EX-10.2 3 w24117exv10w2.htm EXHIBIT 10.2

**Exhibit 10.2**

**THE REGISTRANT HAS APPLIED FOR CONFIDENTIAL TREATMENT OF CERTAIN PROVISIONS OF THIS EXHIBIT WITH THE SECURITIES AND EXCHANGE COMMISSION. THE CONFIDENTIA PORTIONS OF THIS EXHIBIT ARE MARKED WITH ASTERISKS (\*\*\*) AND HAVE BEEN OMITTED. THE OMITTED PORTIONS OF THIS EXHIBIT WILL BE FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT.**

**SUPPLY AGREEMENT**

     AGREEMENT, (this **“Agreement”**) is dated as of                     , **2006**by and between NOVAVAX, Inc., a Delaware corporation having its principal place of business at 508 Lapp Road, Malvern, Pennsylvania 19355, (“**NOVAVAX**” or **“Supplier”**) and ESPRIT Pharma, Inc., a Delaware corporation having its principal place of business at 2 Town Center Boulevard, East Brunswick, New Jersey 08816 (**“ESPRIT”**or **“Buyer”**). Supplier and Purchaser may be referred to individually as a **“Party”**or collectively as the **“Parties**.**”**

     WHEREAS, Supplier has been engaged in the development and supply of a product, IND # 63975, to be marketed, distributed and sold under a trademark mutually agreed upon between Buyer and Supplier;

     WHEREAS, on the date hereof, Buyer and Supplier also entered into a license agreement for the license by Supplier to Buyer of certain intellectual property enabling the manufacture, sale and use by Purchaser of topically- or transdermally-administered product containing no active ingredient other than testosterone, which utilize Supplier’s micellar nanoparticle technology in the field of women’s health in product that is marketed under Supplier’s IND No. 63957 (the “**License Agreement**”); and

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     WHEREAS, Buyer desires to have Supplier manufacture Product (as defined in Article 1 below) under a trademark mutually agreed upon between Buyer and Supplier, for sale by Buyer or its designee.

     NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and efficiency of which are hereby acknowledged, the parties hereto agree as follows:

**ARTICLE 1. DEFINITIONS**

     As used throughout this Agreement, each of the following terms shall have the respective meaning set forth below:

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|  | 1.1. |  | “**Affiliate**” means, with respect to any Party, any entity that directly or indirectly controls, is controlled by, or is under common control with such Party, and for such purpose “control” means (i) directly or indirectly owning, controlling or holding more than fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest in an entity or (ii) the possession, direct or indirect, of the power to direct or cause the direction of the management or the policies of the entity, whether through the ownership of voting securities, by contract or otherwise. Any such corporation, entity or business structure shall only be considered an Affiliate for so long as such ownership or control exists. |
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|  | 1.2. |  | “**cGMP**” means Good Manufacturing Practices according to 21 CFR Parts 210 and 211. |

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|  | 1.3. |  | “**CPI**” means United States Department of Labor, Bureau of Labor Statistics, Consumer Price Index, All Urban Consumers, United States City Average, All Items, (1982-84=100) excluding the food and energy components, or the successor index that most closely approximates the CPI. |
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|  | 1.4. |  | “**Damages**” has the meaning ascribed to such term in Section 16.1 (Indemnification by Supplier). |
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|  | 1.5. |  | **“Facility”**shall mean **Supplier’s**manufacturing location at Red Lion Road in Philadelphia, PA where product will be produced, packaged, and labeled. |
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|  | 1.6. |  | “**FDA**” means the United States Food and Drug Administration and successor bodies. |
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|  | 1.7. |  | “**Intellectual Property Rights**” means the intellectual property, trade secrets, know-how, technology and information, whether or not protected by patents, to the extent required in the reasonable judgment of Supplier to manufacture the Product. |
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|  | 1.8. |  | “**License Agreement**” means the license agreement referred to in the second recital of this Agreement. |
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|  | 1.9. |  | “**Net Sales**” has the meaning ascribed to such term in the License Agreement. |
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|  | 1.10. |  | “**Permitted Raw Materials Inventory**” has the meaning ascribed to such term in Section 8.3.1 (Permitted Raw Material Inventory). |

