EX-10.4 5 nvax-20200930xex10d4.htm EX-10.4

Exhibit 10.4

CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

SUPPLY AND LICENSE AGREEMENT

BETWEEN

SERUM INSTITUTE OF INDIA PRIVATE LIMITED

AND

NOVAVAX, INC.

Dated: 30 July, 2020

SUPPLY AND LICENSE AGREEMENT

This Supply and License Agreement (the "Agreement") is entered into and made effective as of July 30, 2020 (the "Effective Date"), by and between Serum Institute of India Private Limited., an Indian company having its principal place of business at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028 ("SIIPL", which expression shall, unless repugnant to the context thereof, mean and include its successors and permitted assigns), and Novavax, Inc., a Delaware, USA corporation having its principal place of business at 21 Firstfield Road, Gaithersburg, MD 20878 USA ("Novavax", which expression shall, unless repugnant to the context thereof, mean and include its Affiliates). Novavax and SIIPL may each be referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Novavax has developed and is the exclusive owner of NVX-CoV2373 ("Drug Substance") and Matrix-M[™] ("Adjuvant") which are collectively referred to as the ("Vaccine Components");

WHEREAS, SIIPL is a global vaccine manufacturer specializing in life saving vaccines;

WHEREAS, SIIPL desires to use the Vaccine Components and Licensed Know-How to Develop, Manufacture, and Commercialize by SIIPL a vaccine product derived from a coformulation of the Vaccine Components (not as a combination product with any other active ingredient), and use such vaccine product in the Field (hereinafter referred to as the "Product");

WHEREAS, subject to the terms of this Agreement, Novavax agrees to (a) continuously supply to SIIPL Vaccine Components as per the Forecast requirement of SIIPL in the SIIPL Territory, (b) grant to SIIPL an exclusive license in the SIIPL Exclusive Territory (defined hereunder) to use the Vaccine Components to enable SIIPL to Manufacture, and Commercialize the Product, (c) grant to SIIPL a nonexclusive license in the SIIPL Non- Exclusive Territory (defined hereunder) to use the Vaccine Components to enable SIIPL to Manufacture, and Commercialize the Product, and (d) provide to SIIPL that Licensed Know- How Controlled by Novavax or its Affiliates (including the improvements if any), in accordance with the terms and conditions of this Agreement.

NOW THEREFORE, SIIPL AND NOVAVAX AGREE AS FOLLOWS:

ARTICLE 1.DEFINITIONS

Capitalized terms used in this Agreement will have the meaning ascribed to them in the preamble and recitals to this Agreement above, Appendix A, or otherwise as defined in this Agreement below.

ARTICLE 2. SUPPLY AND OTHER RESPONSIBILITIES

2.1 Supply.

- a. Supply of Vaccine Components to SIIPL. During the Term, Novavax will supply to SIIPL its requirements of Vaccine Components as per a Forecast to Manufacture and Commercialize the Product in the SIIPL Territory. Vaccine Components shall be in mutually acceptable standard fill volumes, concentration, and bulk packaging and meet other specifications and requirements set forth in a Quality Agreement to be negotiated and executed by the Parties within [***] of the Effective Date (the "Vaccine Component Specifications").
- **b.** Transfer of Licensed Know-How to SIIPL. Novavax will provide to SIIPL all of the Licensed Know-How to the extent necessary to Manufacture and Commercialize the Product in the SIIPL Territory.
- **c. Pharmacovigilance Agreement.** Prior to SIIPL's commencement of Development and Commercialization of the Product in the SIIPL Territory, the Parties will negotiate and enter into a safety reporting agreement on customary, commercially reasonable and mutually agreeable terms.

2.2 Safety Stock.

Subject to the last sentence of this Section 2.2, Novavax shall establish a safety stock of the Vaccine Components and shall thereafter maintain such safety stock exclusively available to SIIPL in quantities [***] (the "Safety Stock"). Novavax shall keep SIIPL [***] informed of the level of the Safety Stock. If the Safety Stock drops below [***], Novavax shall use [***] to replenish the Safety Stock [***]. [***] Parties agree that the quantity of Vaccine Components to be kept in the Safety Stock shall be [***].

2.3 Product Branding.

SIIPL will have [***] with respect to, the creation, development, selection, and approval of all trademarks and trade dress under which the Product is Commercialized in the SIIPL Territory, provided that SIIPL will [***] on all substantive matters relating to the creation, development, selection, and approval of the trademarks and trade dress to be used in the Commercialization of the Product in the SIIPL Territory, and will [***] with respect thereto. In addition, SIIPL will have [***] with respect to, filing, prosecuting, registering, maintaining, and protecting the trademarks and trade dress to be used to Commercialize the Product in the SIIPL Territory at [***] costs and expense.

2.4 Responsibilities of Novavax.

a. Supply of Vaccine Components. During the Term, Novavax will have [***] with respect to obtaining and maintaining the facilities and necessary raw materials, equipment, qualified personnel, Regulatory Approvals, licenses, and permits, to

Manufacture and deliver to SIIPL the Vaccine Components in accordance with this Agreement. Novavax will solely be responsible for all vendors, employees, contractors, and other Persons employed or engaged by it to Manufacture the Vaccine Components. Novavax will provide to SIIPL [***] necessary to enable SIIPL to formulate the components of the Vaccine Components (i.e. the Drug Substance and the Adjuvant), [***], so as to enable SIIPL to formulate the Vaccine Components and Manufacture the Product.

b. Novavax Improvements. In the event Novavax makes any Novavax Improvements during the Term to the Vaccine Components, the same shall be provided to SIIPL [***] under the terms and conditions agreed herein this Agreement.

2.5 Responsibilities of SIIPL.

- a. Manufacture of the Product. Subject to and as further described in Sections 2.5.b. and 2.5.c., SIIPL will have [***], and shall use its [***], with respect to obtaining and maintaining the facilities and all necessary raw materials, equipment, qualified personnel, Regulatory Approvals, licenses, and permits to Develop and Manufacture the Product as necessary to perform its obligations under this Agreement within the SIIPL Territory. SIIPL will solely be responsible for all vendors, employees, contractors, and other Persons employed or engaged by it, and all costs and expenses incurred, in the performance of such obligations. Notwithstanding the previous, SIIPL agrees to provide rights of access to regulatory files related to countries that at any time during the Term belonged in the SIIPL Non-Exclusive Territory and agrees to work in collaboration with Novavax or its designee. SIIPL and Novavax, including any of their licensees agree that in no case will it use a permit, a regulatory licenses or a contractual arrangement as a means of preventing the other Party or any of its licensees from Developing, Manufacturing and/or Commercializing the Product in the SIIPL Non-Exclusive Territory.
- **b. Development of the Product**. SIIPL will have [***] with respect to the Development of the Product throughout the SIIPL Territory, subject to and as further described in this Section 2.5.b. SIIPL will obtain and maintain all Regulatory Approvals required to Develop and Commercialize the

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Product throughout the SIIPL Territory. SIIPL will perform all Development of the Product (including all regulatory actions) in accordance with the written plan for such Development to be mutually agreed by the Parties [***] (the "Development Plan"). The Development Plan will include a [***] Development activities for the Product and approximate timelines for such activities, provided that such timelines are subject to change due to applicable timelines and requirements of Governmental Authorities, including for obtaining and maintaining permissions and other Regulatory Approvals. The Development Plan will include all Development activities necessary to file each BLA and to obtain and maintain all Regulatory Approvals to Commercialize the Product in each country in the SIIPL Territory and any other activities otherwise recommended or required by the applicable regulatory authority in any country in the SIIPL Territory to obtain or maintain such Regulatory Approvals. SIIPL will update the Development Plan [***], and will provide each such update to Novavax for review and approval. In addition, any such update shall be provided to the JSC in accordance with Section 2.7. SIIPL will incorporate all reasonable comments received from Novavax regarding Development activities for the Product that are relevant to obtaining or maintaining Regulatory Approvals to Commercialize the Product in any country in the SIIPL Territory.

- **Regulatory Activities.** Subject to and as further described in this Section 2.5.(c), SIIPL will have [***] with respect to all regulatory activities for the Product in the SIIPL Territory, including obtaining and maintaining, in its name or the name of its designee / Affiliates, all Regulatory Approvals, licenses, and permits required to Commercialize the Product in the SIIPL Territory, and any correspondence or meetings with regulatory authorities regarding any of the foregoing, provided that SIIPL shall give Novavax [***] notice that SIIPL will be providing any such submissions for Novavax' review, which review shall not unreasonably delay such filings, or as may be decided by the Parties mutually, in advance of SIIPL 's filing or submission thereof, and SIIPL will incorporate any reasonable comments received from Novavax into such regulatory submissions (including with respect to the inclusion or exclusion of Novavax' Confidential Information). SIIPL will conduct such regulatory activities in accordance with the thencurrent Development Plan. SIIPL will be solely responsible for all costs and expenses incurred by it to obtain and maintain such Regulatory Approvals required to Commercialize the Product in the SIIPL Territory. [***] Novavax will [***] and Novavax may, at either Party's request, participate in any meetings (in person or by teleconference) with any regulatory authority regarding any Regulatory Approval necessary to Commercialize the Product in the SIIPL Territory, [***].
- **d. Diligence Obligations**. SIIPL will perform all activities set forth in the Development Plan and use its [***] to perform all such activities in accordance with the applicable timeframes set forth in the Development Plan. In addition, SIIPL will use [***] to Develop and obtain Regulatory Approval for the Product in all countries in the SIIPL Territory.
- **2.6 Restrictions on Use.** SIIPL may use the Vaccine Components supplied by Novavax and the Licensed Know How under this Agreement solely to (i) Manufacture the Product in

the Field for the SIIPL Territory, (ii) conduct analytical and process development activities, and (iii) Commercialize the Product in the SIIPL Territory. SIIPL will not, and will cause its Affiliates and other Permitted Recipients not to, (a) attempt to reverse engineer the Vaccine Components or otherwise analyze, circumvent, or design around the Vaccine Components, or (b) sell the Vaccine Components to any third party. Notwithstanding the foregoing. Upon [***] notice to Novavax, SIIPL may transfer Vaccine Components to Affiliates. Further, SIIPL may transfer the Vaccine Components to third party manufacturers engaged to Manufacture of the Product ("Permitted Recipients") upon [***], provided that Permitted Recipients are bound by written restrictions on use and confidentiality no less stringent than those specified in this Agreement, and SIIPL remains liable to Novavax for such Permitted Recipient's use of Vaccine Components. Nothing set forth in this Agreement will limit Novavax' ability to Manufacture or supply Vaccine Components to any third party or to use the Vaccine Components for any other purposes.

2.7 Governance.

a. Joint Collaboration Steering Committee.

