2373 Vaccine Immunity and SARS-CoV-2 Protection at [*] in Rhesus Macaques**

Study 702-110. This study is designed to evaluate the long-term immunogenicity and protective efficacy of NVX-CoV-2373 nanoparticle vaccine when administered with Matrix-MTM by IM injections on Study Days 0 and 21, to Non-Human Primates (NHP). Each study group will contain [***] NHPs ([***] per sex). Blood samples will be collected prior to vaccination and at

multiple time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at [***] following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.3.12 Subtask: Immunogenicity and Protective Efficacy of Sub-Protective Doses of NVX-CoV-2373 in Rhesus Macaques

Study 702-111. This study is designed to evaluate the immunogenicity and protective efficacy of sub-optimal doses of NVX-CoV-2373 nanoparticle vaccine administered with a fixed dose of Matrix-MTM by IM injections on Study Days 0 and 21, to NHPs. Each study group will contain [***] NHPs ([***] per sex). Blood samples will be collected prior to vaccination and at various time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at [***] following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the USG team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type / Data Rights
	Manufacturing					
4.01		***	5.01	3.1.1	Reviewer	***
4.02	***	***	5.02	3.1.2	Reviewer	***
4.03	***	***	5.03	3.1.3	Reviewer	***
4.04	***	***	5.04	3.1.4	Reviewer	***
4.05	***	***	5.05	3.1.5	Reviewer	***
4.06	***	***	5.06	3.1.6	Reviewer	***
4.07	***	***	5.07	3.1.7	Reviewer	***
4.07a	***	***	5.07a	3.1.8	Reviewer	***
4.07b	*** ¹	***	5.07b	3.1.8	Reviewer	***
	Clinical					
4.08	***	***	5.08	3.2.1.1	Reviewer	*** ²
4.08a	***	***	5.08	3.2.9	Reviewer	***
4.08b	***	***	5.08	3.2.10	Reviewer	***
4.08c	***	***	5.08	3.2.11	Reviewer	***
4.09	Reserved					
4.10	Reserved					

¹ [***]

² As used herein, "Government Purpose Rights" has the meaning set forth in Article XI, Section 11.01(9) of the Base Agreement, as modified by Section 8.2(b) below.

4.11	Reserved					
4.12	***	***	5.12	3.2.5	Reviewer	***
4.13	Reserved					
4.14	***	***	5.14	3.2.7	Reviewer	***
4.15	***	***	5.15	3.2.1.2 3.2.8	Reviewer	***
Non- Clinical						
4.16	***	***	5.16	3.3.1	Reviewer	***
4.17	***	***	5.17	3.3.2	Reviewer	***
4.18	***	***	5.18	3.3.3	Reviewer	***
4.19	***	***	5.19	3.3.4	Reviewer	***
4.20	***	***	5.20	3.3.5	Reviewer	***
4.21	***	***	5.21	3.3.6	Reviewer	***
4.22	***	***	5.22	3.3.7	Reviewer	***
4.23	***	***	5.23	3.3.8	Reviewer	***
4.24	***	***	5.24	3.3.9	Reviewer	***
4.25	***	***	5.25	3.3.10	Reviewer	***
4.26	***	***	5.26	3.3.11	Reviewer	***
4.27	***	***	5.27	3.3.12	Reviewer	***
Regulatory Affairs						
4.28	***	***	5.28	3.4.1	Reviewer	***
4.29	***	***	5.29	3.4.2	Reviewer	***
4.30	***	***	5.30	3.4.3	Reviewer	***
Project Management						
4.31	***	***	5.31	3.5	Reviewer	***
4.32	***	***	5.32	3.5.1	Reviewer	***
4.33	***	***	5.33	3.5.2	Reviewer	***
4.34	***	***	5.34	3.5.3	Reviewer	***
4.35	***	***	5.35	3.5.4	Reviewer	***
4.36	***	***	5.36	3.5.4	Reviewer	***
4.36a	***	***	5.36a	3.5.4	Reviewer	***
4.36b	***	***	5.36b	3.5.4	Reviewer	***
4.37	***	***	5.37	3.5.5	Reviewer	***
4.38	***	***	5.35	N/A	Reviewer	***
TBD	***	***	Option 1	3.6	Reviewer	***

Note 1: Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with deliverables under this project.

Note 2: The USG agrees to permanently transfer USG material, in the form of mutually agreed upon quantities of Clinical Drug Substance/Product, to Novavax for its own use in related drug trials. To enable the foregoing, the USG transfers all its right, title and interest in and to the Clinical Drug Substance/Product to Novavax. In consideration of such right, Novavax agrees (a) that Novavax shall [***]; (b) that Novavax agrees to [***]; and, (c) Novavax will, upon reasonable request from the USG, obtain and share data from the use of the Clinical Drug Substance/Product, in a mutually agreed upon format. All transfers of material produced under the project, shall obtain prior written approval by the Government, with material quantities, destinations, applications, and USG benefits clearly delineated in a mutually agreed upon format.

5.0 MILESTONE PAYMENT SCHEDULE

The milestones below are for reference and costs for the project will be invoiced monthly on a cost reimbursable basis as the work progresses.

MS #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
	Manufacturing		***
5.01	***	***	***
5.02	***	***	***
5.03	***	***	***
5.04	***	***	***
5.05	***	***	***
5.06	***	***	***
5.07	***	***	***
5.07a	***	***	***
5.07b	***	***	***
5.07c	[***] ¹	***	***
5.07d	[***] ²	***	***
5.07e	*** ³	***	[***] ³
	Clinical		***
5.08	***	***	***
5.08a	***	***	***
5.08b	***	***	***
5.08c	***	***	***
5.09	Reserved		***

5.10	Reserved		***
5.11	Reserved		***
5.12	***	***	***
5.13	Reserved		***
5.14	***	***	***
5.15	***	***	***
	Non-Clinical		***
5.16	***	***	***
5.17	***	***	***
5.18	***	***	***
5.19	***	***	***
5.20	***	***	***
5.21	***	***	***
5.22	***	***	***
5.23	***	***	***
5.24	***	***	***
5.25	***	***	***
5.26	***	***	***
5.27	***	***	***
	Regulatory Affairs		***
5.28	***	***	***
5.29	***	***	***
5.30	***	***	***

	Project Management		***
5.31	***	***	***
5.32	***	***	***
5.33	***	***	***
5.34	***	***	***
5.35	***	***	***
5.36	***	***	***
5.36a	***	***	***
5.36b	***	***	***
5.37	***	***	***
5.38	***	***	***
	Reservation Fees		
5.39	***	***	***
5.40	***	***	***
5.41	***	***	***
Total (Cost Plus Fixed Fee)		\$1,800,670,981	
Period of Performance (July 6, 2020 – December 31, 2023)		42 Months (Base)	
Option 1: Follow-On Production		Cost: [***]	

1 ***

1. ***
2. ***
3. ***

2 [***]

1. ***
2. ***

3***

The USG and Novavax agree that billable costs for the duration of the agreement will not exceed the total amount of \$1,800,670,981, as shown in the functional areas set forth in the table below. Novavax acknowledges that any costs above the contract ceiling amounts, to include potential indirect rate adjustments, will be the sole responsibility of Novavax. Any and all milestone payments will be paid ONLY if activities are completed within the current period of performance, ending December 31, 2023.

Functional Area	Ceiling
Manufacturing	***
Clinical	***
Non-Clinical	***
Regulatory Affairs	***
Project Management	***
Total:	\$1,800,670,981

6.0 INSPECTION, ACCEPTANCE, SHIPPING, AND DELIVERY PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR. Further details are provided below.

A. Inspection. Quality inspection of Filled Drug Product (FDP) shall occur when Novavax performs release testing, in order to confirm that the product complies with Novavax's release specifications and criteria. Novavax will submit the Certificate of Analysis, Certificate of Compliance, examples of actual printed labels with lot number, and examples of printed carton labels for quality inspection of all drug product lots via the BARDA Data Infrastructure (BDI) system.

B. Delivery and Acceptance. Novavax shall notify the AOR (via update to BARDA-managed inventory system) at least [***] prior to initial delivery of NVX-CoV-2373 product. Exceptions are permitted if approved by the AOR. Upon notification, the AOR will instruct Novavax to deliver doses either to VMI or one or more, centralized USG-designated distribution sites within the USA.