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|  | 1.11. |  | “**Product**” means the material with IND #63975, including pre-clinical, clinical, trade and sample lots, as more fully described on Schedule A to this Agreement, manufactured and packaged in accordance with the Specifications. |
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|  | 1.12. |  | “**Raw Materials**” means the materials, components, and packaging required to manufacture and package the Product in accordance with the Specifications. |
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|  | 1.13. |  | “**Specifications**” means the specifications for the design, composition, product safety assurance, manufacture, packaging, and/or quality control of the Product, as set forth on Schedule B attached hereto and made a part hereof, as the same may hereafter be modified by mutual agreement of the parties in writing. |
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|  | 1.14. |  | “**Supply Year**” means each consecutive 365-day period (or 366-day period in the event of a leap year) during the Term, commencing on the date of this Agreement. |
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|  | 1.15. |  | “**Territory**” means the United States, its territories including Puerto Rico , Mexico and Canada. |
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|  | 1.16. |  | “**Term**” has the meaning ascribed to such term in ARTICLE 6 (Term; Effective Date). |

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|  | 1.17. |  | “**Unit of Product**” means a month of therapy of Product for an individual end user. |

**ARTICLE 2.** **SUPPLY OF PRODUCT**

     During the Term, Supplier shall supply Buyer with those quantities of Product as ordered by Buyer pursuant to this Agreement, subject to the ordering procedures set forth in ARTICLE 4 (Forecasts; Capacity; Orders) below. Supplier shall sell Product exclusively to Buyer for sale in the Territory, and Buyer shall buy all of its requirements for Product exclusively from Supplier. Each Product sold hereunder will conform to the Specifications for such Product. Subject to the terms and conditions herein, Supplier will provide the facility, equipment, labor, and supervision necessary for the production of the Product in sufficient quantities as required herein.

**ARTICLE 3.** **PRICES FOR PRODUCT**

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|  | 3.1. |  | **Transfer Price.**The transfer price of Product, whether pre-clinical, clinical, commercial or samples, from Supplier to Buyer will be mutually agreed upon between the Parties, based on reasonable commercial terms. All transfer prices for Product referred to in this Section 3.1 shall be increased (on a compounded basis) \*\*\*. For the remainder of the Term, the transfer price of Product from Supplier to Buyer will be \*\*\* of Supplier’s fully burdened manufacturing cost. The estimated transfer price is set forth on Schedule D, attached hereto. |
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|  | 3.2. |  | **Payment Terms.**Payment terms on all orders shall be \*\*\* from the date of receipt of invoice by Buyer. Invoicing shall occur upon shipment. |

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**ARTICLE 4. FORECASTS, CAPACITY; ORDERS**

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|  | 4.1. |  | **Forecasts; Capacity; Capital Expenditures.**Beginning six (6) months prior to the date of which Buyer anticipates first taking delivery of commercial Product, and at the beginning of each calendar quarter thereafter, during the Term, Buyer shall provide Supplier with a binding written forecast of Buyer’s requirements for Product for the shorter of the following twelve (12) months or the remainder of the Term (each, a “**Rolling 12 Month Forecast**”). Each Rolling 12 Month Forecast will be binding within a range of \*\*\* of the stated amount within such Rolling 12 Month Forecast; provided that the first three months of the each Rolling 12 Month Forecast will be binding without reference to the foregoing range. Beginning six (6) months prior to submission of Buyer’s first order of commercial Product, Buyer will provide Supplier with a statement which shall set forth the capacity expectation for Buyer’s requirements during the Term on a monthly basis (**“Capacity”**). The parties understand and agree that any capital expenditures, incurred by Supplier in connection with the performance of its obligations under this Agreement will be borne by Buyer, it being understood that Supplier and Buyer will consult in good faith regarding any such capital expenditure prior to its incurrence. The parties further understand that the foregoing forecasts and Capacity shall include both sample and trade quantities of Product. |
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|  | 4.2. |  | Supplier will use commercially reasonable efforts to meet Buyers demand for Product. |