- **JSC Establishment.** As soon as practicable, but no later than [***] following the 1. Effective Date, the Parties will form a joint collaboration steering committee ("JSC") to monitor and coordinate the Exploitation of the Licensed Products throughout the SIIPL Territory. The JSC will be composed of [***] representatives from each Party and a minimum of [***] representatives of each Party who are fluent in English and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party of such replacement at least [***] prior to the next scheduled meeting of the JSC. Each Party will use [***] to keep an appropriate level of continuity in representation. The JSC will have a chairperson ("JSC Chairperson"). A designated representative of Novavax will be the JSC Chairperson until [***], and thereafter the JSC Chairperson will be selected alternately, [***], by SIIPL and then by Novavax. The JSC Chairperson will be responsible for setting the agenda for JSC meetings, with input from the other members, and for conducting the JSC meetings. The JSC will conduct its responsibilities hereunder in good faith and with reasonable care and diligence. Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the time frames set forth hereunder.
- **2. JSC Responsibilities.** The JSC will have oversight and information sharing responsibilities and functions with respect to the worldwide Development, Manufacture, Commercialization, and other Exploitation of the Products. The JSC will, amongst other duties and responsibilities:

- i) [***];
 ii) [***];
 iii) [***]; and
 iv) [***].
- 3. Global Allocation Tenets. The Parties are aware that Novavax is under a contractual arrangement with the Coalition for Epidemic Preparedness Innovations ("CEPI") under which Novavax has committed to sell [***] Product to a global allocation body endorsed by CEPI. Given the uncertainty associated with the global purchase of COVID-19 vaccine during the Pandemic Period, including the Product, the Parties agree that the JSC shall operate in full conformity with Novavax' obligations to CEPI and to the global allocation body it endorses. Furthermore, the Parties agree that during the Pandemic Period, for all Product for which the Drug Substance component has been Manufactured at any other location besides at a facility owned or controlled by SIIPL or an Affiliate, shall only be made available for purchase by the global allocation body endorsed by CEPI, currently expected to be the "COVAX Facility" or such other purchasing authority that Novavax in good faith represents has been endorsed and approved by CEPI. The JSC agrees to review and approve all such purchases during the Pandemic Period as directed by Novavax under its arrangement with CEPI.

b. JSC Meetings.

- 1. Meeting Agendas. Each Party will disclose to the other Party the proposed agenda items for each meeting of the JSC along with appropriate information at least [***] in advance of each such meeting; provided that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting. Each Party will submit to the JSC at least [***] prior to any meeting of the JSC all reports and other information required to be submitted by such Party to the JSC at such meeting under this Agreement.
- **Meetings.** The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than [***], unless otherwise agreed by the Parties. The JSC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method. [***] costs and expenses relating to attendance at and participation in any JSC meetings.
- **3. Meeting Minutes.** Within [***] following each meeting of the JSC, the chairperson of the JSC will cause to be prepared and will provide to the other Party a draft of [***] detailed written minutes describing all matters reviewed or considered by the JSC, together with all determinations made and actions taken by the JSC and a summary of the reasons therefor stated by the members at the meeting. The

minutes of any meeting of the JSC must be finalized by approval of the members of the JSC within [***] after the meeting. The minutes, including all drafts thereof, will be the Confidential Information of both Parties.

4. Non-Member Attendance. Each Party may from time to time invite a [***] number of participants (which may include legal counsel), in addition to its representatives, to attend a meeting of the JSC in a non-voting capacity, if such participants have expertise that is relevant to the planned agenda for such JSC meeting; provided that if a Party intends to have any third party (including any consultant) attend such a meeting, then such Party will provide [***] notice to the other Party reasonably in advance of such meeting and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 12 (Confidential Information). Notwithstanding anything to the contrary set forth in this Agreement, if the other Party objects in good faith to the participation of such third party in such meeting due to a bona fide concern regarding competitively sensitive information that is reasonably likely to be discussed at such meeting, then such third party will not be permitted to participate in such meeting (or the portion thereof during which such competitively sensitive information is reasonably likely to be discussed).

c. Decision Making.

- 1. General Process. The JSC will only have the powers expressly assigned to it in this Section 2.7 (Governance) and elsewhere in this Agreement and will not have the authority to: (a) [***]; or (b) [***]. All decisions of the JSC will be made [***]. No action taken at any meeting of the JSC will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached if [***] voting representatives of each Party are present or participating in such meeting.
- 2. Decisions of JSC. The JSC will use good faith efforts, in compliance with this Section 2.7.C.2 (Decisions of the JSC), to [***] resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter that is within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of [***], then a Party may refer such matter for resolution in accordance with Section 2.7.D.1 (Referral to Executive Officers) to the Chief Executive Officer of Novavax (or an executive officer of Novavax designated by the Chief Executive Officer of Novavax who has the power and authority to resolve such matter) and the Chief Executive Officer of SIIPL (or an executive officer of SIIPL designated by the Chief Executive Officer of SIIPL who has the power and authority to resolve such matter) (collectively, the "Executive Officers").

d. Resolution of JSC Disputes.

1. **Referral to Executive Officers.** If a Party makes an election under Section 2.7.C.2 (Decisions of the JSC) to refer a matter on which the JSC cannot reach a [***]

decision for resolution by the Executive Officers, then the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so referred to them [***], and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

- 2. Final Decision-Making Authority. If the Executive Officers are unable to reach agreement on any such matter referred to them within [***] after such matter is so referred (or such longer period as the Executive Officers may agree upon), then:
 - (i) [***] will have final decision making authority on all aspects related to [***];
 - (ii) [***] will have final decision making authority on all aspects related to [***]; or
 - (iii) In relation to [***], [***] will have the final decision making authority for that country.
- **e.** Limitations on Decision-Making. Notwithstanding anything to the contrary set forth in this Agreement, without the other Party's [***] consent, no decision of the JSC or a Party's Executive Officer (in the exercise of a Party's final decision making authority on any such matters), in each case, may [***].
- 2.8 Step in Rights of Novavax. Unless there is [***] in the event SIIPL is unable to fulfil its commitments towards supply of [***] volumes of the Product within a particular country in the SIIPL Territory ("Shortfall"), then, for each such case of Shortfall on a case-by-case and country-by-country bases, Novavax may provide SIIPL a written notice of [***] that if SIIPL is unable to remedy the **Shortfall within** said period of [***] ("**Shortfall Notice**"), then Novavax may, temporarily, step- in to manufacture and commercialize or cause the manufacture and commercialization of the remainder of the agreed volumes of the Product for that particular Shortfall. Once the agreed supply volumes have been achieved and the Shortfall has been remedied, Novavax shall cease forthwith from any further commercialization of Product within the applicable country in the SIIPL Territory and SIIPL shall resume all its rights and obligations towards manufacture and commercialize of the Product within the applicable country in SIIPL Territory. Nothing agreed herein shall be deemed or interpreted to affect the license rights granted to SIIPL hereunder for commercialisation of the Product within the SIIPL Territory, provided that if SIIPL is unable to remedy any Shortfall within [***] of receipt of the Shortfall Notice, then the Parties agree to mutually decide on the terms and conditions thereafter [***]. The Parties agree that during the any such [***] notice period to remedy any Shortfall, this Agreement shall otherwise continue to remain in force.

ARTICLE 3.FORECASTS AND ORDERS.

3.1 Forecast. Within [***] of the Effective Date, SIIPL will provide Novavax with a [***] forecast of SIIPL's anticipated demand for the Vaccine Components for Manufacture of the Product in SIIPL Territory (the "**Forecast**") for Novavax' review and acceptance. SIIPL will update such Forecast on a [***] basis within [***] for Novavax' review and

acceptance. The quantity specified for [***] of each Forecast accepted by Novavax (an "Accepted Forecast") will be binding upon both Parties and not subject to change (a "Firm Order"). Thereafter it is agreed that the subsequent [***] of each Accepted Forecast (the "Non-Binding Period") will be a good faith, non-binding estimate of the quantities of Vaccine Components required by SIIPL for the Manufacturing of the Product, provided that the forecasted volumes for [***] of the Non-Binding Period may not change by greater than [***]% for the same period.

- 3.2 Purchase Order. SIIPL will issue purchase orders for each Firm Order at least [***] prior to the applicable delivery date of each Firm Order. Each purchase order will specify the quantity of Vaccine Components being ordered (which will be in whole Batches), the requested delivery date (the "Delivery Date"), SIIPL's purchase order number, and any other information necessary to ensure the timely Manufacture and delivery of such Vaccine Components (a "Purchase Order"). If any such purchase order requests a quantity of Vaccine Components in excess of the Firm Order, Novavax has the discretion to reject any such excess quantity. Novavax shall notify SIIPL in writing of the actual delivery date for delivery of Vaccine Components ordered (including whether Novavax agrees to supply any excess quantity) under a Purchase Order. No terms, provisions, or conditions of any Purchase Order or other business form or written authorization used by SIIPL or Novavax will have any effect on the rights, duties, or obligations of the Parties under or otherwise modify this Agreement or any Purchase Order, regardless of any failure of SIIPL or Novavax to object to such terms, provisions, or conditions.
- **3.3 Delivery; Title; Risk of Loss**. Unless otherwise agreed by the Parties, Novavax will deliver Vaccine Components [***]. Title and risk of loss will pass [***]. SIIPL will select, oversee, and be responsible for the acts of its designated carrier. SIIPL will, [***], be responsible for securing all necessary import permissions or other rights that may be required by local law or regulation throughout the SIIPL Territory to use the Vaccine Components and Know How to Manufacture the Products.

ARTICLE 4.INSPECTION, QUALITY, AND AUDIT

- 4.1 Inspection; Acceptance and Rejection. SIIPL will inspect shipments upon receipt for any visible damage or missing quantities of the Vaccine Components or Licensed Know-How. SIIPL may also test shipments of Vaccine Components using the applicable methods of analysis specified in the Quality Agreements. If there are any issues with a shipment of Vaccine Components or Licensed Know-How or if SIIPL [***] believes that the Vaccine Components do not comply with the Vaccine Component Specification, cGMP, or other applicable requirements under the Quality Agreements then SIIPL must notify Novavax [***] after its receipt of a shipment. If SIIPL does not notify Novavax within such period, then SIIPL will be deemed to have accepted the Vaccine Components or Licensed Know-How as conforming to the order and meeting the applicable Vaccine Component Specifications and quality requirements under this Agreement.
- **4.2 Rejection Procedure**. Upon Novavax' receipt of a notice from SIIPL pursuant to Section 4.1(Inspection; Acceptance and Rejection), unless Novavax informs SIIPL to the contrary

within [***] after receipt of such notice, Novavax will replace such missing, damaged, or defective Vaccine Components or License Know-How at [***] cost and expense. To the extent a defect of the Vaccine Components or Licensed Know- How cannot be ascertained by the exercise of [***] diligence by SIIPL within [***] after a delivery, SIIPL will notify Novavax in writing of such defect [***], then the Parties will thereafter use [***] to have Novavax replace such defective Vaccine Components or Licensed Know-How at [***]; provided any such notice must be provided [***].

- 4.3 Disagreement Regarding Defect. In the event of any disagreement between the Parties as to any defect in or non-conformance of any Vaccine Components and Licensed Know-How, including any non-conformity with the Vaccine Component Specifications and defect in the Licensed Know-How, either Party may require that the matter be submitted to [***] to determine whether or not such Vaccine Components or License Know-How is nonconforming or otherwise defective, and the Parties [***]. Notwithstanding the general dispute resolution mechanisms set forth in this Agreement, the decision by [***] will be final and binding, and not subject to appeal. All costs and expenses related to such laboratory services will be borne by [***].
- **4.4 Records**. Each Party will provide [***] to support the other Party's efforts to obtain or maintain Regulatory Approvals related to the Vaccine Components or Product.

