# UNITED STATES DISTRICT COURT DISTRICT OF MARYLAND

\_\_\_\_\_, Individually and on Behalf of All Others Similarly Situated,

Case No.

Plaintiff,

CLASS ACTION COMPLAINT

v.

NOVAVAX, INC., JOHN C. JACOBS and JIM KELLY,

Defendants.

# JURY TRIAL DEMANDED

Plaintiff \_\_\_\_\_\_ ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff s undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Novavax, Inc. ("Novavax" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Novavax securities between March 1, 2022 and October 15, 2024 both dates inclusive (the "Class Period"), seeking

to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Novavax is a biotechnology company that promotes improved global health through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases.

3. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company materially overstated its prospects of its Investigational New Drug ("IND") application for its COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates; (ii) the foregoing was reasonably likely to have a material negative impact on the Company's revenue; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

4. On October 16, 2024, Novavax issued a press release "announc[ing] that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on Novavax's (NVAX) Investigational New Drug (IND) application for its COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates." Novavax specified that "[t]he clinical hold is due to a spontaneous report of a serious adverse event (SAE) of motor neuropathy in a single CIC Phase 2 trial participant outside of the U.S. who received the vaccine in January 2023" and "reported the SAE in September 2024."

On this news, Novavax's stock price fell sharply during intraday trading on October
 16, 2024.

6. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

#### JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

This Court has jurisdiction over the subject matter of this action pursuant to 28
 U.S.C. § 1331 and Section 27 of the Exchange Act.

9. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Novavax is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

10. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

### **PARTIES**

11. Plaintiff, as set forth in the attached Certification, acquired Novavax securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

12. Defendant Novavax is a Delaware corporation with principal executive offices located at 700 Quince Orchard Road, Gaithersburg, Maryland. Novavax's common stock trades in an efficient market The NASDAQ ("NASDAQ") under the ticker symbol "NVAX".

Defendant John C. Jacobs ("Jacobs") has served as the Company's Chief Executive
 Officer ("CEO") and President at all relevant times.

14. Defendant Jim Kelly ("Kelly") has served as the Company's Chief Financial Officer ("CFO"), Executive Vice President, and Treasurer at all relevant times.

15. Defendants Jacobs and Kelly are sometimes referred to herein as the "Individual Defendants."

16. The Individual Defendants possessed the power and authority to control the contents of Novavax's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Novavax's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Novavax, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

17. Novavax and the Individual Defendants are collectively referred to herein as "Defendants."

# **SUBSTANTIVE ALLEGATIONS**

## **Background**

18. Novavax is a biotechnology company that promotes improved global health through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases.

## Materially False and Misleading Statements Issued During the Class Period

19. The Class Period began on March 1, 2022, when Novavax filed an annual report on

Form 10-K with the SEC, reporting the Company's financial and operational results for the year

ended December 31, 2021. In that report, Novavax stated, in relevant part, as follows:

In October 2021, we completed enrollment of our Phase 1/2 study in Australia, which we initiated in September 2021. The trial enrolled 642 healthy adults aged 50 to 70 years across 10 sites and will evaluate the safety, tolerability and immune response of a combination vaccine using NanoFlu Program and NVX-CoV2373, combined with our Matrix- $M^{TM}$  adjuvant. Participants have been either previously infected with the SARS-CoV-2 virus that causes COVID-19 or vaccinated through an authorized vaccine at least eight weeks prior to enrollment. All participants will be randomly assigned to cohorts to evaluate multiple formulations and will be administered doses on Day 0 and again at Day 56. Data from this Phase 1/2 trial are expected in the second quarter of 2022. Data from this Phase 1/2 trial are expected in April of 2022. We expect to initiate a Phase 2 clinical trial for the COVID-Influenza combination vaccine and NanoFlu Program as a standalone vaccine in the second half of 2022.

In May 2021, we announced data from a preclinical study of qNIV/CoV2373 to assess its immunogenicity and protective efficacy in animal models. Preclinical data from this study showed that qNIV/CoV2373 induced functional influenza and COVID-19 antibody responses, with hemagglutination inhibition and ACE2 receptor-inhibiting titers that were comparable between immunization with the combination vaccine and with its respective component vaccines. qNIV/CoV2373 also induced elevated levels of SARS-CoV-2 anti-S IgG two weeks after the first immunization, which increased significantly after the second dose, with levels comparable to animals that received NVX-CoV2373 alone. Human ACE2 receptor inhibiting antibody levels responded similarly. qNIV/CoV2373 also induced antibodies against SARS-CoV-2 neutralizing epitopes that are common between the original COVID-19 strain and the Beta (B.1.351) variant strain. When challenged with SARS-CoV-2, examination of viral load in the upper and lower respiratory tract showed little or no virus was detected four days after infection in

animals immunized with either qNIV/CoV2373 or with NVX-CoV2373 alone. Data from this study are available ahead of publication via the preprint server for biology on bioRxiv.

20. On February 28, 2023, Novavax filed an annual report on Form 10-K with the SEC,

reporting the Company's financial and operational results for the year ended December 31, 2022.

In that report, Novavax stated, in relevant part, as follows:

Our clinical pipeline encompasses vaccine candidates spanning multiple therapeutic areas, with our COVID-19 vaccine, NVX-CoV2373, as our lead product, which has received approval, interim authorization, provisional approval, CMA, or EUA for both adult and adolescent populations in over 40 countries. We advanced NVX-CoV2373 through two pivotal Phase 3 clinical trials that demonstrated high efficacy against both the original COVID-19 strain and commonly circulating COVID-19 variants, while maintaining a favorable safety profile. Beyond COVID-19, our clinical pipeline encompasses seasonal influenza and CIC vaccine, in addition to providing Matrix-MTM adjuvant for collaborations investigating the prevention of malaria.