Upon delivery of product, notification of delivery quantities shall be made to the AOR via the Dose Tracking Tool in accordance with the reporting requirements. Both parties acknowledge that doses delivered under this agreement are intended for clinical use or use under an EUA or a BLA (once such EUA or BLA is received).

Upon receipt of the provided certificates and any inspection of product at the destination site(s) that was timely requested (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection. Inspections may be made by the AOR or a duly authorized

USG representative. The USG shall accept or reject product (through the BARDA-managed inventory system) that conforms to agreement requirements based on Certificates of Analysis and Certificate(s) of Compliance, provided by Novavax, and review of temperature monitoring data. The AOR will correspondingly notify Novavax of acceptance or rejection. However, the USG's acceptance of product will be deemed to have occurred if the USG does not provide written notice of acceptance or rejection within [***] of Novavax's provision of all applicable certificates.

C. Vendor Managed Inventory. Product to be stored as VMI will be shipped to [***], in order to enable shipment to designated site(s). When held in VMI, these materials will be maintained in Novavax's or its designated representative's quality and inventory systems. Product held in VMI is subject to the following requirements:

- i. Provide temperature controlled storage at the manufacturer's site, approved by the USG, according to cGMP and product specifications.
- ii. Where possible, store agreement products physically segregated from other products. If physical separation is not possible, separation of agreement products must be controlled by a logical Warehouse Management System (WMS) at the case and pallet level.
- iii. Ensure proper labeling of stored materials as USG property.
- iv. Provide the USG access to review the security systems in place and request updates as needed, in accordance with the Security Plan.
- v. Include in the Government's dose tracking tool, inventory for drug product (number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result, and the current expiration date (if applicable).
- vii. Conduct testing necessary to ensure continued use of the stored material for pandemic response.
- vii. Make appropriate updates to the regulatory documentation, supporting the continued use of the stored material for pandemic response.
- viii. If using a storage site, provide the quality agreement, specify the location and terms of the storage contract.

For accepted product in VMI, Novavax must notify the AOR of any proposed movement of the product within the BARDA-managed inventory tracking system. Any deviations, Out of

Specification (OOS) results, or other product issues, shall be reported to the USG within [***] of Novavax identification.

D. Government Sites. Product to be shipped to USG-designated distribution sites shall be shipped trackable by GPS. Novavax will include the following information on the packing lists provided with bulk shipments to the centralized depots:

- i. Transaction Information (TI)
- ii. Transaction History (TH)
- iii. Transaction Statement (TS)
- iv. Centers for Disease Control (CDC) Purchase Order (PO) Number

Novavax will also transmit bulk shipment Advance Shipment Notices (ASN) to the CDC via Electronic Data Interchange (EDI).

E. Title and Physical Risk of Loss. Title to product will transfer upon [***]. Novavax will [***]. If product is initially delivered to a [***], risk of loss will transfer upon [***].

Novavax will notify the AOR (via e-mail or phone) of any storage or quality deviation for product held in VMI, within [***]. To the extent that Novavax is responsible for the correction, repair or replacement of USG property held in VMI, and replacement upon loss or damage of such product is feasible, the USG will accept replacement of such property.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV-2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV-2373, as well as its sf9/baculovirus manufacturing platform, (all "Background IP") through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov-2373 manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes (collectively "Background Know-How"), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated

using, the Background Know-How (collectively, "Background Data"), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents ("Background Materials"). On June 8, 2020, Novavax and the U.S. Department of Defense entered into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV-2373 which acknowledged Background IP and made no explicit U.S. Government claims to Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax's prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) Background IP License to Novavax. Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) Ownership. Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing ("Foreground IP").

(b) Foreground IP Special License. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government ("Foreground IP Special License").

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

8.2 Rights to Data.

(a) Subject Data. Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)³ after three (3) years from the date of delivery. As used herein, "Subject Data" shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) Transfer of Data. Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

(c) Background IP Limited License. To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

³ As used herein, "Government Use" as used "Purpose Rights" has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus (the "Technology"). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

Novavax agrees to the following:

- a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA.
- b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.
- c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

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a. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

- i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:
 - a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;
 - b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or
 - c. any filing that anticipates Federal bankruptcy protection; and
- ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application under the provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

- i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV-2373 vaccine;
- ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-CoV-2373 and any confirmatory instrument pertaining thereto; and
- iii. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11. SECURITY

The security classification level for this effort is UNCLASSIFIED. Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with the execution of this project.

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

14.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: [***]

EMAIL: [***]

PHONE: [***]

AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-Enabling Biotechnologies

Alternate AOR

NAME: [***]

EMAIL: [***]

PHONE: [***]

AGENCY NAME/DIVISION/SECTION: HHS

ENCLOSURE 3: (SUPERSEDED)

N/A – This enclosure has been superseded from the original and is no longer applicable.

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ENCLOSURE 4: PATENT LISTING

[Pursuant to Regulation S-K, Item 601(a)(5), this enclosure setting forth the patent listing has not been filed. The Registrant agrees to furnish supplementally a copy of any omitted exhibits to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.]

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Attachment 1:

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

**EMERGENCY USE AUTHORIZATION (EUA) OF
THE NOVAVAX COVID-19 VACCINE, ADJUVANTED TO PREVENT
CORONAVIRUS DISEASE 2019 (COVID-19)**

You are being offered the Novavax COVID-19 Vaccine, Adjuvanted to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The Novavax COVID-19 Vaccine, Adjuvanted has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide:

- a two-dose primary series to individuals 12 years of age and older.
- a first booster dose to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:
 - individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent¹ COVID-19 booster vaccine is not accessible or clinically appropriate,
 - individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

Exhibit [•]

CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS OF THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.



December 1, 2023

Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

Attention: [*****], Vice President, Government Alliance Management
and Contracting

Subject: Modification No. 20 to Project Agreement No. 01; MCDC2011-001

Reference: MCDC Base Agreement No. 2020-530

Dear [*****]:

In accordance with the terms and conditions of the referenced MCDC Base Agreement, Modification No. 19 hereby amends Project Agreement No. 20 as follows:

DESCRIPTION OF MODIFICATION

1) The Term of the Project Agreement clause of the Project Agreement is hereby amended to read as indicated in bold below:

2. TERM OF THE PROJECT AGREEMENT

The period of performance for this Project Agreement is from July 06, 2020 through March 31, 2024 (*this is a 3 month no-cost extension*).

2) Attachment A, Statement of Work, of the Project Agreement is hereby amended as attached herein.

Except as provided herein, all Terms and Conditions of the referenced MCDC Base Agreement, Project Agreement, and preceding modifications remain unchanged and in full force and effect.

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Novavax, Inc.

Advanced Technology International

By: /s/ Kevin J. Cline

By: /s/ [*****]

Name: Kevin J. Cline

Name: [*****]

Title: VP Government Contracting

Title: Sr. Subcontracts Administrator

Date: 12/8/2023

Date: 12/11/2023

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Attachment A
Statement of Work
(Incorporated as of as of Modification No. 20)

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Attachment A
Statement of Work

(Incorporated as of Modification No. 20; Changes to Sections 4,5, and 14 are indicated below)

For

Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

27 November 2023

RPP #: 20-11

Project Identifier: MCDC2011-001

Consortium Member: Novavax, Inc.

Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

Requiring Activity: Joint Mission between the Department of Health and Human Services and Department of Defense to Combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the ability to manufacture and deliver up to 100M doses of a SARS-CoV-2 vaccine, NVX-

CoV-2373, which is suitable for use in humans under a sufficiently informed deployment strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the “prototype project” will effectively demonstrate Novavax’s ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial ([*****]) and is stored at refrigerated temperature (2-8°C).

Successful development of the prototype will demonstrate Novavax’s ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

Successful completion of the prototype will require three coordinated and integrated lines of effort:

- a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
- b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.
- c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG’s deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are “positive” or “negative” is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10 U.S.C. 4022(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population (≈560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above.

One lot will be manufactured initially, with approximately 3M doses delivered in support of this agreement. In addition, the following lots will also be delivered under this agreement:

1. A second partial lot of approximately [*****] doses with expiry of [*****].
2. A third partial lot of approximately [*****] (Up to [*****]) doses with expiry no earlier than [*****]. Actual requirements will depend on jurisdiction/pharmacy and federal entity orders.

Delivery of doses to the USG is contingent on the following:

1. Timing of EUA approval by FDA.
2. Timing of label language and artwork approval by FDA.
3. Timing of Advisory Committee on Immunization Practices (ACIP) recommendation.