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|  | 4.3. |  | **Change Orders.**Quarterly requirements contained in any 12 Month Rolling Forecast may be changed with \*\*\* prior written notice from Buyer to Supplier provided that Supplier consents to such change order in writing (which consent may be withheld by Supplier in its sole discretion). |
|  |  |  |  |
|  | 4.4. |  | **Conflicts.**To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern. |

**ARTICLE 5.** **ADDITIONAL UNDERSTANDINGS OF THE PARTIES**

|  |  |  |  |
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|  | 5.1. |  | **Chemistry, Manufacturing, and Control.**Supplier will be responsible, at Buyer’s expense, for all work associated with initial chemistry, manufacturing and controls in accordance with Schedule C attached to this Agreement. Buyer shall reimburse Supplier for all its costs and expenses incurred in connection with such work. Schedule C represents Supplier’s best estimate, in 2006 pricing, of the projected, anticipated costs for the CMC set forth therein. Supplier anticipates, but cannot guarantee, that such reasonable costs and expenses will not exceed be greater than \*\*\* of the total estimated costs and expenses set forth in Schedule C, \*\*\*. If the Costs in Schedule C exceed \*\*\*, as adjusted by the CPI, Supplier and Buyer shall refer the pricing issues to the Joint Steering Committee, established under the License Agreement, for a fair and equitable resolution based on reasonable commercial terms under the circumstances. Supplier shall invoice Buyer for such costs and expenses on a Calendar Quarterly basis within \*\*\* of the end of each Calendar Quarter and |

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|  |  |  | Buyer shall pay Supplier the invoiced amount within \*\*\* of receiving such invoice. |
|  | 5.2. |  | **Other Affiliates.**If any other Affiliate of Buyer desires to purchase the Product from Supplier under the terms of this Agreement, then, upon the execution of a copy of this Agreement by such Affiliate, Supplier shall accord such Affiliate all of the benefits hereof and treat such affiliate as a **“**Buyer**”**for the purposes of this Agreement; provided, however, that this section will not be construed to relieve Buyer of any of its obligations hereunder. |
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|  | 5.3. |  | **Exclusive Rights.**During the Term, Supplier shall supply Buyer, on an exclusive basis, with the Product for sale in the Territory and neither Supplier nor any of its Affiliates shall sell or distribute the Product. Furthermore, during the Term Buyer shall purchase all of its requirements for the Product exclusively from Supplier. |
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|  | 5.4. |  | **Insurance.**Each of Supplier and Buyer agrees to procure and maintain in full force and effect during the Term valid and collectible insurance policies of a type and coverage amount consistent with Supplier’s and Buyer’s past practice prior to the date hereof. Should Supplier require additional insurance to be carried by Buyer, any incremental cost will be for the account of Buyer. Upon request, Buyer and Supplier shall provide the other Party with appropriate Certificates of Insurance or other written evidence reasonably satisfactory evidencing such insurance coverage. |

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|  | 5.5. |  | During the Term, Supplier shall maintain a workforce of appropriate size, training and experience sufficient in the reasonable judgment of Supplier for manufacturing the Product in an amount not to exceed Capacity. If Buyer requires additional personnel for maintaining its equipment and facilities and otherwise necessary to fulfill Supplier’s other obligations hereunder, the incremental cost thereof will be borne solely by Buyer. |

**ARTICLE 6. TERM; EFFECTIVE DATE**

     The term of this Agreement shall commence on the date hereof and remain in effect until \*\*\* (the **“Expiration Date”**), unless sooner terminated as expressly provided under this Agreement (the **“Term”**). Notwithstanding anything to the contrary contained herein, this Agreement will be effective the date of this Agreement.