4.5 Right of Reference; Regulatory Cooperation.

- a. Documentation. Novavax will provide SIIPL with applicable information, reports, documents, certificates, and any other materials regarding Vaccine Components and Licensed Know-How that are [***] for SIIPL to Manufacture the Product, to Develop the Product and to obtain and maintain Regulatory Approval for the Product in the SIIPL Territory. Novavax will submit, maintain, and keep updated drug master files for the Vaccine Components and each facility in which Novavax Manufactures the Vaccine Components, SIIPL will submit, maintain, and keep updated drug master files for the Product and each facility in which SIIPL Manufactures the Product, and, following the Technology Transfer, for the Vaccine Components and each facility in which SIIPL Manufactures the Vaccine Components.
- b. Right of Reference. Each Party hereby grants to the other Party a right of reference to the drug master files described in the forgoing Section 4.5(a) (Documentation) for use in obtaining Regulatory Approvals for the Vaccine Components or the Product as permitted under this Agreement or any other agreement between the Parties. Each Party will, at the other Party's written request, provide accurate and complete copies of the applicable clinical study reports, authorize the appropriate regulatory authorities to reference such drug master files in support of BLAs and other regulatory submissions for the Vaccine Components or the Product (as applicable), and/or provide copies of all such authorization letters and take other [***] actions with regulatory authorities with respect to the Vaccine Components or the Product as requested by such regulatory authorities or the other Party in connection with obtaining and maintaining Regulatory Approvals for the Vaccine Components and the

Product as set forth in this Agreement.

- **4.6 Quality Inspection**. SIIPL will have the right to inspect Novavax' facilities, offices, or other properties used or utilized for the manufacture, storage, handling, and shipping of Vaccine Components pursuant to the Quality Agreements [***] at [***] sole expense. All such audits will occur with [***] notice (but no less than [***) on Novavax' premises during Novavax' normal business hours. If Novavax uses any contract manufacturer(s) to satisfy its obligations under this Agreement, Novavax will provide its quality inspection reports for such contract manufacturer(s) upon request from SIIPL.
- **4.7 Regulatory Inquiries**. Novavax will [***] notify SIIPL in writing of any governmental or regulatory inquiries, inspections, or audits directly related to the Vaccine Components and Licensed Know-How and any findings related to the same. SIIPL will permit such governmental or regulatory body to inspect and audit its facilities and documents, including facilities and documents of its contract manufacturer(s), related to Vaccine Components at [***] cost and expense, and notify and update Novavax of such inquiries, inspections and audits.
- 4.8 Recalls. Each Party will [***] notify the other in writing in detail if (a) any batch of Vaccine Components provided hereunder or Product is alleged or proven to be the subject of a recall, market withdrawal, or correction in such Party's territory; (b) such Party [***] determines that a recall is necessary; or (c) such Party becomes aware of any quality or risk issues related to Vaccine Components or Product. SIIPL will be responsible for instituting a recall, market withdrawal, or correction of the Product at [***] cost and expense, unless a recall is required due solely to the failure of the Vaccine Components Manufactured by Novavax to meet the Vaccine Component Specification at the time of delivery, or failure of Novavax to Manufacture Vaccine Components in accordance with cGMP or other Applicable Laws, in which case SIIPL will also be responsible for instituting a recall, market withdrawal, or correction at [***] cost and expense. Each Party will cooperate as [***] requested by the Party responsible for recall.
- **4.9 Safety Reporting**. Each Party will advise the other Party in writing of any adverse event related to the Vaccine Components or Product within [***] after becoming aware of such event, and provide any and all information, document, and materials that are related to such adverse event. Further details of the Parties' obligations in regard to safety reporting will be set forth in the Pharmacovigilance Agreements.

ARTICLE 5. TECHNOLOGY TRANSFER

5.1 Technology Transfer. [***] the execution of this Agreement, Novavax shall transfer to SIIPL (a) all Licensed Know-How Controlled by Novavax that necessary to use the Vaccine Components for the Manufacture of the Product, including assays, specifications, diagrams, technology, manufacturing process descriptions, protocols, and other written know-how by providing copies or samples of relevant documentation, materials, and other embodiments of any such Licensed Know-How ("Technology Transfer").

ARTICLE 6. LICENSE GRANTS

6.1 License Grants to SIIPL.

- a. Exclusive License. Subject to the terms and conditions of this Agreement, Novavax hereby grants to SIIPL an exclusive but royalty bearing license under the Novavax Proprietary Rights to the extent necessary to use Vaccine Components and Licensed Know-How to Develop, formulate, Manufacture, make, have made, import, export, use, have used, offer for sale, sell, and have sold or otherwise and Commercialize the Product within the SIIPL Exclusive Territory in the Field during the Term (the "SIIPL Exclusive License does not and will not be deemed to allow SIIPL to make or have made the Vaccine Components in whole or part under this Agreement. This SIIPL Exclusive License shall continue during and after the Pandemic Period until expiration or termination of this Agreement.
- b. Non-Exclusive License. Subject to the terms and conditions of this Agreement, Novavax hereby grants to SIIPL a non-exclusive but royalty bearing license under the Novavax Proprietary Rights to the extent necessary to use Vaccine Components and Licensed Know-How to Develop, formulate, Manufacture, make, have made, import, export, use, have used, offer for sale, sell, and have sold or otherwise and Commercialize the Product within the SIIPL Non-Exclusive Territory in the Field during the Pandemic Period. For the purpose of clarity, this non-exclusive license does not and will not be deemed to allow SIIPL to make or have made the Vaccine Components in whole or part under this Agreement. After the Pandemic Period, Novavax may, during the Term, notify in writing to SIIPL of any bona fide opportunity to license to a third party one or more countries in the SIIPL Non-Exclusive Territory. Upon any such written notice, SIIPL shall have [***] from receipt of the written notice to match or improve such bona fide terms with Novavax or, failing that, Novavax has the sole discretion to remove such country or countries from the SIIPL Non-Exclusive Territory with due written notice to SIIPL.
- **c. Sub-License.** SIIPL may sub-license to a third party in the SIIPL Exclusive Territory, the Vaccine Components and Licensed Know-How with [***].
- 6.2 Covenant Not to Sue. SIIPL, on behalf of itself and its Affiliates, hereby covenants not to assert or cause to be asserted, and will cause its Affiliates not to assert or cause to be asserted, against any Covenant Beneficiary [***]. Each Covenant Beneficiary that is not party to this Agreement is a third party beneficiary solely of this Section6.2(Covenant Not to Sue). If SIIPL or any of its Affiliates sells, assigns, exclusively licenses, transfers, or otherwise grants any right under any SIIPL Improvement to a third party, then SIIPL or such Affiliate, as applicable, will require such purchaser, assignee, licensee, or transferee to agree in writing to be bound by the same covenant to the same extent as made by SIIPL and its Affiliates in this Section 6.2(Covenant Not to Sue).
- **6.3** No Implied Licenses. Neither Party is granted any rights to any Patent Rights, Know-

How, or other intellectual property rights owned or Controlled by the other Party, other than as explicitly identified herein. Nothing herein will affect the Parties' respective ownership of any Patent Rights, Know-How, or other intellectual property rights owned by such Party.

ARTICLE 7. PAYMENT, INVOICING AND TERMS

- 7.1 SIIPL Royalty Payment. SIIPL shall pay Novavax with respect to SIIPL's sale of Product a royalty in an amount equal to percent (50%) of the Revenue on a Calendar Quarter bases (the "SIIPL Royalty Payment"). All payments under this Agreement shall be made in United States Dollars. Payments pertaining to SIIPL Royalty Payment, as applicable, shall be fully paid [***] on the basis of the applicable sales of Product recognized under US GAAP for the prior Calendar Quarter.
- **7.2 Vaccine Component Payment.** The payments pertaining to DS Price and Adjuvant Price to be paid by SIIPL to Novavax or its designee will be initiated [***] and will thereafter be due and payable upon receipt of the applicable invoice from Novavax (the "Vaccine Component Payment").

7.3 Taxes. The amounts payable by one Party (the "Paying Party") to the other Party (the "Payee Party") pursuant to this Agreement (each, a "Payment") shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 7.3, the Payee Party shall be solely responsible for paying any and all taxes on income (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by the Paying Party), excluding applicable Indian GST levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Paying Party shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if the Payee Party is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, applicable withholding Tax, it may deliver to the Paying Party or the appropriate Governmental Authority (with the assistance of the Paying Party to the extent that this is [***] required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Paying Party of its obligation to withhold such Tax and the Paying Party shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that the Paying Party has received evidence of the Payee Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] prior to the time that the Payments are due. If, in accordance with the foregoing, the Paying Party withholds any amount, it shall pay to the Payee Party the balance when due, make timely payment to the proper Governmental Authority of the withheld amount and [***] send to the Payee Party necessary certificates as issued by the Governmental Authorities for such payment along with the relevant withholding tax certificates. The Parties will cooperate and use [***] to reduce, mitigate, or eliminate adverse tax consequences.

ARTICLE 8. RECORDS AND REPORTS OF BOOKS OF ACCOUNTS

- **8.1 Records; Reports.** During the term of this Agreement and for a minimum period of [***] thereafter, SIIPL shall keep detailed, accurate and up to date records and books of account [***], showing [***] such during the previous [***]. SIIPL shall ensure that such records and books of accounts are sufficient to ascertain the [***] with respect to the Product supplied in each country under this Agreement.
- **8.2** Quarterly Reports. As agreed in this Agreement, SIIIIPL shall furnish a certificate from its Certified Auditors for the calculation of SIIPL Royalty Payment and Vaccine Component Payment as per ARTICLE 7 for every Calendar Quarter (the "Quarterly Certificates") within [***] of end of each such quarter. As used herein, "Certified Auditors" means an auditor firm duly licensed to practice as an auditor and whose lead individual responsible for quarterly audits will have [***] and who is responsible and liable under Applicable Law.

8.3 Royalty Certifications.

a. As agreed in this Agreement, SIIPL shall furnish Quarterly Certificates from their Certified Auditors for the calculation of SIIPL Royalty Payment and Vaccine Component Payment.

SIIPL shall pay any underpayment reflected in a Quarterly Certificate within [***] of the applicable Calendar Quarter, and may credit any overpayment based on the results disclosed by such Quarterly Certificates against future SIIPL Royalty Payment or Vaccine Component Payment due Novavax.

- b. The Parties agree to conduct [***] reconciliation of the payments made in accordance with Section 8.3 a. Within [***], SIIPL shall furnish Novavax with an certificate issued by [***] certifying the total amount of the SIIPL Royalty Payment accrued in such preceding calendar year (the "[***] Recalculation Certificate"). Along with the delivery of an [***] Recalculation Certificate, SIIPL shall pay any underpayment reflected in such [***] Recalculation Certificate, and may credit any overpayment against future SIIPL Royalty Payment or Vaccine Component Payment due Novavax.
- **c.** Any disputes with respect to any amount due under this Section 8.3 may be referred by either Party for dispute resolution in accordance with Section 14.5 (Negotiation; Resolution).