Any additional manufacturing and deliveries will be contingent on 1) USG demand, 2) FDA guidance on strain changes, and 3) agreement on price.

The scope includes the following activities:

- o Manufacturing**

Manufacturing of up to 100M doses of NVX-CoV-2373 vaccine (or a variant construct if terms, including price, can be agreed upon) for distribution to the USG upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.

Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to

the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.

Comparability among clinical vaccine lots and commercial lots using a comparability protocol.

Validation of manufacturing processes will be performed to cGMP standards.

o Clinical

Phase 3 pivotal clinical trial harmonized with USG clinical strategies.

A Phase 3 clinical trial in pediatric populations (<18 years).

Phase 2 studies in at-risk subpopulations (e.g., co-morbidities, ****], immunocompromised), as well as studies to support manufacturing site comparability.

o Non-clinical

Studies to support EUA and regulatory approval (BLA).

o Regulatory

EUA submission when data supports it, while maintaining progress toward eventual BLA submission.

BLA submission when appropriate.

Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.

Meetings as needed with regulators.

o Project Management

Mandatory reporting requirements, as described in the Base Agreement.

Submission of Quarterly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.

Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.

Final prototype project report and applicable patents report(s).

Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).

All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials (******) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – [***] Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant**

[*****] to supply large-scale manufacturing of vaccine doses will be manufactured at [*****] and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-

up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supply up to 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supply **up to** 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply up to 100M Vaccine Doses

Antigen will be manufactured to supply up to 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of up to 100M Vaccine Doses

Up to 100M doses of finished vaccine in [*****] vials will be manufactured. This will include secondary packaging. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system to enable shipment of product to the Biomedical Advanced Research and Development Authority (BARDA)-managed inventory system (McKesson depots). Novavax will perform activities to establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.1.8 Subtask: Manufacture of 3M Doses and Subsequent Manufacturing

Initially, approximately 3M doses will be manufactured at Serum Institute of India (Pune, India) or other FDA-approved location, for delivery as soon as feasible after receipt of EUA from the FDA, at an agreed-upon price per dose. In addition, the following lots will also be delivered under this agreement:

1. Novavax will deliver approximately [*****] doses within [*****] business days of fully executed Modification #17, from a lot that has [*****] expiry and is acceptable for use under EUA.
2. Novavax will deliver approximately [*****] (Up to [*****]) doses within [**] business days of FDA release of the new lot or [*****], whichever comes later, but no later than [*****] by both parties. The lot will have expiry no earlier than [*****]. Actual requirements will depend on jurisdiction/pharmacy and federal entity orders.

The manufacture and delivery of any doses beyond this quantity is dependent upon USG demand, FDA guidance on strain selection, and agreement between the parties on price, to be incorporated via a mutually agreed upon modification.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 US/Mexico Efficacy Study, Adults \geq 18 and $<$ 75 years

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a “crossover” component where patients that received placebo were offered the vaccine after [*****].

Population: Adults \geq 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: US/Mexico.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M – dose determined by Phase 2 dose confirmation study, Placebo; \sim 0.5 mL dose Intramuscular (IM) injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL N: \sim 30,000 (adjusted for expected endpoint incidence). [*****].

3.2.1.1 Subtask: Phase 3 US/Mexico Efficacy Study, Adults \geq 18, Booster Study

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a booster component where patients will receive a booster dose of vaccine approximately [*****] after completion of the dose regimen, and a second booster dose no less than [*****] after the previous booster.

Enrollment: TOTAL N: \sim 25,000 (adjusted for expected enrollment).

3.2.1.2 Subtask: Phase 3 US/Mexico Efficacy Study, Adolescents \geq 12 and $<$ 18 years, Adolescent/Adolescent Booster Study

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a booster component where patients will receive a booster dose of vaccine approximately [*****] after completion of the dose regimen. A subgroup of patients (approximately 200) will receive a second booster dose no less than [*****] after the previous booster.

Enrollment: TOTAL N: \sim 2500 (adjusted for expected enrollment).

3.2.2 Reserved

3.2.3 Reserved

3.2.4 Reserved

3.2.5 Subtask: Lot-to-Lot Consistency/Comparability Study (US or other)

Study: Phase 2 lot-to-lot consistency/comparability study (US or other), 2019nCoV-307.

Population: Adults \geq 18 to $<$ 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded.

Test Product(s); Dose Regimen; Route of Administration Vaccine + Matrix-M; [*****].

Enrollment: ~300 per cohort, each cohort having [*****]. Study size may be adjusted to allow non-inferiority testing.

3.2.6 Reserved

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: Phase 3 Pediatric Study

Study: Phase 2/3 pediatric study, 2019nCoV-503.

Population: Children \geq 6 months to $<$ 12 years (3 age cohorts).

Locations: [*****].

Primary Objectives: Safety, immunogenicity, effectiveness (determined by immunogenicity).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration Vaccine + Matrix-M [*****].

Enrollment: N = 1,200 ([*****]); N = 1,200 ([*****]); N = 1,200 ([*****]); TOTAL: N = 3,600; [*****].

3.2.9 Subtask: Heterologous Boosting Study with Prototype Vaccine (formerly Novavax 307b, now 312)

A study (N=300) will be performed to measure the immune response of heterologous boosting (after mRNA vaccine priming). Previous participants of this study who received 2 or 3 doses of mRNA vaccine + 1 Novavax boost, will receive a second Novavax boost.

Outcomes/Measures: Compare immune responses following second NVX boost in mRNA primed participants to responses seen in initial part of study for NVX primed and mRNA primed

and boosted individuals. Reactogenicity for [*****] following second NVX boost and additional safety data through end of study. Magnitude and breadth of immune response as measured by IgG and pseudoneutants to vaccine and forward drift variants, will be assessed.

3.2.10 Subtask: Adult and Adolescent Heterologous Booster Study with BA.5 Vaccine and/or Other Variants, as Recommended by FDA (formerly Novavax 311, now as denoted below)

Additional cohorts will be added to this study, to include a boost with a BA.5 (Omicron) specific Novavax vaccine (different than the prototype vaccine). These cohorts will consist of:

- 1) 12-17 year olds previously vaccinated with 2 or 3 doses of mRNA vaccines [*****] prior to enrollment (now Study 314).
- 2) Adults previously vaccinated with 3 doses of mRNA vaccines [*****] prior to enrollment (now Study 311, Part 2).
- 3) Novel variant adults previously vaccinated with 3 doses of mRNA vaccines [*****] prior to enrollment (now Study 313).

3.2.11 Subtask: Higher Dose Booster Safety and Immunogenicity Study (Novavax 205)

A new study will be conducted in adults to evaluate whether higher antigen doses of monovalent and bivalent vaccines produce better immune responses than the current [*] µg dose.

Population: Adults over the age of 50 with >2 prior doses of mRNA vaccine [*****] prior to enrollment.

Intervention: Randomized into one of 8 study arms.

- Prototype at [*]ug.
- XBB.1.5 at [*]ug or [**]ug or []ug of antigen.
- Bivalent at [***]+[**]ug or [***]+[***]ug or [***]+[***]ug of antigen.
- mRNA arm (if available).

Outcomes/Measures: Comparing low, medium, and high dose groups.

- Reactogenicity for [***] following vaccination and additional safety data through end of study.
- Magnitude and breadth of immune response by IgG and pseudoneutants to vaccine (prototype and BA.5) and forward drift variants.

3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Subtask: Mouse Study, Immunogenicity

Study 702-100. [***] in mice for vaccine efficacy profile to comply with FDA guidelines.

3.3.2 Subtask: Rhesus Study, Immunogenicity

Study 702-099. [****] in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Subtask: Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster [****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Subtask: Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice [****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Subtask: Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster [****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Subtask: Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster [****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Subtask: Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Subtask: Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (Cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Subtask: Neutralizing Assay Histopathology for On-going [*]**

Histopathology readings for current neutralization studies in [***]. This will support the safety profile of the vaccine for FDA approval.