**ARTICLE 7. TERMINATION**

|  |  |  |  |
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|  | 7.1. |  | **Breach.**This Agreement may be terminated, prior to the Expiration Date, by either Party by giving ninety (90) days written notice of its intent to terminate and stating the grounds therefor if the other Party shall materially breach or materially fail in the observance or performance of any representation, warranty, guarantee, covenant or obligation under this Agreement. The Party receiving the notice shall have seventy-five (75) days from the date of receipt thereof to cure the breach or failure. Notwithstanding anything to the contrary contained herein, payment defaults will have a ten (10) day cure period. In the event such breach or failure is cured, the notice shall be of no effect. |

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|  | 7.2. |  | **Termination of License Agreement.**Subject to earlier expiration or termination, this Agreement will terminate simultaneously with the termination of the License Agreement. |
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|  | 7.3. |  | **Insolvency, Etc.**This Agreement may be terminated, prior to the Expiration Date, upon thirty (30) days written notice by either Party: (i) in the event that the other Party hereto shall (a) apply for or consent to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (b) make a general assignment for the benefit of its creditors, (c) commence a voluntary case under the United States Bankruptcy Code, as now or hereafter in effect (the **“Bankruptcy Code”**), (d) file a petition seeking to take advantage of any law (the **“Bankruptcy Laws”**) relating to bankruptcy, insolvency, reorganization, winding-up, or composition or readjustment of debts, or (e) take any corporate action for the purpose of effecting any of the foregoing; or (ii) if a proceeding or case shall be commenced against the other Party hereto in any court of competent jurisdiction, seeking (a) its liquidation, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (b) the appointment of a trustee, receiver, custodian, liquidator or the like of the Party or of all or any substantial part of its assets, or (c) similar relief under any Bankruptcy Laws, or an order, judgment or decree approving any of the foregoing shall be entered and continue unstayed for a period of sixty (60 days; or (iii) an order for relief against the other Party hereto shall be entered in an involuntary case under the Bankruptcy Code. |

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|  | 7.4. |  | **Effect of Termination.**Notwithstanding the termination of this Agreement for any reason, each Party hereto shall be entitled to recover any and all Damages which such Party shall have sustained by reason of the breach by the other Party hereto of any of the terms of this Agreement. Termination of this Agreement for any reason shall not release either Party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either Party hereto which is expressly stated elsewhere in this Agreement to survive such termination. In the case of a termination under Section 7.1 (Breach) above, the non-defaulting Party may pursue any remedy available in law or in equity with respect to such breach, subject to the terms of Section 17.1 (Arbitration). | | | |
|  | | | | 7.4.1. |  | **Buyer’s Commitment to Purchase.**In the event that this Agreement expires or is terminated for any reason (other than Supplier’s material breach, gross negligence or willful misconduct), \*\*\*. Buyer shall accept delivery of any such Permitted Raw Materials Inventory within \*\*\* after such expiration or termination at the location designated by Buyer. If Buyer instructs Supplier to scrap any such Permitted Raw Material Inventory, \*\*\*. |

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**ARTICLE 8. DELIVERY; INVENTORY**

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|  | 8.1. |  | **Delivery.**All charges for packing, hauling, storage, bar coding, and transportation to point of delivery are not included in the Transfer Price and Transfer Price shall be F.O.B. the Facility (i.e., Buyer will pay for shipment). All shipments must be accompanied by a packing slip which describes the articles, states the purchase order number and shows the shipment’s destination. Supplier agrees to promptly forward the original bill of lading or other shipping receipt for each shipment in accordance with Buyer’s instructions. Supplier further agrees to promptly render, after delivery of goods or performance of services, correct and complete invoices to Buyer, and to accept payment by check or at Buyer’s discretion, other cash equivalent (including electronic transfer of funds). |
|  |  |  |  |
|  | 8.2. |  | **Shipment.**The risk of loss with respect to Product shall remain with Supplier until the point at which any such Product is delivered to the loading dock at the Facility. Supplier will pack all Product ordered hereunder in a manner suitable for shipment and sufficient to enable the Product to withstand the effects of shipping, including handling during loading and unloading. |
|  |  |  |  |
|  | 8.3. |  | **Product Inventory.**Supplier will maintain inventory of commercial Product on a first-in, first-out basis. In no event shall Supplier be required to, and Supplier will not, order more than \*\*\* Raw Materials at Capacity and Supplier will use commercially reasonable efforts to manage such inventory as efficiently as possible. |