ARTICLE 9. INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property Rights

- **a.** Subject to Sections 9.1(c) and 9.1(e), all proprietary rights, including any and all Intellectual Property Rights in the Product shall be exclusively owned and Controlled by and, shall remain exclusive property of [***].
- **b.** All proprietary rights, including any Intellectual Property Rights, in the [***] shall be exclusively owned and Controlled by [***].
- **c.** All proprietary rights, including any Intellectual Property Rights, in the [***] shall be exclusively owned and Controlled by [***].
- **d.** Nothing herein will affect the Parties' respective ownership of any Intellectual Property Rights or Know-How (i) existing and Controlled by such Party as on the Effective Date of the Agreement or (ii) was developed or obtained by or on behalf of such Party independent of this Agreement, and without reliance upon the Confidential Information of the other Party ("**Background IP**"). For the sake of clarity all Intellectual Property Rights in relation to the Vaccine Components and the Licensed Know-How, shall be the exclusive proprietary concern of Novavax.

- **9.2 Prosecution and Maintenance.** As between the Parties, [***] would be responsible for the filing, prosecution and maintenance of any and all Intellectual Property Rights in relation to [***] and, during the Term, would take into account any [***] comments and suggestions of [***] in relation to the filing, prosecution and maintenance of such patents.
- **9.3 Notification of Infringement.** Either Party shall [***] notify the other Party with such details as it has in its possession of any infringement any of any Intellectual Property Rights licensed under this Agreement (an "Infringement") as and when it becomes aware of such Infringement.
- **9.4 Enforcement.** As between the Parties, [***] shall have the sole right, but not the obligation, to bring at [***] own expense, an infringement action against any Person (an "**Infringer**") infringing its Intellectual Property Rights in relation to the [***]. [***] shall be entitled to name [***] as a party to any such infringement action in the [***] if required to do so by Applicable Law or with [***] consent.
- 9.5 Back-Up Enforcement Rights. If for any reason [***] fails to (1) initiate proceedings against any Infringer in the SIIPL Territory within [***] of receipt of the notice of Infringement from [***] or [***] of otherwise becoming aware of the Infringement or (2) continue to prosecute such proceedings thereafter then [***] shall, at [***] cost and expense, have the right, but not the obligation, to bring proceedings (or continue any existing proceedings commenced by [***]) against such Infringer and [***] shall [***] cooperate in any such proceedings as requested.
- **9.6 Infringement Actions.** The Party exercising any enforcement rights under Section 9.4 or Section 9.5:
 - **a.** shall have full control over the conduct of the action;
 - **b.** shall keep the other Party [***] informed of the progress of and developments in any proceedings against Infringers; and
 - c. may negotiate settlements with Infringers; provided any such settlement negotiated under Section 9.5 shall be subject to [***], which decision to grant or deny shall be communicated to [***] in writing within a period of [***] from [***] receipt the applicable written request by [***].

ARTICLE 10. WARRANTIES, REPRESENTATIONS AND COVENANTS

10.1 Novavax Representations and Warranties. Novavax represents and warrants to SIIPL that:

- **a.** the Vaccine Components supplied to SIIPL hereunder has been Manufactured according to all Applicable Laws and cGMPs; and
- **b.** to its knowledge as of the Effective Date, Novavax Controls all rights, title, and interests in and to Intellectual Property Rights in the Vaccine Components and the Licensed Know-How necessary for it to grant the licenses under Section 6.1 (License Grant);
- **10.2 SIIPL Representation and Warranty.** SIIPL represents and warrants to Novavax that all Product shall be manufactured and commercialized by SIIPL according to all Applicable Laws and cGMPs.
- **10.3 Mutual.** Each Party represents, warrants and covenants to the other Party:
 - **a.** Organization; Good Standing; Authority. It is duly organized, validly existing, and in good standing under the laws of its country of organization. It has the full right, power, and authority to enter into and perform this Agreement. This Agreement has been duly executed and delivered by an authorized signatory of each Party and constitutes a legal, valid, and binding obligation of such Party, enforceable in accordance with its terms.
 - **b. No Conflicts**. The execution, delivery, and performance of this Agreement by such Party does not conflict with such Party's charter documents, bylaws, or other organizational documents, any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate Applicable Law or any order, writ, decree, judgment, injunction, determination, or award of any Governmental Authority having jurisdiction over it.
 - **c.** Compliance with Law. It will, and will ensure that its Affiliates, comply with all Applicable Laws and, to the extent applicable, professional certification or licensing requirements, with respect to the performance of its obligations under this Agreement.
 - **d. No Litigation**. There is no action or proceeding pending or, to the knowledge of such Party, threatened that could reasonably be expected to impair or delay the ability of such Party to perform its obligations under this Agreement.
 - e. No Debarment. Neither Party nor any of its Affiliates, or any of their employees, contractors or agents performing any activities under this Agreement, has been debarred or is subject to debarment pursuant to the relevant sections of the U.S. Food Drug & Cosmetic Act, as amended, or any foreign equivalent or that is the subject of a conviction described in such statutes and regulations.
 - **f. Authorization**. Each Party's representative signing below has the authority to bind its respective Party. Each Party hereto has the power and authority to execute and deliver the Agreement and to perform the obligations hereunder.

- **g.** Anti-Corruption. The Parties agree that, at all times in connection with and throughout the term of this Agreement, they and their Affiliates will comply with and that they will take commercially reasonable measures to ensure that their subcontractors, agents or other third parties will comply with all applicable anti- corruption legislation including the United States Foreign Corrupt Practices Act 1977, as amended, and their foreign equivalents under Applicable Law..
- h. Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANYKIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANYTECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

ARTICLE 11. INDEMNIFICATION; INSURANCE; LIABILITY

- 11.1 By SIIPL. SIIPL will indemnify, defend, and hold harmless Novavax, its Affiliates, and their respective directors, officers, employees, and agents (collectively, the "Novavax Indemnitees") from and against any and all losses, liabilities, damages, costs, fees, and expenses (including reasonable attorneys' fees) (collectively, "Losses") suffered by Novavax Indemnities in connection with any suits or claims brought by third parties ("Claims") arising out of or resulting from [***], except to the extent the Losses arise out of or result from an obligation of Novavax to indemnify SIIPL Indemnitees pursuant to Section 11.2 (Indemnification By Novavax).
- 11.2 By Novavax. Novavax will indemnify, defend, and hold harmless SIIPL, its Affiliates, and their respective directors, officers, employees, and agents (collectively "SIIPL Indemnitees") from and against any and all Losses suffered by SIIPL Indemnitees in connection with Claims arising out of or resulting from [***], except to the extent the Losses arise out of or result from an obligation of SIIPL to indemnify the Novavax Indemnitees pursuant to Section 11.1 (Indemnification By SIIPL).

- [***] written notice of any claim for which indemnification is sought hereunder. The indemnifying Party will have the right to control the defense and settlement of a claim, at [***] expense, and the indemnifying Party will act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the Claim. The indemnified Party will reasonably cooperate in the investigation, defense, and settlement of such claim at the indemnifying Party's expense. Neither Party will enter into any settlement agreement that [***]. Any indemnified Party will have the right to participate in, but not control, the defense and settlement of a claim and to employ separate legal counsel of its own choice; provided, however, that such employment will be at [***] expense, unless (a) the employment thereof has been specifically authorized by the indemnifying Party, or (b) the indemnifying Party has failed to assume the defense and employ counsel (in which case the indemnified Party may control the defense and settlement of such claim). Notwithstanding the aforesaid, Parties agree that, [***].
- **11.4 Insurance**. Each Party will obtain and maintain, at its own cost and expense, the insurance policies in such amounts and with such scope of coverage as are adequate to cover such Party's obligations under this Agreement.
- 11.5 Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHERPARTY OR ANY THIRD PARTY FOR ANY [***]. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.5 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT [***].

ARTICLE 12. CONFIDENTIAL INFORMATION

12.1 Definition. "Confidential Information" means any and all proprietary scientific, technical, clinical, financial, business, and other information and material disclosed by

one Party in the performance of this Agreement (the "Disclosing Party") to the other Party (the "Receiving Party"), including ideas, concepts, technology, inventions, discoveries, improvements, intellectual property, know-how, trade secrets, operations, plans, pricings, personnel, customers, business opportunities, research, development, data, notes, reports, samples, formulations, analyses, protocols, techniques, manuals, statements, schedules, forecasts, studies, records, systems and programs, disclosed in writing or orally or visually, whether or not marked "confidential." Confidential Information will also include the existence, terms, and conditions of this Agreement, as well as all information and documents regarding the conclusion, implementation, and termination of this Agreement, which information shall be deemed the Confidential Information of each Party. All reports provided by one Party to the other Party hereunder will be the Confidential Information of the reporting Party, who will be deemed the Disclosing Party with respect thereto.

- 12.2 Reasonable Precautions. The Receiving Party agrees (a) to hold the Disclosing Party's Confidential Information in confidence and to take all reasonable precautions to protect such Confidential Information (including all precautions the Receiving Party employs with respect to its confidential materials), (b) not to divulge any such Confidential Information to any third party, and (c) not to make any use whatsoever at any time of such Confidential Information, except, in the case of (b) or (c), solely as necessary to perform the obligations or exercise the rights of the Receiving Party. Any employee, consultant, professional advisor or agent of a Party or is Affiliates given access to any such Confidential Information must have a legitimate "need to know" and be subject to written obligations of non-disclosure and non-use no less stringent than those set forth in this Agreement.
- 12.3 Exceptions. The following will not be considered Confidential Information to the extent that the Receiving Party can establish with competent written proof that such information (a) is, at the time of disclosure to the Receiving Party, in the public domain, or through no fault of the Receiving Party enters the public domain, (b) was rightfully in the Receiving Party's possession or known by it prior to receipt from the Disclosing Party, (c) was rightfully disclosed to it by another Person without restriction, or (d) was independently developed by it by persons without access to such information and without use of any Confidential Information of the Disclosing Party.
- **12.4 Permitted Disclosure**. In the event that a Receiving Party is required to disclose any of the Disclosing Party's Confidential Information by law, regulation, rule, court order, or any governmental authority, the Receiving Party will use [***] to provide [***] notice thereof to the Disclosing Party and cooperate [***] with the Disclosing Party in seeking additional measures to guard the confidentiality thereof..
- **12.5 Termination of the Agreement**. Upon termination or expiration of the Agreement, the Receiving Party will turn over to the Disclosing Party, or destroy (at the Disclosing Party's request), all Confidential Information of the Disclosing Party and all documents, media, or other items containing any such Confidential Information and

any and all copies or extracts thereof at the cost of the Disclosing Party; provided, however, the Receiving Party may retain one archival copy of the Confidential Information at a secure location for archival purposes only and all provisions of confidentiality agreed herein this ARTICLE 12 shall continue to apply to such archival copy retained by the Receiving Party.

12.6 Survival. This ARTICLE 12 (Confidential Information) will survive the termination or expiration of this Agreement for a period [***].