3.3.10 Subtask: Mouse Study, Immunogenicity [*] Studies**

Individual immunogenicity studies [***] in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.3.11 Subtask: Durability of NVX-CoV-2373 Vaccine Immunity and SARS-CoV-2 Protection at [*] in Rhesus Macaques**

Study 702-110. This study is designed to evaluate the long-term immunogenicity and protective efficacy of NVX-CoV-2373 nanoparticle vaccine when administered with Matrix-MTM by IM injections on Study Days 0 and 21, to Non-Human Primates (NHP). Each study group will contain [***] NHPs ([***] per sex). Blood samples will be collected prior to vaccination and at multiple time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at [***] following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.3.12 Subtask: Immunogenicity and Protective Efficacy of Sub-Protective Doses of NVX-CoV-2373 in Rhesus Macaques

Study 702-111. This study is designed to evaluate the immunogenicity and protective efficacy of sub-optimal doses of NVX-CoV-2373 nanoparticle vaccine administered with a fixed dose of Matrix-MTM by IM injections on Study Days 0 and 21, to NHPs. Each study group will contain [***] NHPs ([***] per sex). Blood samples will be collected prior to vaccination and at various time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at [***] following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the USG team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type / Data Rights
Manufacturing						
4.01	****	****	5.01	3.1.1	Reviewer	****
4.02	****	****	5.02	3.1.2	Reviewer	****
4.03	****	****	5.03	3.1.3	Reviewer	****
4.04	****	****	5.04	3.1.4	Reviewer	****

4.05	****	****	5.05	3.1.5	Reviewer	****
4.06	****	****	5.06	3.1.6	Reviewer	****
4.07	****	****	5.07	3.1.7	Reviewer	****
4.07a	****	****	5.07a	3.1.8	Reviewer	****
4.07b	**** ¹	****	5.07b	3.1.8	Reviewer	****
	Clinical					
4.08	****	****	5.08	3.2.1.1	Reviewer	**** ²
4.08a	****	****	5.08	3.2.9	Reviewer	****
4.08b	****	****	5.08	3.2.10	Reviewer	****
4.08c	****	****	5.08	3.2.11	Reviewer	****
4.09	Reserved					
4.10	Reserved					
4.11	Reserved					
4.12	****	****	5.12	3.2.5	Reviewer	****
4.13	****					
4.14	****	****	5.14	3.2.7	Reviewer	****
4.15	****	****	5.15	3.2.1.2 3.2.8	Reviewer	****
	Non- Clinical					
4.16	****	****	5.16	3.3.1	Reviewer	****
4.17	****	****	5.17	3.3.2	Reviewer	****
4.18	****	****	5.18	3.3.3	Reviewer	****
4.19	****	****	5.19	3.3.4	Reviewer	****
4.20	****	****	5.20	3.3.5	Reviewer	****
4.21	****	****	5.21	3.3.6	Reviewer	****
4.22	****	****	5.22	3.3.7	Reviewer	****
4.23	****	****	5.23	3.3.8	Reviewer	****
4.24	****	****	5.24	3.3.9	Reviewer	****
4.25	****	****	5.25	3.3.10	Reviewer	****
4.26	****	****	5.26	3.3.11	Reviewer	****
4.27	****	****	5.27	3.3.12	Reviewer	****
	Regulatory Affairs					
4.28	****	****	5.28	3.4.1	Reviewer	****
4.29	****	****	5.29	3.4.2	Reviewer	****

¹ [****.]

² As used herein, "Government Purpose Rights" has the meaning set forth in Article XI, Section 11.01(9) of the Base Agreement, as modified by Section 8.2(b) below.

4.30	****	****	5.30	3.4.3	Reviewer	****
	Project Management					
4.31	****	****	5.31	3.5	Reviewer	****
4.32	****	****	5.32	3.5.1	Reviewer	****
4.33	****	****	5.33	3.5.2	Reviewer	****
4.34	****	****	5.34	3.5.3	Reviewer	****
4.35	****	****	5.35	3.5.4	Reviewer	****
4.36	****	****	5.36	3.5.4	Reviewer	****
4.36a	****	****	5.36a	3.5.4	Reviewer	****
4.36b	****	****	5.36b	3.5.4	Reviewer	****
4.37	****	****	5.37	3.5.5	Reviewer	****
4.38	****	****	5.35	N/A	Reviewer	****
TBD	***	***	Option 1	3.6	Reviewer	***

Note 1: Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with deliverables under this project.

Note 2: The USG agrees to permanently transfer USG material, in the form of mutually agreed upon quantities of Clinical Drug Substance/Product, to Novavax for its own use in related drug trials. To enable the foregoing, the USG transfers all its right, title and interest in and to the Clinical Drug Substance/Product to Novavax. In consideration of such right, Novavax agrees (a) that Novavax shall [****]; (b) that Novavax agrees to [***]; and, (c) Novavax will, upon reasonable request from the USG, obtain and share data from the use of the Clinical Drug Substance/Product, in a mutually agreed upon format. All transfers of material produced under the project, shall obtain prior written approval by the Government, with material quantities, destinations, applications, and USG benefits clearly delineated in a mutually agreed upon format.

5.0 MILESTONE PAYMENT SCHEDULE

The milestones below are for reference and costs for the project will be invoiced monthly on a cost reimbursable basis as the work progresses.

MS #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
	Manufacturing		****
5.01	****	****	****
5.02	****	****	****

5.03	****	****	****
5.04	****	****	****
5.05	****	****	****
5.06	****	****	****
5.07	****	****	****
5.07a	****	****	****
5.07b	****	****	****
5.07c	****	****	****
5.07d	****	****	****
5.07e	****	****	****
Clinical			****
5.08	****	****	****
5.08a	****	****	****
5.08b	****	****	****
5.08c	****	****	****
5.09	Reserved	****	****
5.10	Reserved	****	****
5.11	Reserved	****	****
5.12	****	****	****
5.13	Reserved	****	****
5.14	****	****	****
5.15	****	****	****
Non-Clinical			****
5.16	****	****	****
5.17	****	****	****
5.18	****	****	****
5.19	****	****	****
5.20	****	****	****
5.21	****	****	****
5.22	****	****	****

5.23	****	****	****
5.24	****	****	****
5.25	****	****	****
5.26	****	****	****
5.27	****	****	****
	Regulatory Affairs		****
5.28	****	****	****
5.29	****	****	****
5.30	****	****	****
	Project Management		****
5.31	****	****	****
5.32	****	****	****
5.33	****	****	****
5.34	****	****	****
5.35	****	****	****
5.36	****	****	****
5.36a	****	****	****
5.36b	****	****	****
5.37	****	****	****
5.38	****	****	****
	Reservation Fees		
5.39	****	****	****
5.40	****	****	****
5.41	****	****	****
Total (Cost Plus Fixed Fee)		\$1,800,670,981	
Period of Performance (July 6, 2020 – March 31, 2024)		45 Months (Base)	
Option 1: Follow-On Production		Cost: ****	

1****

2****
3****

The USG and Novavax agree that billable costs for the duration of the agreement will not exceed the total amount of \$1,800,670,981, as shown in the functional areas set forth in the table below. Novavax acknowledges that any costs above the contract ceiling amounts, to include potential indirect rate adjustments, will be the sole responsibility of Novavax. Any and all milestone payments will be paid ONLY if activities are completed within the current period of performance, ending March 31, 2024.

Functional Area	Ceiling
Manufacturing	****
Clinical	****
Non-Clinical	****
Regulatory Affairs	****
Project Management	****
Total:	\$1,800,670,981

6.0 INSPECTION, ACCEPTANCE, SHIPPING, AND DELIVERY PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR. Further details are provided below.

A. Inspection. Quality inspection of Filled Drug Product (FDP) shall occur when Novavax performs release testing, in order to confirm that the product complies with Novavax's release specifications and criteria. Novavax will submit the Certificate of Analysis, Certificate of Compliance, examples of actual printed labels with lot number, and examples of printed carton labels for quality inspection of all drug product lots via the BARDA Data Infrastructure (BDI) system.

B. Delivery and Acceptance. Novavax shall notify the AOR (via update to BARDA-managed inventory system) at least****] prior to initial delivery of NVX-CoV-2373 product. Exceptions are permitted if approved by the AOR. Upon notification, the AOR will instruct Novavax to deliver doses either to VMI or one or more, centralized USG-designated distribution sites within the USA.

Upon delivery of product, notification of delivery quantities shall be made to the AOR via the Dose Tracking Tool in accordance with the reporting requirements. Both parties acknowledge that doses delivered under this agreement are intended for clinical use or use under an EUA or a BLA (once such EUA or BLA is received).