We are developing our quadrivalent nanoparticle influenza vaccine ("qNIV") candidate, previously known as NanoFlu, which we advanced through a successful Phase 3 study published in September 2021, demonstrating the utility for a standalone influenza vaccine or for use in a combination vaccine. We have subsequently updated our qNIV for further development. We continue to progress in a Phase 2 trial our stand-alone influenza vaccine candidate, qNIV and our CIC vaccine candidate, which combines NVX-CoV2373 and our updated qNIV approach in a single formulation. In October 2022, we announced positive results from the Phase 1/2 CIC clinical trial demonstrating the CIC vaccine's ability to generate both antibody and polyfunctional CD4+ T-cell (lymphocytes that help coordinate the immune response) responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and homologous and heterologous influenza strains. In December 2022, we initiated a Phase 2 CIC dose-refinement trial that also includes further stand-alone updated qNIV evaluation.

In addition to COVID-19 and seasonal influenza, we remain interested in continuing the development of both our RSV Program for respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate ("RSV F Vaccine") and Matrix-M<sup>TM</sup> adjuvant collaborations for malaria. An ongoing Phase 3 trial is being conducted for R21, a malaria candidate, by our partner, the Jenner Institute, University of Oxford, which is formulated with our Matrix-M<sup>TM</sup> adjuvant.

21. On February 28, 2024, Novavax filed an annual report on Form 10-K with the SEC,

reporting the Company's financial and operational results for the year ended December 31, 2023.

In that report, Novavax stated, in relevant part, as follows:

On November 2023, we shared that we previously evaluated 11 discrete CIC formulations in our Phase 2 dose-confirming trial, in which we then selected the CIC dose formulation and remain on track to initiate the Phase 3 trial. We also observed a favorable reactogenicity profile with our combination vaccine that was clinically indistinguishable from the licensed influenza vaccine comparators. This preliminary data suggests that our technology can increase the antigen load while maintaining acceptable tolerability. Pending regulatory concurrence from the U.S. FDA, we expect to initiate a pivotal Phase 3 trial for our CIC vaccine candidate in the second half of 2024, with potential accelerated approval and launch in the fall of 2026.

In May 2023, we announced preliminary topline data from our Phase 2 trial for CIC, stand-alone influenza, and high-dose COVID-19 vaccine candidates. All three vaccine candidates contain our Matrix- $M^{TM}$  adjuvant, showed preliminary robust immune responses, reassuring safety profiles, and reactogenicity that was comparable to the licensed influenza vaccine comparator arms. The Phase 2 dose-confirming randomized, observer-blinded trial evaluated the safety and effectiveness (immunogenicity) of different formulations of the CIC and influenza vaccine candidates, and higher doses of Novavax's COVID-19 vaccine in 1,575 adults aged 50 through 80 years. The CIC vaccine candidate achieved both anti-SARS-CoV-2 immunoglobulin G (IgG) and neutralizing levels comparable to our prototype vaccine. In addition, several of the combination formulations achieved responses to both SARS-CoV-2 and to the four homologous influenza strains that were comparable to the reference comparators, supporting their prioritization for advanced development.

22. The statements referenced in  $\P$  19-21 were materially false and misleading because

Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company materially overstated its prospects of its Investigational New Drug ("IND") application for its COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates; (ii) the foregoing was

reasonably likely to have a material negative impact on the Company's revenue; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

### **The Truth Emerges**

23. On October 16, 2024, Novavax issued a press release "announc[ing] that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on Novavax's (NVAX) Investigational New Drug (IND) application for its COVID-19-Influenza Combination (CIC) and stand-alone influenza vaccine candidates." Novavax specified that "[t]he clinical hold is due to a spontaneous report of a serious adverse event (SAE) of motor neuropathy in a single CIC Phase 2 trial participant outside of the U.S. who received the vaccine in January 2023" and "reported the SAE in September 2024."

24. On this news, Novavax's stock price fell sharply during intraday trading on October16, 2024.

25. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

#### PLAINTIFF'S CLASS ACTION ALLEGATIONS

26. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the Company's securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

27. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Novavax securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Novavax or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

28. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

29. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

30. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Novavax;
- whether the Individual Defendants caused Novavax to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Novavax securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

31. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

32. Plaintiff will rely, in part, upon the presumption of reliance established by the fraudon-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Novavax securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Novavax securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 33. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a

presumption of reliance upon the integrity of the market.

34. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v*. *United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

### <u>COUNT I</u>

# (Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

35. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

36. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

37. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Novavax securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Novavax securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

38. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Novavax securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Novavax's finances and business prospects.

39. By virtue of their positions at Novavax, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

40. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Novavax, the Individual Defendants had knowledge of the details of Novavax's internal affairs.

41. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of

Novavax. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Novavax's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Novavax securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Novavax's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Novavax securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

42. During the Class Period, Novavax securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Novavax securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Novavax securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Novavax securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

43. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

44. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

### COUNT II

## (Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

45. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

46. During the Class Period, the Individual Defendants participated in the operation and management of Novavax, and conducted and participated, directly and indirectly, in the conduct of Novavax's business affairs. Because of their senior positions, they knew the adverse non-public information about Novavax's misstatement of income and expenses and false financial statements.

47. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Novavax's financial condition and results of operations, and to correct promptly any public statements issued by Novavax which had become materially false or misleading.

48. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and

public filings which Novavax disseminated in the marketplace during the Class Period concerning Novavax's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Novavax to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Novavax within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Novavax securities.

49. Each of the Individual Defendants, therefore, acted as a controlling person of Novavax. By reason of their senior management positions and/or being directors of Novavax, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Novavax to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Novavax and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

50. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Novavax.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule
23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and postjudgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

# **DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: \_\_\_\_\_, 2024