ARTICLE 13.TERM AND TERMINATION

- **13.1 Term**. This Agreement will come into full force and effect on the Effective Date and will remain in full force and effect on a country-by-country basis until the fifteenth (15th) anniversary of the First Commercial Sale of the Product in the SIIPL Territory, unless earlier terminated pursuant to the terms of this Agreement (the "**Term**").
- **13.2 Termination**. This Agreement may be terminated by either Party:
 - **a. For Material Breach**. Immediately upon written notice to the other Party if the other Party materially breaches this Agreement and such material breach is not discontinued or cured within [***] after the breaching Party's receipt of an initial written notice by the non-breaching Party with reasonable detail as to the nature and scope of the applicable breach; or
 - **b.** For Bankruptcy. By giving [***] notice to the other Party if the other Party becomes insolvent or a bankruptcy action or any other insolvency proceeding is instituted against it and not dismissed within [***].
- 13.3 Effects of Expiration and Termination by SIIPL for Cause.
 - **a.** Upon expiration of this Agreement on a country-by-country basis in accordance with Section 13.1, Novavax hereby grants and agrees to grant to SIIPL a fully-paid, non-exclusive, royalty-free license under its Intellectual Property Rights in the Vaccine Components and/or Licensed Know-How (as they exist upon such expiration) to Manufacture and Commercialize the Product in any such country in the SIIPL Territory.
 - b. Upon early termination of this Agreement by SIIPL for a (i) material breach by Novavax in accordance with Section 13.2.a. or (ii) Bankruptcy of Novavax in accordance with Section 13.2.b., Novavax hereby grants and agrees to grant to SIIPL a non-exclusive, royalty bearing (as described in the last sentence of this Section 13.3) license under its Intellectual Property Rights in the Vaccine Components and/or Licensed Know-How (as they exist upon such termination) to Manufacture and Commercialize the Product in the SIIPL Territory for the remainder of what would have been the Term on a country-by-country basis if this Agreement were not terminated under Section 13.3; provided that in the event of bankruptcy SIIPL shall reasonably insure that the then-

- existing economic arrangements will be paid to Novavax, or its successor in bankruptcy as the case may be, to the extent reasonably feasible for SIIPL to do so. In the event of such termination, SIIPL shall pay a royalty in an amount equal to [***].
- 13.4 Survival. In the event of any termination or expiration of this Agreement, each of the provisions of ARTICLE 4, Section 6.2 (Covenant Not to Sue), ARTICLE 8 (Records and Reports of Books of Accounts, Section 9.1 (Ownership of Intellectual Property Rights), ARTICLE 11 (Indemnification; Insurance; Liability), ARTICLE 12 (Confidential Information), Section 13.3 (Effects of Termination by SIIPL for Cause)(in which case, Article 7 and 8 shall also survive), Section 13.4. (Survival), ARTICLE 14 (General Provisions), and Appendix A will survive termination or expiration of this Agreement and continue to be enforceable. In no event will termination of this Agreement release either Party from any accrued obligation, including SIIPL's obligation to pay any amounts that became due on or before the effective date of termination.

ARTICLE 14.GENERAL PROVISIONS

- **14.1 Further Actions**. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as necessary in order to carry out the purposes and intent of this Agreement.
- 14.2 Manufacturing Agreement. The Parties agree that Novavax and SIIPL shall enter into a manufacturing agreement on terms and conditions as may be mutually agreed, wherein SIIPL shall manufacture the Drug Substance and Product for Novavax (the "Manufacturing Agreement"). This agreement when executed shall run in parallel to the license Agreement and the same shall be treated as independent co-parallel agreements. The Parties agree that they have mutually agreed to the financial terms with respect to the said Manufacturing Agreement. For clarity, such agreed financial terms have been duly recorded in Appendix B herein annexed.
- 14.3 Force Majeure. No Party will be liable for failure to perform any obligation under this Agreement(other than any obligations to make payments as and when due hereunder) where such failure is caused by earthquake, storms, flood, fire, other acts of nature, epidemics (excluding the Sars-Cov-2 Corona Virus pandemic and any quarantine period thereunder), war, rebellions, riots, public disturbance, acts of terrorism, acts or omissions of any government, any rules, regulations, or orders issued by any Governmental Authority or by any office, department, agency, or instrumentality thereof, ban on imports, strikes, or other labor disputes, provided [***]. If the state of force majeure continues for more than [***], then [***].
- **14.4 Governing Law**. This Agreement will be governed by and construed in accordance with [***], without giving effect to the principles of choice or conflict of laws provisions thereof, and the Parties expressly agree that the 1980 United Nations Convention on Contracts for the International Sale of Goods will not apply to or affect any term of this Agreement.
- 14.5 Negotiation; Escalation. The Parties will negotiate in good faith and use [***] to

settle any dispute under this Agreement, other than matters subject to resolution under Article 2.7 (Governance). Any dispute as to the breach, enforcement, interpretation, or validity of this Agreement will be referred to the Executive Officers. If the Executive Officers are unable to resolve such dispute within [***] after such dispute is referred to them ([***]), then, upon the written request of either Party to the other Party, other than a dispute relating to the scope, validity, enforceability, or infringement of any Patent Rights or trademark rights ([***]), the dispute will be subject to remedial action by any such Party in compliance with Section 14.4 (Governing Law).

- 14.6 Equitable Remedy. The Parties acknowledge and agree that there may be no adequate remedy at law for any breach of a Party's obligations under ARTICLE 10 (Warranties) ARTICLE 12(Confidential Information) and, which breaches may result in irreparable harm to the other Party, and therefore, that upon any such breach or any threat thereof, the non-breaching Party will been entitled to appropriate equitable relief (without the posting of any bond) in addition to whatever remedies it might have at law.
- Agreement by a Party to the other Party are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any foreign counterpart thereto, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or any foreign counterpart thereto. Subject to Section 13.3, (Effects of Expiration or Termination by SIIPL for Cause), the Parties agree that the Parties shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterpart thereto. All payments to be made by SIIPL under this Agreement, including the royalty payments pursuant to ARTICLE 7 (SIIPL Royalties), shall be considered "royalties" for purposes of Section 365(n) of the U.S. Bankruptcy Code.
- **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier (return receipt

requested)addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Novavax:

Novavax, Inc. 21 Firstfield Road Gaithersburg, MD 20878 Attn: [***]

If to SIIPL:

Serum Institute of India Pvt. Ltd. 212/2 off Soli Poonawalla Road Hadapsar, Pune $411028\,$

India

Attention: [***]

with a copy to:

[***]

Serum Institute of India Private Limited 212/2, Off Soli Poonawalla Road, Hadapsar Pune 411028

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given when received on the date indicated in the applicable return receipt.

- **Publicity.** Except as expressly permitted herein, neither Party may issue any press release or make any other public announcement concerning the execution or existence of this Agreement or any of the terms hereof (i) without the [***] consent of the other Party, [***] or (ii) unless required by Applicable Law, provided that such Party shall give the other Party a prior intimation of the same.
- **14.10 Severability**. If any provision of this Agreement is determined to be invalid, illegal, or unenforceable, then such provision will be deemed to be severable from the remainder of this Agreement and will not cause the invalidity or unenforceability of the remainder of this Agreement. The Parties will substitute, by written agreement, valid provisions for such invalid, illegal, or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal, or

- unenforceable provisions that it can be [***] assumed that the Parties would have entered into this Agreement with such valid provisions.
- **14.11 Waiver**. No failure on the part of either Party to exercise, and no delay in exercising, any right, power, remedy, or privilege under this Agreement or provided by statute or law or in equity or otherwise, will impair, prejudice, or constitute a waiver of any such right, power, remedy, or privilege or be considered as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise thereof or the exercise thereof or the exercise of any other right, power, remedy or privilege.
- **14.12 Assignment**. Each Party's rights and obligations under this Agreement may not be directly or indirectly assigned, delegated or transferred, in whole or in part, to a third party by assignment or other means without the [***], however, either Party may transfer any and all of its rights and/or obligations hereunder to any of its Affiliates by providing [***] notice of [***]. In addition, either Party may assign and transfer all of its rights and obligations hereunder to any third party that acquires all or substantially all of the stock or assets of the business to which this Agreement relates (by merger, stock or asset purchase, operation of law, or otherwise). In such an event where such third party which acquires all or substantially all of the stock or assets of the business of either Party to which this Agreement relates (by merger, stock or asset purchase, operation of law, or otherwise) does not honour this Agreement, or refuses to be bound by the terms of this Agreement, [***].
- 14.13 Change of Control. This Agreement will be binding on and inure to the benefit of the Parties, their, executors, administrators, successors, and permitted assigns. In the event of any merger, acquisition or any such Change of Control, such acquiring party of Novavax shall be bound by the terms and conditions of this Agreement and in the event such acquiring party does not agree or is restricted under Applicable Laws to be bound by the terms of this Agreement, [***].
- **14.14 Data Protection**. The Parties do not envisage that any material personal data will be exchanged between the Parties in the performance of this Agreement and hence no data protection act(s) / law(s) will be applicable to either Party.
- **14.15 Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to

have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified(subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person will be construed to include the person's successors and assigns, (f) the words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Sections, Schedules, or Exhibits will be construed to refer to Articles, Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent, "approve," or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging), (i) references to any specific law, rule or regulation, or Section or other division thereof, will be deemed to include the thencurrent amendments thereto or any replacement or successor law, rule or regulation

- (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," and (l) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement, in the Quality Agreements, in the Pharmacovigilance Agreements, or otherwise, the terms and conditions of this Agreement will govern, provided that the terms of the Quality Agreements or Pharmacovigilance Agreements (as applicable) will control with respect to any such conflict with the terms of this Agreement relating to quality or safety matters for the Vaccine Components or Product.
- **14.16 Performance by Affiliates**. Only in the event either Party assigns any of its rights and obligations under this Agreement to any of its Affiliates, then in such event, each Party hereby guarantees the performance by such Affiliates of such Party's obligations under this Agreement and will cause such assignee Affiliate to comply with the provisions of this Agreement in connection with such performance.
- **14.17 Independent Contractors**. Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee, or a joint venture relationship between the Parties. The respective activities of the Parties hereunder will be provided as independent contractors. Neither Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.
- **14.18** No Third Party Beneficiaries. No Person other than each Party and any of its and permitted assignees and assignee Affiliates hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

- 14.19 Entire Agreement. This Agreement together with the Pharmacovigilance Agreements and the Quality Agreements sets forth all intentions, understandings, covenants, promises, warranties, representations, conditions, rights, and obligations of the Parties and supersedes all previous and contemporaneous agreements, understandings, negotiations and proposals relating to the subject matter hereof. No subsequent modifications or amendments to this Agreement will be binding upon the Parties unless reduced in writing and signed by the respective authorized officers of the Parties.
- **14.20** Execution in Counterparts. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed an original, and all of which counterparts, taken together, will constitute one and the same instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused their authorized representatives to execute this Agreement on the date first above written.

SIIPL	NOVAVAX, INC.
By:/s/[***]	By:/s/ John A. Herrmann
Name: [***]	Name: John A. Herrmann
Title: Director R&D	Title: EVP, CLO & Secretary
Date: 30/7/2020	Date: 30 July 2020

Appendix A Definitions

- **A-1** "Accepted Forecast" shall have the meaning ascribed in Section 3.1 (Forecast).
- **A-2** "Adjuvant" shall have the meaning ascribed to it in the Recitals.
- A-3 "Adjuvant Price" means [***].
- **A-4** "**Affiliate**" means:
 - (i) with respect to Novavax, any Person that controls, is controlled by, or is under common control with another Person, and
 - (ii) with respect to SIIPL, mean any [***].