Upon receipt of the provided certificates and any inspection of product at the destination site(s) that was timely requested (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection. Inspections may be made by the AOR or a duly authorized USG representative. The USG shall accept or reject product (through the BARDA-managed inventory system) that conforms to agreement requirements based on Certificates of Analysis and Certificate(s) of Compliance, provided by Novavax, and review of temperature monitoring data. The AOR will correspondingly notify Novavax of acceptance or rejection. However, the USG's acceptance of product will be deemed to have occurred if the USG does not provide written notice of acceptance or rejection within [****] of Novavax's provision of all applicable certificates.

C. Vendor Managed Inventory. Product to be stored as VMI will be shipped to [***], in order to enable shipment to designated site(s). When held in VMI, these materials will be maintained in Novavax's or its designated representative's quality and inventory systems. Product held in VMI is subject to the following requirements:

- i. Provide temperature controlled storage at the manufacturer's site, approved by the USG, according to cGMP and product specifications.
- ii. Where possible, store agreement products physically segregated from other products. If physical separation is not possible, separation of agreement products must be controlled by a logical Warehouse Management System (WMS) at the case and pallet level.
- iii. Ensure proper labeling of stored materials as USG property.
- iv. Provide the USG access to review the security systems in place and request updates as needed, in accordance with the Security Plan.
- v. Include in the Government's dose tracking tool, inventory for drug product (number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result, and the current expiration date (if applicable).
- vii. Conduct testing necessary to ensure continued use of the stored material for pandemic response.

vii. Make appropriate updates to the regulatory documentation, supporting the continued use of the stored material for pandemic response.

viii. If using a storage site, provide the quality agreement, specify the location and terms of the storage contract.

For accepted product in VMI, Novavax must notify the AOR of any proposed movement of the product within the BARDA-managed inventory tracking system. Any deviations, Out of Specification (OOS) results, or other product issues, shall be reported to the USG within [***] of Novavax identification.

D. Government Sites. Product to be shipped to USG-designated distribution sites shall be shipped trackable by GPS. Novavax will include the following information on the packing lists provided with bulk shipments to the centralized depots:

i. Transaction Information (TI)

ii. Transaction History (TH)

iii. Transaction Statement (TS)

iv. Centers for Disease Control (CDC) Purchase Order (PO) Number

Novavax will also transmit bulk shipment Advance Shipment Notices (ASN) to the CDC via Electronic Data Interchange (EDI).

E. Title and Physical Risk of Loss. Title to product will transfer upon [***]. Novavax will [***]. If product is initially delivered to a [***], risk of loss will transfer upon [***].

Novavax will notify the AOR (via e-mail or phone) of any storage or quality deviation for product held in VMI, within [**]. To the extent that Novavax is responsible for the correction, repair or replacement of USG property held in VMI, and replacement upon loss or damage of such product is feasible, the USG will accept replacement of such property.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV-2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV-2373, as well as its sf9/baculovirus manufacturing platform, (all

“Background IP”) through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov-2373 manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes (collectively “Background Know-How”), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated using, the Background Know-How (collectively, “Background Data”), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents (“Background Materials”). On June 8, 2020, Novavax and the U.S. Department of Defense entered into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV-2373 which acknowledged Background IP and made no explicit U.S. Government claims to Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax’s prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) Background IP License to Novavax. Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax’s obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) Ownership. Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in

connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing (“Foreground IP”).

(b) Foreground IP Special License. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government (“Foreground IP Special License”).

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the “Specifically Negotiated License Rights” capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

8.2 Rights to Data.

(a) Subject Data. Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)³ after three (3) years from the date of delivery. As used herein, “Subject Data” shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) Transfer of Data. Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

(c) Background IP Limited License. To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

³ As used herein, “Government Use” as used “Purpose Rights” has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus (the "Technology"). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

Novavax agrees to the following:

- a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA.
- b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations

to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.

c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

a. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

- i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:
 - a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;
 - b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or
 - c. any filing that anticipates Federal bankruptcy protection; and
- ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application under the provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

- i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as

defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV-2373 vaccine;

- ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-CoV-2373 and any confirmatory instrument pertaining thereto; and
- iii. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11. SECURITY

The security classification level for this effort is UNCLASSIFIED. Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with the execution of this project.

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

14.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: [****]

EMAIL: [****]

PHONE: [****]

AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-Enabling Biotechnologies (JPEO, JPL-EB)

Alternate AOR

NAME:****

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EMAIL: ****

PHONE: [****]

AGENCY NAME/DIVISION/SECTION: Health and Human Services, Biomedical Advanced Research Development Authority (HHS/BARDA)

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ENCLOSURE 3: (SUPERSEDED)

N/A – This enclosure has been superseded from the original and is no longer applicable.

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ENCLOSURE 4: PATENT LISTING

[Pursuant to Regulation S-K, Item 601(a)(5), this enclosure setting forth the patent listing has not been filed. The Registrant agrees to furnish supplementally a copy of any omitted exhibits to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.]

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Attachment 1:

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

**EMERGENCY USE AUTHORIZATION (EUA) OF
THE NOVAVAX COVID-19 VACCINE, ADJUVANTED TO PREVENT
CORONAVIRUS DISEASE 2019 (COVID-19)**

You are being offered the Novavax COVID-19 Vaccine, Adjuvanted to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The Novavax COVID-19 Vaccine, Adjuvanted has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide:

- a two-dose primary series to individuals 12 years of age and older.
- a first booster dose to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:
 - individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent¹ COVID-19 booster vaccine is not accessible or clinically appropriate,
 - individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

Exhibit [•]



CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS OF THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

February 6, 2024

Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

Attention: [*****], Senior Vice President, Commercial Strategy

Subject: Modification No. 21 to Project Agreement No. 01; MCDC2011-001

Reference: MCDC Base Agreement No. 2020-530

Dear [***]:

In accordance with the terms and conditions of the referenced MCDC Base Agreement, Modification No. 21 hereby amends Project Agreement No. 01 as follows:

DESCRIPTION OF MODIFICATION

1) Attachment A, Statement of Work, of the Project Agreement is hereby amended as attached herein.

Except as provided herein, all Terms and Conditions of the referenced MCDC Base Agreement, Project Agreement, and preceding modifications remain unchanged and in full force and effect.

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Novavax, Inc.

Advanced Technology International

By: /s/ Kevin J. Cline

By: /s/ [*****]

Name: Kevin J. Cline

Name: [*****]

Title: VP Government Alliances and Contracting

Date: 2/13/2024

Title: Sr. Subcontracts Administrator

Date: 2/15/2024

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Attachment A
Statement of Work

(Incorporated as of Modification No. 21; Changes to Section 5 are indicated in Attachment A.)

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Attachment A
Statement of Work

(Incorporated as of Modification No. 21; Changes to Section 5 are indicated below)

For

Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

01 February 2024

RPP #: 20-11

Project Identifier: MCDC2011-001

Consortium Member: Novavax, Inc.

Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

Requiring Activity: Joint Mission between the Department of Health and Human Services and Department of Defense to Combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the ability to manufacture and deliver up to 100M doses of a SARS-CoV-2 vaccine, NVX-CoV-2373, which is suitable for use in humans under a sufficiently informed deployment

strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the “prototype project” will effectively demonstrate Novavax’s ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial ([****]) and is stored at refrigerated temperature (2-8°C).

Successful development of the prototype will demonstrate Novavax’s ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

Successful completion of the prototype will require three coordinated and integrated lines of effort:

- a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
- b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.
- c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG’s deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are “positive” or “negative” is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10 U.S.C. 4022(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to

production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population (~560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above.

One lot will be manufactured initially, with approximately 3M doses delivered in support of this agreement. In addition, the following lots will also be delivered under this agreement:

1. A second partial lot of approximately [****] doses with expiry of [***].
2. A third partial lot of approximately [**] (Up to [***]) doses with expiry no earlier than [*****]. Actual requirements will depend on jurisdiction/pharmacy and federal entity orders.

Delivery of doses to the USG is contingent on the following:

1. Timing of EUA approval by FDA.
2. Timing of label language and artwork approval by FDA.
3. Timing of Advisory Committee on Immunization Practices (ACIP) recommendation.

Any additional manufacturing and deliveries will be contingent on 1) USG demand, 2) FDA guidance on strain changes, and 3) agreement on price.

The scope includes the following activities:

- o **Manufacturing**

Manufacturing of up to 100M doses of NVX-CoV-2373 vaccine (or a variant construct if terms, including price, can be agreed upon) for distribution to the USG upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.

Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.

Comparability among clinical vaccine lots and commercial lots using a comparability protocol.