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|  | 8.3.1. |  | **Permitted Raw Material Inventory.**To shorten lead times hereunder and to support variations in demand, as and if necessary, Supplier shall during the Term maintain such inventory of Raw Materials as are reasonably required to manufacture and package Product in accordance with the Specifications in a quantity equivalent to \*\*\* of Buyer’s forecasted purchase volume (the foregoing amount of inventory which conforms to the Specifications being hereinafter referred to collectively as the **“Permitted Raw Material Inventory”**) or such other specific amount of Permitted Raw Material Inventory as may be agreed to by both parties in writing in advance. Supplier’s purchase price and the cost of carrying Permitted Raw Material Inventory shall be for the account of Buyer. The quantity of Permitted Raw Material Inventory shall be adjusted by Supplier as needed based upon \*\*\*. In the event that Buyer’s requirements for Product materially exceed Buyer’s current forecasted needs, Supplier shall draw from the Permitted Raw Material Inventory to meet such excess requirements. Supplier shall then replenish the Permitted Raw Material Inventory within \*\*\*. |

**ARTICLE 9.** **INSPECTION**

     Buyer shall have the right, upon reasonable notice to Supplier and during regular business hours, to inspect and audit not more than \*\*\* per \*\*\* period the facilities being used by Supplier for production and storage of the Product to assure compliance by Supplier with cGMP

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and applicable FDA and other rules and regulations and with other provisions of this Agreement. Supplier shall notify Buyer as promptly as practicable of any audit, review or inspection by any regulatory authority relating, directly or indirectly, to the Product, and shall in any event notify Buyer of any such audit, review or inspection within 24 hours of Supplier’s first being informed of any such event. Supplier and Buyer will work together to remedy or cause the remedy of any deficiencies which may be noted in any such audit or, if any such deficiencies can not reasonably be remedied within such seven (7) day period, develop a written plan to remedy such deficiencies as soon as possible; and the costs of such remedy shall be borne by the Supplier.

**ARTICLE 10. DEFECTIVE PRODUCT/INSPECTIONS/TESTING**

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|  | 10.1. |  | **Disposition of Defective Product.**Buyer shall notify Supplier of the existence and nature of any non-compliance or defect and Supplier shall have a reasonable opportunity, not to exceed \*\*\* from receipt of notification, to inspect such defective Product and provide Buyer with detailed written instructions to return or dispose of such defective Product. Buyer shall have no obligation to pay for any Product that is subject to such a claim of non-compliance or defect. If Supplier fails to so inspect and instruct Buyer as to the disposition of such defective Product, Buyer may dispose of such defective Product as it sees fit and Supplier shall promptly (i) reimburse Buyer for all direct, out-of-pocket costs incurred by Buyer in such disposition, and (ii) replace such defective Product at its own cost and expense. |
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|  | 10.2. |  | **Independent Testing.**If, after Supplier’s inspections of such Product, the parties disagree as to the Product’s conformance to the Specifications or |

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|  |  |  | whether the Product has such a defect, either Party may deliver the Product to an independent third-Party laboratory, mutually and reasonably acceptable to both parties, for analytical testing to confirm the Product’s conformance to the Specifications or the presence or absence of defects. All costs associated with such third-Party testing shall be at Supplier’s expense. No inspection or testing of or payment for Product by Buyer or any third-Party agent of Buyer shall constitute acceptance by Buyer thereof, nor shall any such inspection or testing be in lieu or substitution of any obligation of Supplier for testing, inspection and quality control as provided in the Specifications or under applicable local, state, or federal laws, rules, regulations, standards, codes or statutes. | |
|  | 10.3. | |  | **Reports.**Promptly after Buyer’s reasonable written request, Supplier shall provide Buyer written reports relating to any aspects of the Product that are identified in the Specifications. |
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|  | 10.4. | |  | **Complaint Handling**. Supplier and Buyer each, shall promptly convey to and inform the other of any customer or user complaints received by Buyer or Supplier in connection with Product. |
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|  | 10.5. | |  | **Quality Control.**Prior to each shipment of Product to Buyer, Supplier shall conduct or have conducted quality control testing of Product in accordance with the Specifications and such other Supplier approved quality control testing procedures that are consistent with FDA cGMPs. Supplier shall retain or have retained accurate and complete records pertaining to such testing. |