For purposes of the preceding definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with ") shall mean the possession, directly or indirectly, of more than 50% of the outstanding voting securities of or comparable equity interest in any other type of a Person, or otherwise having the legal power to direct the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

- **A-5** "**Agreement**" has the meaning set forth in the preamble.
- **A-6** "[***] **Recalculation Certificate**" shall have the meaning ascribed in Section 8.3.b. (Royalty Certifications).
- **A-7** "Applicable Law" means collectively all laws, rules, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit, or similar right granted under any of the foregoing), and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party.
- **A-8** "Background IP" shall have the meaning ascribed to it in Section 9.1.e (Ownership of Intellectual Property Rights).
- A-9 "BLA" or "Biologics License Application" means a Biologics License Application submitted under section 351(a) of the United States Public Health Service Act, 42 U.S.C. \\$\\$ 201 et seq., as amended from time to time, or substantially similar application or submission filed with a regulatory authority in a country or group of

- countries to obtain Regulatory Approval to Commercialize a Product in that country or in that group of countries, including all supplements and amendments thereto.
- **A-10** "Calendar Quarter" means each successive period of three months commencing on January 1, April 1, July 1, and October 1.
- **A-11** "Calendar Year" means each successive period of 12 months commencing on January 1 and ending on December 31.
- **A-12** "**cGMPs**" means current Good Manufacturing Practices regulations and standards enforced by the U.S. Food and Drug Administration, European Medicines Agency, or other applicable regulatory bod(ies) in other jurisdictions.
- "Change of Control" means, with respect to a Party, that: (a) any third party acquires A-13 directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such third party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such third party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) any merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning 50% or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the shareholders or equity holders of such Party approve any plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially all of such Party's assets, in each case, through one or more related transactions, other than to an Affiliate or pursuant to one or more related transactions that would result in shareholders or equity holders of such Party immediately prior to such transaction owning more than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or(d) the sale or transfer to any third party, in one or more related transactions, of all or substantially all of such Party's consolidated assets taken as a whole.
- **A-14** "Claims" shall have the meaning ascribed to it in Section 11.3 (Indemnification by SIIPL).
- A-15 "Commercialize", "Commercializing" or "Commercialization" means any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, offering for sale, and sale of a pharmaceutical, biologic, or vaccine product and interacting with Governmental Authority in the applicable country or region for such pharmaceutical, biologic, or vaccine product regarding the foregoing, but excluding activities directed to Manufacturing, Medical Affairs, or Development. "Commercialize," "Commercializing", "Commercialized" will be construed accordingly.

- A-16 "Commercialization Plan" means a written plan for the Commercialization of Product in the SIIPL Territory (as such plan may be amended from time to time) setting forth the Commercialization activities to be performed by SIIPL in accordance with the terms and conditions of this Agreement. The Commercialization Plan must include in reasonable detail the: (a) [***]; and (b) [***]. At least [***] prior to the anticipated First Commercial Sale of a Product, SIIPL will prepare an initial SIIPL Commercialization Plan and submit each such initial SIIPL Commercialization Plan to the JSC to review, discuss, and determine whether to approve.
- **A-17** "Commercialization Report" means a written executive summary outlining SIIPL's Commercialization activities by Calendar Quarter with respect to each Product in the SIIPL Territory, [***], which report shall be provided at least [***] in advance of each JSC meeting.
- **A-18** "Commercially Reasonable Efforts" means, with respect to the Exploitation of a Product by a Party, those efforts and resources, including allocation of [***] personnel, equivalent to [***]. Commercially Reasonable Efforts requires, with respect to an obligation, that the Party: (a) [***], (b) [***], and (c) [***].
- **A-19** "Confidential Information" shall have the meaning ascribed to it in Section 12.1.
- **A-20** "Control" or "Controlled" the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, (b) with respect to Patent Rights, Regulatory

Approvals, regulatory submissions, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, regulatory submissions, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case((a) and (b)), without (i) breaching or otherwise violating the terms of any arrangement or agreement with a third party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense, or (ii) incurring any additional payment obligations to a third party as a result of such access, right to use, license, or sublicense, and(c) with respect to any product or materials, the legal authority or right to grant a license or sublicense under Patent Rights that cover such product or materials or Know-How that relates to such product or materials on the terms set forth herein.

- **A-21** "Covenant Beneficiary" means Novavax or any of Novavax' Affiliates, or any of its or their direct or indirect licensees, sublicensees, importers, exporters, suppliers, manufacturers, distributors, contractors, agents, or customers.
- **A-22** "Delivery Date" shall have the meaning ascribed in Section 3.1 (Forecast).
- A-23 "Develop", "Developing" or "Development" means all internal and external research, development, and regulatory activities related to pharmaceutical, biologic, or vaccine products, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and clinical trials, (b)and preparation, submission, review, and development of data or information for the purpose of submission to a regulatory authority to obtain authorization to conduct clinical trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical, biologic, or vaccine product, but excluding activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include development and regulatory activities for additional forms, formulations, or indications for a pharmaceutical, biologic, or vaccine product after receipt of Regulatory Approval of such product (including label expansion), including clinical trials initiated following receipt of Regulatory Approval or any clinical trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable regulatory authority as a condition of such Regulatory Approval with respect to an approved formulation or indication (such as post-marketing studies, observational studies, pediatric studies, implementation and management of registries and analysis thereof, in each case, if required by any regulatory authority in any region worldwide to support or maintain Regulatory Approval for a pharmaceutical, biologic, or vaccine product in such region). "Develop," "Developing," "Developed" will be construed accordingly.
- **A-24** "Development Plan" has the meaning set forth in Section 2.6.b (Development of the Product).

- A-25 "Development Report" means a [***] written executive summary report outlining by Calendar Quarter the progress of the Development activities taken by SIIPL with respect to the Product in the SIIPL Territory, which report shall be provided to the JSC as least [***] in advance of each JSC meeting. For clarity, such reports will contain [***] to allow the Parties to evaluate the progress of the Development activities in each such meeting, including against the objectives and timelines included therefor in the Development Plan. In addition, SIIPL will include in such report such other data and information generated in the performance of activities under the Development Plan or as may be [***] requested by Novavax related to the Development of the Product.
- **A-26** "Disclosing Party" shall have the meaning ascribed to it in Section 12.1 (Confidential Information Definition).
- **A-27** "**DP Cost**" means [***].
- **A-28** "**Drug Substance**" shall have meaning ascribed to it in the Recitals.
- **A-29** "**DS Price**" means [***].
- **A-30** "Effective Date" has the meaning set forth in the preamble.
- **A-31** "Executive Officers shall have the meaning ascribed to it in Section 2.7.c.2 (Decisions of JSC).
- **A-32** "Exploit" means to make, have made, use, offer to sell, sell, Develop, Manufacture, perform Medical Affairs, Commercialize, or otherwise exploit. When used as a noun, Exploitation means any and all activities involved in Exploiting.
- **A-33** "Field" means human prophylactic uses of a vaccine for SARS-CoV-2 disease.
- **A-34** "Firm Order" shall have the meaning ascribed in Section 3.1 (Forecast).
- **A-35** "First Commercial Sale means, with respect to a Product in any country or region, the first sale of the Product to a third party for distribution, use, or consumption in such country or region after receipt of Regulatory Approval for such Product in such country or region.
- **A-36** "Forecast" shall have the meaning ascribed in Section 3.1 (Forecast).
- A-37 "Fully-Loaded Cost" means [***].

- **A-38** "Governmental Authority" means any legislative, executive, or judicial unit of any governmental authority or instrumentality (international, national, federal, state, provincial, or municipal, in any country or other jurisdiction), or any tribunal, department, agency, board, bureau, commission, official, or other regulatory, administrative, or judicial authority thereof, including any administrative or regulatory agency or commission, and any court, in each instance having legal jurisdiction over the subject matter before it.
- **A-39** "**Infringement**" shall have the meaning ascribed to it in Section 9.3 (Infringement).
- **A-40** "**Infringer**" shall have the meaning ascribed to it in Section 9.4 (Infringer).
- **A-41 Intellectual Property Rights**" shall mean and refer to Patent Rights as well as rights in all other intellectual property including trademarks, trade names, service marks, domain names, copyrights, trade secrets, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature whether registered or applications for registration thereof.
- **A-42** "JSC" shall have the meaning ascribed to it in Section 2.7a.1 (JSC Establishment).
- **A-43** "JSC Chairperson" shall have the meaning ascribed to it in Section 2.7a.1 (JSC Establishment).
- **A-44** "**Know-How**" means any proprietary information and materials, including records, discoveries, improvements, modifications, processes, techniques, methods, assays, chemical or biological materials, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, inventions, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how, and trade secrets (in each case, patentable, copyrightable, or otherwise).
- **A-45** "Licensed Know-How" means all Know-How that is Controlled by Novavax or its Affiliates as of the Effective Date in relation to the Vaccine Components and which is necessary for the Development, Manufacture or Commercialization of Product
- **A-46** "Licensed Patents" means the Patent Rights of Novavax in relation to the Vaccine Components, which are licensed to SIIPL under this Agreement, and which are annexed herein as Appendix C.
- **A-47** "Losses" has the meaning set forth in Section 11.1(Indemnification By SIIPL).

- **A-48** "Manufacture" or "Manufacturing" means activities which include, without limitation, the formulation, processing, packaging, labeling, filling, finishing, assembly, shipping, storage, or freight of any pharmaceutical, biologic, or vaccine product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, process development, qualification, and validation, scale-up, preclinical, clinical, and commercial manufacture and analytic development, and product characterization, but excluding activities directed to Development, Medical Affairs, or Commercialization. "Manufacturing" and "Manufactured" will be construed accordingly.
- **A-49** "Manufacturing Agreement" has the meaning set forth in Section 14.2 (Manufacturing Agreement).
- A-50 "Medical Affairs" means any and all activities conducted by or on behalf of a Party's or any of its Affiliates' medical affairs departments, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator initiated studies), and charitable donations to the extent related to medical affairs and not to activities that involve the promotion, marketing, sale, or other Commercialization of the Product and are not conducted by or on behalf of a Party's or any of its Affiliates' medical affairs departments. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.
- A-51 "Net Sales" means the gross receipts representing sales of the Product to third parties (whether an end-user, a distributor or otherwise) by SIIPL or its Affiliates less applicable deductions for the following invoiced or itemized items to the extent actually allowed and taken by such third parties and not otherwise recovered by or reimbursed to SIIPL or its Affiliate in connection with such Product:
 - i. [***];
 ii. [***];
 iii. [***];
 v. [***];

If SIIPL or its Affiliate receives non-cash consideration for a Product sold to a third party during the Term, then [***].

No deduction will be made for any cost incurred by SIIPL [***]. If a single item falls into more than one of the categories set forth in clauses (i)-(vi) above, then such item may not be deducted more than once.

Transfers or sales between SIIPL and its Affiliates will be disregarded for purposes of calculating Net Sales, except if such purchaser is an end user.