Validation of manufacturing processes will be performed to cGMP standards.

o Clinical

Phase 3 pivotal clinical trial harmonized with USG clinical strategies.

A Phase 3 clinical trial in pediatric populations (<18 years).

Phase 2 studies in at-risk subpopulations (e.g., co-morbidities, [*****], immunocompromised), as well as studies to support manufacturing site comparability.

o Non-clinical

Studies to support EUA and regulatory approval (BLA).

o Regulatory

EUA submission when data supports it, while maintaining progress toward eventual BLA submission.

BLA submission when appropriate.

Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.

Meetings as needed with regulators.

o Project Management

Mandatory reporting requirements, as described in the Base Agreement.

Submission of Quarterly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.

Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.

Final prototype project report and applicable patents report(s).

Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).

All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials ([*****]) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – [****] Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant

[*****] to supply large-scale manufacturing of vaccine doses will be manufactured at [*****] and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supplyup to 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supplyup to 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply up to 100M Vaccine Doses

Antigen will be manufactured to supply up to 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of up to 100M Vaccine Doses

Up to 100M doses of finished vaccine in f*** vials will be manufactured. This will include secondary packaging. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system to enable shipment of product to the Biomedical Advanced Research and Development Authority (BARDA)-managed inventory system (McKesson depots). Novavax will perform activities to establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.1.8 Subtask: Manufacture of 3M Doses and Subsequent Manufacturing

Initially, approximately 3M doses will be manufactured at Serum Institute of India (Pune, India) or other FDA-approved location, for delivery as soon as feasible after receipt of EUA from the FDA, at an agreed-upon price per dose. In addition, the following lots will also be delivered under this agreement:

1. Novavax will deliver approximately [***] doses within [**] business days of fully executed Modification #17, from a lot that has [***] expiry and is acceptable for use under EUA.
2. Novavax will deliver approximately [***] (Up to [***]) doses within [**] business days of FDA release of the new lot or [*****], whichever comes later, but no later than [*****], unless agreed to by both parties. The lot will have expiry no earlier than [*****]. Actual requirements will depend on jurisdiction/pharmacy and federal entity orders.

The manufacture and delivery of any doses beyond this quantity is dependent upon USG demand, FDA guidance on strain selection, and agreement between the parties on price, to be incorporated via a mutually agreed upon modification.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 US/Mexico Efficacy Study, Adults \geq 18 and $<$ 75 years

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a “crossover” component where patients that received placebo were offered the vaccine after [*****].

Population: Adults \geq 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: US/Mexico.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M – dose determined by Phase 2 dose confirmation study, Placebo; \sim 0.5 mL dose Intramuscular (IM) injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL N: \sim 30,000 (adjusted for expected endpoint incidence). [*****].

3.2.1.1 Subtask: Phase 3 US/Mexico Efficacy Study, Adults \geq 18, Booster Study

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a booster component where patients will receive a booster dose of vaccine approximately [*****] after completion of the dose regimen, and a second booster dose no less than [*****] after the previous booster.

Enrollment: TOTAL N: \sim 25,000 (adjusted for expected enrollment).

3.2.1.2 Subtask: Phase 3 US/Mexico Efficacy Study, Adolescents \geq 12 and $<$ 18 years, Adolescent/Adolescent Booster Study

Study: Phase 3 – US/Mexico Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301. This includes a booster component where patients will receive a booster dose of vaccine approximately [*****] after completion of the dose regimen. A subgroup of patients (approximately 200) will receive a second booster dose no less than [*****] after the previous booster.

Enrollment: TOTAL N: \sim 2500 (adjusted for expected enrollment).

3.2.2 Reserved

3.2.3 Reserved

3.2.4 Reserved

3.2.5 Subtask: Lot-to-Lot Consistency/Comparability Study (US or other)

Study: Phase 2 lot-to-lot consistency/comparability study (US or other), 2019nCoV-307.

Population: Adults \geq 18 to $<$ 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded.

Test Product(s); Dose Regimen; Route of Administration Vaccine + Matrix-M; [*****].

Enrollment: ~300 per cohort, each cohort having [*****]. Study size may be adjusted to allow non-inferiority testing.

3.2.6 Reserved

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: Phase 3 Pediatric Study

Study: Phase 2/3 pediatric study, 2019nCoV-503.

Population: Children \geq 6 months to < 12 years (3 age cohorts).

Locations: [*****].

Primary Objectives: Safety, immunogenicity, effectiveness (determined by immunogenicity).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration Vaccine + Matrix-M [*****].

Enrollment: N = 1,200 ([*****]); N = 1,200 ([*****]); N = 1,200 ([*****]); TOTAL: N = 3,600; [*****].

3.2.9 Subtask: Heterologous Boosting Study with Prototype Vaccine (formerly Novavax 307b, now 312)

A study (N=300) will be performed to measure the immune response of heterologous boosting (after mRNA vaccine priming). Previous participants of this study who received 2 or 3 doses of mRNA vaccine + 1 Novavax boost, will receive a second Novavax boost.

Outcomes/Measures: Compare immune responses following second NVX boost in mRNA primed participants to responses seen in initial part of study for NVX primed and mRNA primed and boosted individuals. Reactogenicity for [*****] following second NVX boost and additional safety data through end of study. Magnitude and breadth of immune response as measured by IgG and pseudoneutants to vaccine and forward drift variants, will be assessed.

3.2.10 Subtask: Adult and Adolescent Heterologous Booster Study with BA.5 Vaccine and/or Other Variants, as Recommended by FDA (formerly Novavax 311, now as denoted below)

Additional cohorts will be added to this study, to include a boost with a BA.5 (Omicron) specific Novavax vaccine (different than the prototype vaccine). These cohorts will consist of:

- 1) 12-17 year olds previously vaccinated with 2 or 3 doses of mRNA vaccines [****] prior to enrollment (now Study 314).
- 2) Adults previously vaccinated with 3 doses of mRNA vaccines [****] prior to enrollment (now Study 311, Part 2).
- 3) Novel variant adults previously vaccinated with 3 doses of mRNA vaccines [****] prior to enrollment (now Study 313).

3.2.11 Subtask: Higher Dose Booster Safety and Immunogenicity Study (Novavax 205)

A new study will be conducted in adults to evaluate whether higher antigen doses of monovalent and bivalent vaccines produce better immune responses than the current [****] μ g dose.

Population: Adults over the age of 50 with >2 prior doses of mRNA vaccine [****] prior to enrollment.

Intervention: Randomized into one of 8 study arms.

- Prototype at [****]ug.
- XBB.1.5 at [**]ug or [****]ug or [****]ug of antigen.
- Bivalent at [****]+[****]ug or [**]+[**]ug or [****]+[****]ug of antigen.
- mRNA arm (if available).

Outcomes/Measures: Comparing low, medium, and high dose groups.

- Reactogenicity for [****] following vaccination and additional safety data through end of study.
- Magnitude and breadth of immune response by IgG and pseudoneutants to vaccine (prototype and BA.5) and forward drift variants.

3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Subtask: Mouse Study, Immunogenicity

Study 702-100. [*****] in mice for vaccine efficacy profile to comply with FDA guidelines.

3.3.2 Subtask: Rhesus Study, Immunogenicity

Study 702-099. [*****] in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Subtask: Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster [*****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Subtask: Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice [*****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Subtask: Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster [*****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Subtask: Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster [*****] for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Subtask: Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Subtask: Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (Cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Subtask: Neutralizing Assay Histopathology for On-going [***]**

Histopathology readings for current neutralization studies in [*****] This will support the safety profile of the vaccine for FDA approval.