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|  |  |  | Supplier shall notify Buyer in writing at least ten (10) days prior to any change in the testing methods and shall provide Buyer a copy of the revised testing methods within ten (10) days of implementation of the changes. Each shipment of Product hereunder shall be accompanied by a certificate of analysis for each lot of Licensed Product therein. |

**ARTICLE 11. FAILURE TO SUPPLY; FORCE MAJEURE**

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|  | 11.1. |  | **Force Majeure Events.**If either Party is prevented from performing any of its obligations hereunder due to any cause which is beyond the non-performing Party’s reasonable control, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; war or civil commotion; strike, lock-out or labor disturbances; or failure of public utilities or common carriers (a **“Force Majeure Event”**), such non-performing Party shall not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event. Such non-performance will be excused for six (6) months or as long as such event shall be continuing (whichever occurs sooner), provided that the non-performing Party gives prompt written notice to the other Party of the Force Majeure Event. Such non-performing Party shall exercise all commercially reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable. |
|  |  |  |  |
|  | 11.2. |  | **Failure to Supply.**Notwithstanding the provisions of Section 11.1 (Force Majeure Events), in the event that Supplier shall be unable or unwilling or |

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|  |  |  | shall fail to supply any Product in such quantities as Buyer shall request and in compliance with the delivery periods set forth in Section 4.3 (Change Orders) (whether due to the occurrence of a Force Majeure Event, following the commencement of a case by or against Supplier under the Bankruptcy Code or otherwise (hereinafter referred to as a **“Failure to Supply”**), then Buyer shall be permitted (after the expiration of a \*\*\* cure period following written notice from Buyer to supplier of such Failure to Supply and such Failure to Supply has not been cured by Supplier) to (i) to obtain such Product from another supplier including Cardinal, or (ii) to use, sell, and make Product itself in the Cardinal Red Lion facility or at another location. In this regard, Supplier shall (at no cost to Supplier) take all actions and provide all such cooperation and support reasonably necessary and reasonably within its control to give Buyer the right to enter, upon reasonable notice and during regular business hours, and shall be given access to, the Facility (or any other location where the Equipment is used or stored) so that Buyer may use or retrieve all records maintained in connection with the manufacturing equipment. Supplier’s obligations under this Section shall survive the termination of this Agreement for a period of \*\*\*. Upon the occurrence of any such Failure to Supply and through and until such time as Supplier fully resumes its supply obligations hereunder: (a) Supplier shall (at no cost to Supplier) take all reasonable actions within its control, execute and deliver all documents, and provide all such assistance as Buyer reasonably requests to enable Buyer to obtain Product from another supplier or to manufacture |

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|  |  |  | Product itself; (b) Supplier shall (at no cost to Supplier) make available to Buyer or its designee access to any and all Intellectual Property Rights (to the extent not already granted pursuant to the License Agreement) and any other technical and proprietary materials, information and techniques necessary or helpful for Buyer to procure required Raw Materials or produce or arrange an alternative supplier of Product; (c) Supplier shall (at no cost to Supplier) provide advice and consultation in connection therewith; (d) Buyer shall purchase Product from Supplier once Supplier has cured the failure to supply; and (e) Buyer shall terminate any contractual arrangements contemplated by clause (a) of this sentence once Supplier has cured the failure to supply. As soon as reasonably practicable after an uncured Failure to Supply, Supplier shall furnish Buyer with Licensed Know-How (as defined in the License Agreement) which is necessary to enable Buyer to manufacture or have manufactured Product as contemplated by this Agreement. In the event either party hereto believes it to be in the best interest of both parties, as the licensor and licensee of the Licensed Product in the Territory, to designate and qualify an alternate contract manufacturer of the Licensed Product, each party shall consider in good faith the views of the other party as to the advisability of engaging an alternate contract manufacturer. If agreed by the parties that an alternate contract manufacturer should be designated and qualified, the parties shall cooperate to ensure the transition of the Licensed Product manufacturing to a third party in a manner that minimizes any interruption of supply of Licensed Product within the Territory. |