- **A-52** "Non-Binding Period" shall have the meaning ascribed in Section 3.1 (Forecast).
- A-53 "Novavax Exclusive Territory" shall mean a) during the Pandemic Period (as determined by the WHO) the countries of [***] and b) immediately following the Pandemic Period, any other country designated as a high income country (including sub-designations of high income countries (e.g., a "low high income country") according to the then most recent published Word Bank classification of world countries as of the first day of the end of the Pandemic Period or included within the Novavax Territory in accordance with Section 6.1.b. (Non-Exclusive License).

- **A-54** "Novavax Improvements" shall mean and include all Know-How related to the Vaccine Components invented or developed solely by either Party or jointly by both Parties during the Term in the performance of this Agreement.
- **A-55** "Novavax Indemnitees" shall have the meaning ascribed to it in Section 11.1 (Indemnification by SIIPL).
- **A-56** "Novavax Proprietary Rights" shall mean all proprietary rights, including any and all Intellectual Property Rights, in the Licensed Patents and Novavax Improvements.
- **A-57** "Pandemic Period" shall mean worldwide situation / period which the World Health Organization declares as Public Health Emergency of International Concern in relation to the SARS-CoV-2 virus.
- **A-58** "Payee Party" shall have the meaning ascribed to it in Section 7.3 (Taxes).
- **A-59** "Paying Party" shall have the meaning ascribed to it in Section 7.3 (Taxes).
- **A-60 "Payment"** shall have the meaning ascribed to it in Section 7.3 (Taxes).
- A-61 "Patent Rights" means all rights, title and interests in and to (a) all national, regional, and international patents and patent applications filed in any country of the world including provisional patent applications and all supplementary protection certificates, (b) all patent applications filed either from such patents, patent applications, or provisional applications or from an application claiming priority from any of these, including any continuation, continuation-in part, divisional, provisional, converted provisional, or continued prosecution application, or any substitute applications, (c) any patent issued with respect to or in the future issued from any such patent applications, including utility models, petty patents and design patents and certificates of invention, and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, reexaminations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications. For sake of clarity, in relation to Novavax, Patent Rights in the Vaccine Components shall include the Licensed Patents, list of which is annexed to this Agreement in Appendix B.
- **A-62** "Permitted Recipients" shall have the meaning ascribed to in Section 2.6 (Restrictions on Use).
- **A-63** "**Person**" means any individual, corporation, partnership, limited liability company, firm, association, joint venture, joint stock company, trust, unincorporated organization, or other entity, or any Governmental Authority.
- **A-64** "Pharmacovigilance Agreement" has the meaning set forth in Section 2.1c (Pharmacovigilance Agreement).

- **A-65** "**Product**" has the meaning set forth in the Recitals.
- **A-66** "Purchase Order" shall have the meaning ascribed in Section 3.1 (Forecast).
- **A-67** "Quality Agreement" means an agreement containing customary and commercially reasonable terms that will provide, among other things, quality standards for the Vaccine Components or Product, as applicable, the requirements for product release, the respective roles and responsibilities of each Party in these processes, the standards and procedures for the handling of any deviations from the usual quality standards or product release requirements, and/or any complaints, the processes and allocation of responsibilities for reporting of these matters, and related topics.
- **A-68** "Quarterly Certificates" shall have the meaning ascribed to in Section 8.2 (Quarterly Reports).
- **A-69** "Receiving Party" shall have the meaning ascribed to it in Section 12.1 (Confidential Information Definition).
- **A-70** "Regulatory Approval" means any and all approvals (including supplements, amendments, pre-and post-approvals, and all pricing and reimbursement approvals), licenses, registrations or authorizations, including marketing approvals and authorizations, required by relevant Governmental Authorities for the Development, Manufacture, or Commercialization of the Vaccine Components or Product, as applicable.
- **A-71** "**Regulatory Report**" means a brief description in English of [***] provided to the JSC [***] of receipt thereof.
- **A-72** "Revenue" means the Net Sales of Product, less (a) DS Price, (b) Adjuvant Price and (c) DP Price. (a), (b) and (c) collectively referred to as "Agreed Cost Price".
- **A-73** "Safety Stock" shall the meaning ascribed to it in 2.2 (Safety Stock).
- **A-74** "Shortfall" shall have the meaning ascribed to it in Section 2.8 (Shortfall Notice).
- **A-75** "Shortfall Notice" shall have the meaning ascribed to it in Section 2.8 (Shortfall Notice).
- **A-76** "SIIPL Exclusive License" shall have the meaning ascribed to it in Section 6.1.a. (Exclusive License).
- A-77 "SIIPL Exclusive Territory" shall mean India.

- **A-78** "SIIPL Improvements" shall mean and include all Know-How, invented or developed by SIIPL during the formulation, Manufacture, Development and further Commercialization of the Product during the Term and which are not Novavax Improvements.
- **A-79** "SIIPL Indemnitees" shall have the meaning ascribed to it in Section 11.2 (Indemnification by Novavax).
- **A-80** "SIIPL Proprietary Rights" shall mean all proprietary rights, including any and all Intellectual Property Rights, in the SIIPL Improvements.
- **A-81** "SIIPL Royalty Payment" shall have the meaning ascribed to it in Section 7.1 (SIPL Royalty Payment).
- **A-82** "SIIPL Non-Exclusive Territory" shall mean a) during the Pandemic Period all the other countries EXCEPT SIIPL Exclusive Territory and Novavax Exclusive Territory and b) immediately following the Pandemic Period only those countries designated as low or middle income countries (including any sub-designations of low or middle income countries (e.g., a "high middle income country") according to the then most recent published Word Bank classification of countries as of the first day of the end of the Pandemic Period ("LMIC"), subject to and may be modified in accordance with Section 6.1.b. (Non-Exclusive License).
- **A-83** "SIIPL Territory" shall mean SIIPL Exclusive Territory and SIIPL Non-Exclusive Territory together.
- **A-84** "**Term**" has the meaning set forth in Section 13.1 (Term).
- **A-85** "Technology Transfer" has the meaning set forth in ARTICLE 5 (Technology Transfer).
- **A-86** "Vaccine Components" shall have the meaning ascribed to it in the Recitals.
- **A-87** "Vaccine Component Payment" shall have the meaning ascribed to it in Section 7.2 (Vaccine Component Payment).
- **A-88** "Vaccine Component Specifications" shall have the meaning ascribed to it in the Section 2.1.a (Supply of Vaccine Components to SIIPL) as further described in the Quality Agreement.

Appendix B

Novavax shall pay SIIPL a royalty (the "Novavax Royalty Payment") for sales by Novavax of Product supplied by SIIPL or its licensees in the SIIPL Nonexclusive Territory in the applicable year. Such Novavax Royalty Payment shall equal fifty percent (50%) of the Revenue for Products sold by Novavax during a calendar year, as further articulated and described in the Manufacturing Agreement.

Appendix C

Licensed Patents

[Beginning on the following page]

{The schedule of licensed patents follows this cover page.}

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

EX-10.5 6 nvax-20200930xex10d5.htm EX-10.5

Exhibit 10.5

CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Amendment to

SUPPLY AND LICENSE AGREEMENT DATED 30 JULY 2020 ("Agreement")

Between

Novavax, Inc.

And

Serum Institute of India Private Limited

This Amendment ("Amendment") to the SUPPLY AND LICENSE AGREEMENT dated July 30, 2020 ("Agreement"), is entered into between Novavax, Inc., a Delaware, USA corporation having its principal place of business at 21 Firstfield Road, Gaithersburg, MD 20878 USA ("Novavax", which expression shall, unless repugnant to the context thereof, mean and include its Affiliates) and Serum Institute of India Private Limited, a company incorporated under the Companies Act, 1956 with registration number U80903PN1984PTC03294, and having its registered address as 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028 ("SIIPL", which expression shall, unless repugnant to the context thereof, mean and include its successors and permitted assigns), and is entered into and made effective as of September 11, 2020 ("Effective Date of Amendment"). All capitalized terms or otherwise undefined terms herein this Amendment shall have the same meaning and interpretation as in the Agreement

WHEREAS, Novavax and SIIPL entered into said Agreement under which Novavax agreed to (a) continuously supply to SIIPL Vaccine Components as per the Forecast requirement of SIIPL in the SIIPL Territory, (b) grant to SIIPL an exclusive license in the SIIPL Exclusive Territory to use the Vaccine Components to enable SIIPL to Manufacture, and Commercialize the Product, (c) grant to SIIPL a nonexclusive license in the SIIPL Non–Exclusive Territory to use the Vaccine Components to enable SIIPL to Manufacture, and Commercialize the Product, and (d) provide to SIIPL that Licensed Know–How Controlled by Novavax or its Affiliates (including the improvements if any), in accordance with the terms and conditions of the Agreement;

WHEREAS, subsequently, Parties have negotiated in good faith and subject to the mutually agreed terms and conditions stated herein, Novavax has agreed to additionally grant SIIPL a non–exclusive license to Manufacture the Drug Substance for the purpose of Manufacturing of the Product ("Purpose of the Amendment"); and

WHEREAS, it is the express mutual intent of Parties to amend and supplement certain terms and conditions of the Agreement to reduce to and record in writing the Purpose of the Amendment, and therefore Parties have mutually decided to execute this Amendment to the Agreement; and

NOW THEREFORE, SIIPL and Novavax agree to amend the Agreement as under:

- 1. The definition of Vaccine Components as listed under Appendix A, Clause 86, shall stand amended and modified as under—
 - "<u>A-87</u> "Vaccine Components" shall mean the Adjuvant, and any reference to "Vaccine Components" anywhere in the Agreement shall be read and interpreted accordingly".
- 2. The definition of SIIPL Improvements as listed under Appendix A, Clause 78, shall stand amended and modified as under—
 - "A-78 "SIIPL Improvements" shall mean and include all Know-How, invented or developed <u>during the Term (a)</u> by SIIPL during the formulation, Manufacture, Development and further Commercialization of the Product <u>or (b) solely by SIPPL during the Manufacture of the Drug Substance</u>; <u>provided in no case shall SIIPL Improvements include</u> Novavax Improvements."
- 3. Any reference to "Product" in the Agreement shall also include a reference to Drug Substance Manufactured by SIIPL as the context dictates
- 4. The definition of Licensed Know-How as listed under Appendix A, Clause 45 shall stand modified and amended as under-
 - "A-45 "Licensed Know-How" means all Know-How that is Controlled by Novavax or its Affiliates as of the Effective Date in relation to the (a) Vaccine Components and (b) Manufacture of the Drug Substance, including any biological materials to be mutually agreed by the Parties, and which is necessary for the Development, Manufacture or Commercialization of Product"
- 5. The definition of Licensed Patents as listed under Appendix , Clause 46 shall stand modified and amended as under—
 - "A-46 "Licensed Patents" means the Patent Rights of Novavax in relation to the (a) Vaccine Components and (b) Drug Substance, and which are licensed to SIIPL under this Agreement, and which are annexed herein as Appendix C."
- 6. The definition of DS Price as listed under Appendix A, Clause 29, shall stand amended and modified as under—
 - "<u>A-29 "DS Price" means [***</u>].
- 7. The definition of DP Price as listed under Appendix A, Clause 27, shall stand amended and modified as under—
 - "A-27 "DP Cost" means [***]
- 8. The definition of Adjuvant Price as listed under Annexure A, Clause 2, shall stand amended and modified as under-
 - "Adjuvant Price" means [***]
- 9. Any and all references to "DP Price" in Agreement shall be replace with "DP Cost".