3.3.10 Subtask: Mouse Study, Immunogenicity [***] Studies**

Individual immunogenicity studies [*****] in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.3.11 Subtask: Durability of NVX-CoV-2373 Vaccine Immunity and SARS-CoV-2 Protection at [***] in Rhesus Macaques**

Study 702-110. This study is designed to evaluate the long-term immunogenicity and protective efficacy of NVX-CoV-2373 nanoparticle vaccine when administered with Matrix-MTM by IM injections on Study Days 0 and 21, to Non-Human Primates (NHP). Each study group will contain [*****] NHPs (***** per sex). Blood samples will be collected prior to vaccination and at multiple time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at [****] following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.3.12 Subtask: Immunogenicity and Protective Efficacy of Sub-Protective Doses of NVX-CoV-2373 in Rhesus Macaques

Study 702-111. This study is designed to evaluate the immunogenicity and protective efficacy of sub-optimal doses of NVX-CoV-2373 nanoparticle vaccine administered with a fixed dose of Matrix-MTM by IM injections on Study Days 0 and 21, to NHPs. Each study group will contain [*****] NHPs ([**] per sex). Blood samples will be collected prior to vaccination and at various time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at [**] following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the USG team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type / Data Rights
Manufacturing						
4.01	[*****]	[*****]	5.01	3.1.1	Reviewer	[*****]
4.02	[*****]	[*****]	5.02	3.1.2	Reviewer	[*****]
4.03	[*****]	[*****]	5.03	3.1.3	Reviewer	[*****]
4.04	[*****]	[*****]	5.04	3.1.4	Reviewer	[*****]
4.05	[*****]	[*****]	5.05	3.1.5	Reviewer	[*****]
4.06	[*****]	[*****]	5.06	3.1.6	Reviewer	[*****]
4.07	[*****]	[*****]	5.07	3.1.7	Reviewer	[*****]
4.07a	[*****]	[*****]	5.07a	3.1.8	Reviewer	[*****]
4.07b	[*****] ¹	[*****]	5.07b	3.1.8	Reviewer	[*****]
Clinical						
4.08	[*****]	[****]	5.08	3.2.1.1	Reviewer	[****] ²
4.08a	[*****]	[****]	5.08	3.2.9	Reviewer	[****]

¹ [*****]

² As used herein, "Government Purpose Rights" has the meaning set forth in Article XI, Section 11.01(9) of the Base Agreement, as modified by Section 8.2(b) below.

4.08b	[*****]	[*****]	5.08	3.2.10	Reviewer	[*****]
4.08c	[*****]	[*****]	5.08	3.2.11	Reviewer	[*****]
4.09	Reserved					
4.10	Reserved					
4.11	Reserved					
4.12	[*****]	[*****]	5.12	3.2.5	Reviewer	[*****]
4.13	Reserved					
4.14	[*****]	[*****]	5.14	3.2.7	Reviewer	[*****]
4.15	[*****]	[*****]	5.15	3.2.1.2 3.2.8	Reviewer	[*****]
Non- Clinical						
4.16	[*****]	[*****]	5.16	3.3.1	Reviewer	[*****]
4.17	[*****]	[*****]	5.17	3.3.2	Reviewer	[*****]
4.18	[*****]	[*****]	5.18	3.3.3	Reviewer	[*****]
4.19	[*****]	[*****]	5.19	3.3.4	Reviewer	[*****]
4.20	[*****]	[*****]	5.20	3.3.5	Reviewer	[*****]
4.21	[*****]	[*****]	5.21	3.3.6	Reviewer	[*****]
4.22	[*****]	[*****]	5.22	3.3.7	Reviewer	[*****]
4.23	[*****]	[*****]	5.23	3.3.8	Reviewer	[*****]
4.24	[*****]	[*****]	5.24	3.3.9	Reviewer	[*****]
4.25	[*****]	[*****]	5.25	3.3.10	Reviewer	[*****]
4.26	[*****]	[*****]	5.26	3.3.11	Reviewer	[*****]
4.27	[*****]	[*****]	5.27	3.3.12	Reviewer	[*****]
Regulatory Affairs						
4.28	[*****]	[*****]	5.28	3.4.1	Reviewer	[*****]
4.29	[*****]	[*****]	5.29	3.4.2	Reviewer	[*****]
4.30	[*****]	[*****]	5.30	3.4.3	Reviewer	[*****]
Project Management						
4.31	[*****]	[*****]	5.31	3.5	Reviewer	[*****]
4.32	[*****]	[*****]	5.32	3.5.1	Reviewer	[*****]
4.33	[*****]	[*****]	5.33	3.5.2	Reviewer	[*****]
4.34	[*****]	[*****]	5.34	3.5.3	Reviewer	[*****]
4.35	[*****]	[*****]	5.35	3.5.4	Reviewer	[*****]
4.36	[*****]	[*****]	5.36	3.5.4	Reviewer	[*****]
4.36a	[*****]	[*****]	5.36a	3.5.4	Reviewer	[*****]
4.36b	[*****]	[*****]	5.36b	3.5.4	Reviewer	[*****]
4.37	[*****]	[*****]	5.37	3.5.5	Reviewer	[*****]
4.38	[*****]	[*****]	5.35	N/A	Reviewer	[*****]
TBD	[*****]	[*****]	Option 1	3.6	Reviewer	[*****]

Note 1: Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with deliverables under this project.

Note 2: The USG agrees to permanently transfer USG material, in the form of mutually agreed upon quantities of Clinical Drug Substance/Product, to Novavax for its own use in related drug trials. To enable the foregoing, the USG transfers all its right, title and interest in and to the Clinical Drug Substance/Product to Novavax. In consideration of such right, Novavax agrees (a) that Novavax shall [*****][*****]; (b) that Novavax agrees to [*****]; and, (c) Novavax will, upon reasonable request from the USG, obtain and share data from the use of the Clinical Drug Substance/Product, in a mutually agreed upon format. All transfers of material produced under the project, shall obtain prior written approval by the Government, with material quantities, destinations, applications, and USG benefits clearly delineated in a mutually agreed upon format.

5.0 MILESTONE PAYMENT SCHEDULE

The milestones below are for reference and costs for the project will be invoiced monthly on a cost reimbursable basis as the work progresses.

MS #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
	Manufacturing	[*****]	[*****]
5.01	[*****]	[*****]	[*****]
5.02	[*****]	[*****]	[*****]
5.03	[*****]	[*****]	[*****]
5.04	[*****]	[*****]	[*****]
5.05	[*****]	[*****]	[*****]
5.06	[*****]	[*****]	[*****]
5.07	[*****]	[*****]	[*****]
5.07a	[*****]	[*****]	[*****]
5.07b	[*****]	[*****]	[*****]
5.07c	[*****]	[*****]	[*****]
5.07d	[*****]	[*****]	[*****]
5.07e	[*****]	[*****]	[*****]
	Clinical		[*****]
5.08	[*****]	[*****]	[*****]
5.08a	[*****]	[*****]	[*****]
5.08b	[*****]	[*****]	[*****]
5.08c	[*****]	[*****]	[*****]
5.09	[*****]		[*****]
5.10	Reserved		[*****]

5.11	Reserved		[*****]
5.12	[*****]	[*****]	[*****]
5.13	[*****]		[*****]
5.14	[*****]	[*****]	[*****]
5.15	[*****]	[*****]	[*****]
	[*****]		[*****]
5.16	[*****]	[*****]	[*****]
5.17	[*****]	[*****]	[*****]
5.18	[*****]	[*****]	[*****]
5.19	[*****]	[*****]	[*****]
5.20	[*****]	[*****]	[*****]
5.21	[*****]	[*****]	[*****]
5.22	[*****]	[*****]	[*****]
5.23	[*****]	[*****]	[*****]
5.24	[*****]	[*****]	[*****]
5.25	[*****]	[*****]	[*****]
5.26	[*****]	[*****]	[*****]
5.27	[*****]	[*****]	[*****]
	Regulatory Affairs		[*****]
5.28	[*****]	[*****]	[*****]
5.29	[*****]	[*****]	[*****]
5.30	[*****]	[*****]	[*****]
	Project Management		[*****]
5.31	[*****]	[*****]	[*****]

5.32	[*****]	[*****]	[*****]
5.33	[*****]	[*****]	[*****]
5.34	[*****]	[*****]	[*****]
5.35	[*****]	[*****]	[*****]
5.36	[*****]	[*****]	[*****]
5.36a	[*****]	[*****]	[*****]
5.36b	[*****]	[*****]	[*****]
5.37	[*****]	[*****]	[*****]
5.38	[*****]	[*****]	[*****]
Reservation Fees			
5.39	[*****]	[*****]	[*****]
5.40	[*****]	[*****]	[*****]
5.41	[*****]	[*****]	[*****]
Total (Cost Plus Fixed Fee)		\$1,800,670,981	
Period of Performance (July 6, 2020 – March 31, 2024)		45 Months (Base)	
Option 1: Follow-On Production		Cost: [*****]	

¹[*****]

[*****]
[*****]
[*****]

²[*****]
[*****]
[*****]
[*****]
[*****]
[*****]
[*****]

³[*****]
The USG and Novavax agree that billable costs for the duration of the agreement will not exceed the total amount of \$1,800,670,981, as shown in the functional areas set forth in the table below. Novavax acknowledges that any costs above the contract ceiling amounts, to include potential indirect rate adjustments, will be the sole responsibility of Novavax. Any and all milestone payments will be paid ONLY if activities are completed within the current period of performance, ending March 31, 2024.