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**ARTICLE 12. LABELING; ARTWORK**

     Buyer shall have the right to determine the appearance and text of any labeling, packaging and promotional material used in connection with the Product or any finished product containing or contained in the Product (“**Packaging and Promotional Material**”). All costs and expenses relating to Packaging and Promotional Material used in connection with the Product will be borne by Buyer.

**ARTICLE 13. CONFIDENTIALITY**

|  |  |  |  |
| --- | --- | --- | --- |
|  | 13.1. |  | **Confidential Information.**All information disclosed by one Party to the other(s) or developed by the parties pursuant to the terms of this Agreement (the **“Confidential Information”**) shall be maintained strictly confidential and used only for the purposes of this Agreement in accordance with this ARTICLE 13 (Confidentiality) (**“Purposes”**). Each Party may also disclose the other’s information to an Affiliate, agent or consultant, who is under a written obligation of confidentiality and non-use at least substantially equivalent to the obligations of this ARTICLE 13 (Confidentiality), with the exceptions that the Parties shall each be free to disclose the existence of this Agreement and the nature of the Product being manufactured hereunder and the terms to its prospective licensees and sub-licensees, investors or prospective investors, lenders and other potential funding sources, or to a third party in connection with a merger or acquisition or proposed merger or acquisition, subject to an obligation of confidentiality and non-use, and provided that such Party shall have used commercially reasonable efforts to obtain a written confidentiality agreement from such third Party contemplated |

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Novavax Esprit Supply Agreement

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|  |  |  | by this sentence**.**Each Party shall guard any confidential information of the other Party with the same level of diligence as it normally guards any of its own internal confidential, proprietary information. Each Party shall be responsible for the breach of any of the provisions of this Article 13 by a person or entity to whom such Party discloses information contemplated hereby. Notwithstanding the foregoing, each Party shall be relieved of the confidentiality and limited use obligations of this Agreement if: |

(a) the information was previously known to the receiving Party as evidenced by the prior written records of such Party without disclosure by the disclosing Party;

(b) the information is or becomes generally available to the public through no fault of the receiving Party;

(c) the information is acquired in good faith in the future by the receiving Party from a third Party not under an obligation of confidence to the disclosing Party with respect to such information; or

(d) the information is independently developed by the receiving Party without reliance on, reference to, or knowledge of, the information disclosed by the disclosing Party. The parties understand and agree that it shall be the receiving Party’s burden of proof to show the applicability of any of the exceptions set forth in clauses (a), (b) (c) or (d) above.

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|  | 13.2. |  | **Exclusions.**Notwithstanding the above obligations of confidentiality and non-use a Party may: |

(a) disclose information to a regulatory agency that is necessary to obtain regulatory approval in a particular jurisdiction; or

(b) disclose information to a government agency if the disclosure is necessary to protect the health and safety of the Party’s workers or the public or as required by law; or

(c) disclose information as and to the extent required to comply with applicable laws and regulations, including the rules and regulations of the U.S. Securities and Exchange Commission.

     In making such disclosures as set forth in this Section 13.2 (Exclusions), the disclosing Party shall use reasonable efforts to promptly first notify the owner of the Confidential Information so as to allow the owner of the confidential information an opportunity to seek a protective order or otherwise limit any such disclosure. In any event, the disclosing Party shall use reasonable efforts to only disclose such information as is required to be disclosed pursuant to the law, regulation, rule or order, and shall use its reasonable efforts to obligate the recipient to secrecy on the same terms as set forth herein. Each Party shall restrict the disclosure of confidential information of the other so that only the persons that need to know it shall be informed and the disclosure be limited to only such portions as necessary for the purposes of this Agreement.