- 10. In Article 2 Clause 2.4 (a) of the Agreement, the words "the Drug Substance and", shall be deleted, and the modified and amended Article 2 Clause 2.4 (a) of the Agreement shall now state as under—
 - "a Supply of Vaccine Components. During the Term, Novavax will have [***] with respect to obtaining and maintaining the facilities and necessary raw materials, equipment, qualified personnel, Regulatory Approvals, licenses, and permits, to Manufacture and deliver to SIIPL the Vaccine Components in accordance with this Agreement. Novavax will solely be responsible for all vendors, employees, contractors, and other Persons employed or engaged by it to Manufacture the Vaccine Components. Novavax will provide to SIIPL [***] necessary to enable SIIPL to formulate the components of the Vaccine Components (i.e., the Adjuvant), [***], so as to enable SIIPL to formulate the Vaccine Components and Manufacture the Product."
- 11. Article 3 (Global Allocation Tenets) shall now state as follows

The Parties are aware that Novavax is under a contractual arrangement with the Coalition for Epidemic Preparedness Innovations ("CEPI") under which Novavax has committed to sell [***] Product to a global allocation body endorsed by CEPI. Given the uncertainty associated with the global purchase of COVID-19 vaccine during the Pandemic Period, including the Product, the Parties agree that the JSC shall operate in full conformity with Novavax' obligations to CEPI and to the global allocation body it endorses. Furthermore, the Parties agree that during the Pandemic Period, for all Product for which the Drug Substance component has been Manufactured at any other location besides at a facility owned or controlled by SIIPL or an Affiliate, shall only be made available for purchase by the global allocation body endorsed by CEPI, currently expected to be the "COVAX Facility" or such other purchasing authority that Novavax in good faith represents has been endorsed and approved by CEPI. The JSC agrees to review and approve all such purchases during the Pandemic Period as directed by Novavax under its arrangement with CEPI. [****].

- 12. Article 4, Clause 4.5 (a) of the Agreement shall stand amended and modified as under-
 - "a. Documentation. Novavax will provide SIIPL with applicable information, reports, documents, certificates, and any other materials regarding Vaccine Components and Licensed Know—How that are [***] for SIIPL to Manufacture the Product, to Develop the Product and to obtain and maintain Regulatory Approval for the Product in the SIIPL Territory. Novavax will submit, maintain, and keep updated drug master files for the Vaccine Components and each facility in which Novavax Manufactures the Vaccine Components, SIIPL will submit, maintain, and keep updated drug master files for the Product and each facility in which SIIPL Manufactures the Product, and, following the Technology Transfer, for the Drug Substance and each facility in which SIIPL Manufactures the Drug Substance."
- 13. Article 4 Clause 4.7 of the Agreement shall stand amended and modified as under-
 - ****4.7 Regulatory Inquiries.** Novavax will [***] notify SIIPL in writing of any governmental or regulatory inquiries, inspections, or audits directly related to the Vaccine Components and Licensed Know–How and any findings related to the same. SIIPL will [***] notify Novavax in writing of any governmental or regulatory inquiries, inspections, or audits directly related to the Drug Substance and any findings related to the same. SIIPL will permit such governmental or regulatory body to inspect and audit its facilities and

- documents, including facilities and documents of its contract manufacturer(s), related to Vaccine Components at [***] cost and expense, and notify and update Novavax of such inquiries, inspections and audits."
- 14. Article 5, Clause 5.1 of the Agreement shall stand amended and modified as under-
 - "5.1 Technology Transfer. Within [***], Novavax shall transfer to SIIPL (a) all Licensed Know—How Controlled by Novavax that is (a) necessary to Manufacture the Drug Substance, including transfer of [***], and (b) necessary to use the Vaccine Components, for the Manufacture of the Product, including assays, specifications, diagrams, technology, manufacturing process descriptions, protocols, and other written know—how by providing copies or samples of relevant documentation, materials, and other embodiments of any such Licensed Know—How ("Technology Transfer")."
- 15. Clause 5.2 stated hereunder shall be inserted in in the Agreement and shall follow Clause 5.1 of the Agreement—
 - "<u>5.2 Drug Substance Manufacture</u>: In addition to the Clause 5.1 of the Agreement, as amended, stated hereinabove, the Parties further agree that for the purpose mentioned in the Amendment, the Technology Transfer and process Development and Manufacture of the Drug Substance shall be dealt in the manner provided hereunder:
 - <u>5.2.1 Premises</u>: The Parties hereby agree that SIIPL shall perform Technology Transfer, Process Development and any Manufacture and further Development of Drug Substance at SIIPL's manufacturing facility, subject to the terms and conditions set forth in this Amendment.
 - **5.2.2 Provision Raw Materials.** The Parties agree that SIIPL shall be free to procure the raw materials necessary for SIIPL to Manufacture the Drug Substance. In the event SIIPL and Novavax agree that SIIPL may procure certain critical raw materials from certain of Novavax' designated vendors, Novavax will instruct and authorize such designated vendors to directly transact with and supply SIIPL such critical raw materials as well as other consumables and information related thereto as may be necessary and required for SIIPL's Manufacture of the Drug Substance at SIIPL's manufacturing facility; provided Novavax shall have no liability and responsibility whatsoever regarding the quality of any such raw materials supplied to SIIPL by any such designated vendor. The list of critical raw materials and Novavax' designated vendors is set forth in Appendix D and the template letter of authorization to be provided by Novavax to its designated vendors is set forth in Appendix E (provided that Novavax may provide such authorization in any form it deems sufficient). The Parties agree that if any raw materials are to be purchased from such Novavax' authorized vendors, SIIPL shall seek prior written approval from Novavax of the quantities of such raw materials as may be required by SIIPL."
- 16. Article 6, Clause 6.1.(c) shall be renumbered as Clause 6.1.(d) and the following new Clause 6.1.(c) shall be inserted in the Agreement—
 - "6.4 Manufacturing License. Subject to the terms and conditions of this Agreement, as amended, Novavax hereby grants to SIIPL a non–exclusive, sublicensable (subject to Novavax' prior written consent) license under the Licensed Know–How and Licensed Patents to Manufacture the Drug Substance solely for use in the Manufacture of the Product in the Territory during the Term in the performance of this Agreement."

- 17. In Article 7, Clause 7.2 of the Agreement shall stand amended and modified as under–
 - "7.2 Vaccine Component Payment. The payments pertaining to Adjuvant Price to be paid by SIIPL to Novavax or its designee will be initiated [***] and will thereafter be due and payable upon receipt of the applicable invoice from Novavax (the "Vaccine Component Payment")."
- 18. Article 9, Clause 9.1.(a) of the Agreement shall stand amended and modified as under-
 - Subject to Sections 9.1(c) and 9.1(<u>d</u>), all proprietary rights, including any and all Intellectual Property Rights in the <u>Product</u> shall be exclusively owned and Controlled by and, shall remain exclusive property of SIIPL.
- 19. Clause 9.1.(e) as stated hereunder shall be inserted in the Agreement, and shall follow Clause 9.1.(d) of the Agreement–
 - "e. Inventorship of SIIPL Improvements pertaining to Drug Substance shall be determined in accordance with U.S. patent laws, and ownership shall follow inventorship. Novavax shall [***] disclose in writing to SIIPL of any Novavax Improvements to the Vaccine Components conceived, developed or reduced to practice during the Term. SIIPL shall [***] disclose in writing to Novavax of any SIIPL Improvements conceived, developed or reduced to practice during the Term."
- 20. Article 10, Clause 10.2 of the Agreement shall stand amended and modified as under-
 - "10.2 SIIPL Representation and Warranty.
 - "<u>a</u>. SIIPL represents and warrants to Novavax that all Product shall be manufactured and commercialized by SIIPL according to all Applicable Laws and cGMPs.
 - <u>B. SIIPL Controls all rights, title, and interests in and to its Background Intellectual Property it will use for the performance of this Agreement; including, without limitation, the Development, Manufacture, Commercialization or Exploitation, as applicable, of the Product and Drug Substance, and such use shall not violate or infringe, to the best of its knowledge, any Intellectual Property Rights of any third party."</u>
- 21. Article 14 Clause 14.2 of the Agreement shall be cancelled and instead the clause stated hereunder shall replace said Clause 14.2–
 - "14.2 Supply of Drug Substance to Novavax-Parties agree that in the event Novavax requires SIIPL to supply the Drug Substance Manufactured by SIIPL in such quantities as may be required by Novavax for its own use, then the same shall be done under terms and conditions (including, without limitation, [***]) mutually agreed to between the Parties in writing at the relevant time."
 - 14.2.2 Purchase of Drug Substance manufactured by Novavax' designated assignee-In the event the Parties agree that Drug Substance shall be supplied by Novavax or its third party designee, then the Parties shall execute any and all necessary additional agreements or instruments to such supply at the relevant time."

- 22. The provisions of this Amendment shall be incorporated into and are hereby made an essential part of the Agreement and this Amendment shall be co-terminus with the Agreement.
- 23. Except for the terms and conditions amended or added by this Amendment, all other terms and conditions of the Agreement shall remain in full force and effect.
- 24. Parties agree and accept that any modification or alteration or amendment to this Amendment shall be invalid unless mutually executed in writing by both Parties.
- 25. This Amendment is for the specific Purpose of the Amendment and for amending the clauses hereinabove and nothing stated in this Amendment shall mean or be interpreted as a waiver of any of the rights of either Party under the Agreement

IN WITNESS WHEREOF, the Parties hereto have caused their authorized representatives to execute this Amendment on the date first above written.

For and on behalf of For and on behalf of

Novavax, Inc. Serum Institute of India Private Limited

/s/ John A. Herrmann III

Name – John A. Herrmann III

Designation – Executive Vice President,

Name – [***]

Designation – [***]

Chief Legal Officer and Corporate Secretary

Appendix D

Authorized Vendors for Supply of Raw Materials from Novavax

[Pursuant to Regulation S-K, Item 601(a)(5), this Appendix setting forth the authorized suppliers for supply of raw materials from Novavax has not been filed. The Registrant agrees to furnish supplementally a copy of any omitted appendixes to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.]

[***]

Appendix E

Draft Authorization Letter

Novavax, Inc. Letterhead
2020
Dear
Re: Authorization for Supply of Raw Material for manufacturing of BV2373 (Drug Substance).
NOVAVAX, INC. ("Novavax") and SERUM INSTITUTE OF INDIA PRIVATE LIMITED ("SIIPL") have entered into certain Supply and License Agreement, under which Novavax has granted SIIPL a manufacturing license for the Novavax' BV2373 (Drug Substance) at its manufacturing facility in India.
In this connection, we hereby authorize you to provide supply of [] to SIIPL in quantities up to under terms and conditions to be negotiated between you and SIIPL. We further authorize you to deal and transact with SIIPL directly in order to expedite the procurement of such materials. For clarity, Novavax shall have no responsibility for payment for any such materials or other liability or obligation.
Sincerely
Name: Title:
CC to: Serum Institute of India Private Limited at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India