Functional Area	Ceiling
Manufacturing	[*****]
Clinical	[*****]

Non-Clinical	[*****]
Regulatory Affairs	[*****]
Project Management	[*****]
Total:	\$1,800,670,981

6.0 INSPECTION, ACCEPTANCE, SHIPPING, AND DELIVERY PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR. Further details are provided below.

A. Inspection. Quality inspection of Filled Drug Product (FDP) shall occur when Novavax performs release testing, in order to confirm that the product complies with Novavax's release specifications and criteria. Novavax will submit the Certificate of Analysis, Certificate of Compliance, examples of actual printed labels with lot number, and examples of printed carton labels for quality inspection of all drug product lots via the BARDA Data Infrastructure (BDI) system.

B. Delivery and Acceptance. Novavax shall notify the AOR (via update to BARDA-managed inventory system) at least [*****] prior to initial delivery of NVX-CoV-2373 product. Exceptions are permitted if approved by the AOR. Upon notification, the AOR will instruct Novavax to deliver doses either to VMI or one or more, centralized USG-designated distribution sites within the USA.

Upon delivery of product, notification of delivery quantities shall be made to the AOR via the Dose Tracking Tool in accordance with the reporting requirements. Both parties acknowledge that doses delivered under this agreement are intended for clinical use or use under an EUA or a BLA (once such EUA or BLA is received).

Upon receipt of the provided certificates and any inspection of product at the destination site(s) that was timely requested (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection. Inspections may be made by the AOR or a duly authorized USG representative. The USG shall accept or reject product (through the BARDA-managed inventory system) that conforms to agreement requirements based on Certificates of Analysis and Certificate(s) of Compliance, provided by Novavax, and review of temperature monitoring data. The AOR will correspondingly notify Novavax of acceptance or rejection. However, the USG's acceptance of product will be deemed to have occurred if the USG does not provide written notice of acceptance or rejection within [*****] of Novavax's provision of all applicable certificates.

C. Vendor Managed Inventory. Product to be stored as VMI will be shipped to [*****], in order to enable shipment to designated site(s). When held in VMI, these materials will be

maintained in Novavax's or its designated representative's quality and inventory systems. Product held in VMI is subject to the following requirements:

- i. Provide temperature controlled storage at the manufacturer's site, approved by the USG, according to cGMP and product specifications.
- ii. Where possible, store agreement products physically segregated from other products. If physical separation is not possible, separation of agreement products must be controlled by a logical Warehouse Management System (WMS) at the case and pallet level.
- iii. Ensure proper labeling of stored materials as USG property.
- iv. Provide the USG access to review the security systems in place and request updates as needed, in accordance with the Security Plan.
- v. Include in the Government's dose tracking tool, inventory for drug product (number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result, and the current expiration date (if applicable).
- vii. Conduct testing necessary to ensure continued use of the stored material for pandemic response.
- vii. Make appropriate updates to the regulatory documentation, supporting the continued use of the stored material for pandemic response.
- viii. If using a storage site, provide the quality agreement, specify the location and terms of the storage contract.

For accepted product in VMI, Novavax must notify the AOR of any proposed movement of the product within the BARDA-managed inventory tracking system. Any deviations, Out of Specification (OOS) results, or other product issues, shall be reported to the USG within [*****] of Novavax identification.

D. Government Sites. Product to be shipped to USG-designated distribution sites shall be shipped trackable by GPS. Novavax will include the following information on the packing lists provided with bulk shipments to the centralized depots:

- i. Transaction Information (TI)
- ii. Transaction History (TH)

iii. Transaction Statement (TS)

iv. Centers for Disease Control (CDC) Purchase Order (PO) Number

Novavax will also transmit bulk shipment Advance Shipment Notices (ASN) to the CDC via Electronic Data Interchange (EDI).

E. Title and Physical Risk of Loss. Title to product will transfer upon [*****] Novavax will [*****]. If product is initially delivered to a [*****], risk of loss will transfer upon [*****].

Novavax will notify the AOR (via e-mail or phone) of any storage or quality deviation for product held in VMI, within [*****]. To the extent that Novavax is responsible for the correction, repair or replacement of USG property held in VMI, and replacement upon loss or damage of such product is feasible, the USG will accept replacement of such property.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV-2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV-2373, as well as its sf9/baculovirus manufacturing platform, (all "Background IP") through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov-2373 manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes (collectively "Background Know-How"), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated using, the Background Know-How (collectively, "Background Data"), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents ("Background Materials"). On June 8, 2020, Novavax and the U.S. Department of Defense entered into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV-2373 which acknowledged Background IP and made no explicit U.S. Government claims to Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax's prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) Background IP License to Novavax. Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) Ownership. Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing ("Foreground IP").

(b) Foreground IP Special License. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government ("Foreground IP Special License").

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

8.2 Rights to Data.

(a) Subject Data. Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)³ after three (3) years from the date of delivery. As used herein, "Subject Data" shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) Transfer of Data. Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

(c) Background IP Limited License. To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus (the "Technology"). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c),

³ As used herein, "Government Use" as used "Purpose Rights" has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

Novavax agrees to the following:

- a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA.
- b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.
- c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

a. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

- i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:

- a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;
- b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or
- c. any filing that anticipates Federal bankruptcy protection; and

- ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application under the provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

- i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV-2373 vaccine;
- ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-CoV-2373 and any confirmatory instrument pertaining thereto; and
- iii. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11.0 SECURITY

The security classification level for this effort is UNCLASSIFIED. Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with the execution of this project.

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

14.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: ****

EMAIL: ****

PHONE: ****

AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-Enabling Biotechnologies (JPEO, JPL-EB)

Alternate AOR

NAME: ****

EMAIL: ****

PHONE: ****

AGENCY NAME/DIVISION/SECTION: Health and Human Services, Biomedical Advanced Research Development Authority (HHS/BARDA)

ENCLOSURE 3: (SUPERSEDED)

N/A – This enclosure has been superseded from the original and is no longer applicable.

FOR OFFICIAL USE ONLY / PROCUREMENT SENSITIVE
143838348_2

ENCLOSURE 4: PATENT LISTING

[Pursuant to Regulation S-K, Item 601(a)(5), this enclosure setting forth the patent listing has not been filed. The Registrant agrees to furnish supplementally a copy of any omitted exhibits to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.]

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FOR OFFICIAL USE ONLY / PROCUREMENT SENSITIVE
143838348_2

Attachment 1:

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

**EMERGENCY USE AUTHORIZATION (EUA) OF
THE NOVAVAX COVID-19 VACCINE, ADJUVANTED TO PREVENT
CORONAVIRUS DISEASE 2019 (COVID-19)**

You are being offered the Novavax COVID-19 Vaccine, Adjuvanted to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The Novavax COVID-19 Vaccine, Adjuvanted has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide:

- a two-dose primary series to individuals 12 years of age and older.
- a first booster dose to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:
 - individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent¹ COVID-19 booster vaccine is not accessible or clinically appropriate,
 - individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, John C. Jacobs, certify that:

I have reviewed this Quarterly Report on Form 10-Q of Novavax, Inc.;

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2024 By: /s/ John C. Jacobs
John C. Jacobs
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, James P. Kelly, certify that:

- 1) I have reviewed this Quarterly Report on Form 10-Q of Novavax, Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2024

By: /s/ James P. Kelly -

James P. Kelly
Executive Vice President, Chief
Financial Officer and Treasurer

Exhibit 32.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO 18 UNITED STATES CODE §1350
(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)**

In connection with the Quarterly Report of Novavax, Inc. (the "Company") on Form 10-Q for the fiscal period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John C. Jacobs, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the dates and periods covered by this Report.

Date: May 10, 2024 By: /s/ John C. Jacobs
John C. Jacobs
President and Chief Executive Officer

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Company specifically incorporates it by reference.

Exhibit 32.2

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 UNITED STATES CODE §1350
(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)**

In connection with the Quarterly Report of Novavax, Inc. (the "Company") on Form 10-Q for the fiscal period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James P. Kelly, Executive Vice President and Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the dates and periods covered by this Report.

Date: May 10, 2024 By:/s/ James P. Kelly

James P. Kelly
Executive Vice President, Chief Financial Officer,
and Treasurer

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Company specifically incorporates it by reference.