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|  | 13.3. |  | **Use of Names.**Neither Party shall state or imply, in any publication, advertisement, sales promotional material, or other medium (a) the name of the other Party or the name(s) of any employee(s) of the other Party; or (b) the name of any Affiliate of the other Party or the name(s) of any employee(s) of such Affiliate without the prior written consent of the other Party. |
|  |  |  |  |
|  | 13.4. |  | **Disclosure Agreement.**Except for the filing of a copy of this Agreement with the Securities and Exchange Commission or other securities commission of such other jurisdictions whose laws may apply to either Party to the extent required by law and such other public announcements as may hereafter become required by law, regulation or rule due to changes from the facts and circumstances in existence as of the date hereof, no Party hereunder shall disclose this Agreement or make any public announcement or filing concerning this Agreement or the subject matter hereof without the prior written consent of the other. In the event that pursuant to the foregoing a Party shall file a copy of this Agreement with the Securities and Exchange Commission or other securities commission of such other jurisdictions whose laws may apply to either Party, it shall use reasonable efforts to seek confidential treatment for all portions thereof reasonably requested by the other Party. Any proposed announcement or filing by a Party shall be made available to the other Party in advance of publication or filing, as the case may be, for review and comment. If a Party decides to make an announcement or disclosure required by law or as otherwise permitted under this section of this Agreement, it will provide the other Party with at least ten (10) days, where |

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|  |  |  | possible, advance written notice of the text of any such written announcement or disclosure or content of any non-written disclosure or announcement, except to the extent applicable law requiring disclosure would not permit such advance notice (such as in the case of certain securities filings), in which case the disclosing Party will give the maximum notice possible under the circumstances, so that the other Party will have an opportunity to comment upon the announcement or disclosure. | |
|  | 13.5. | |  | **Publication.**Except for permissible publications under this Article 13 neither Party will publish any information based upon or derived from the work performed under this Agreement without the prior review and consent of the Parties pursuant to this ARTICLE 13 (Confidentiality). |

|  |  |  |  |
| --- | --- | --- | --- |
|  | 13.6. |  | **Other Confidentiality Obligations.**With respect to information disclosed on or after the date hereof between Buyer and Supplier under the provisions of this Agreement, the provisions of this Agreement shall govern and prevail. In the event of any conflict between this Agreement and any other pending confidentiality agreement between Buyer and Supplier, with respect to information disclosed on or after the date hereof, the terms of this Agreement shall govern and prevail. |

**ARTICLE 14. CERTAIN REPRESENTATIONS, WARRANTIES AND COVENANTS**

|  |  |  |  |
| --- | --- | --- | --- |
|  | 14.1. |  | **Product Warranties.**Supplier warrants to Buyer that all Product supplied in connection with this Agreement shall be of merchantable quality, fit for the purpose intended by this Agreement and shall be manufactured and provided |

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|  |  |  | in accordance and conformity with the Specifications including cGMP standards. |
|  |  |  |  |
|  | 14.2. |  | **Execution and Performance of Agreement.**Each of Supplier and Buyer represents to the other that (i) it has full right, power and authority to enter into and perform its obligations under this Agreement; (ii) the entry into and performance of this Agreement has been duly authorized, executed and delivered by it and each party has obtained all necessary consents and provided all necessary notices, as the case may be, required in connection with this Agreement; and (iii) this Agreement is the valid binding obligation of it enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors’ rights and to general principles of equity. Supplier and Buyer further represent and warrants to the other that the performance of its obligations under this Agreement will not result in a violation or breach of, and will not conflict with or constitute a default under any agreement, contract, commitment or obligation to which such Party or any of its Affiliates is a Party or by which it is bound. |
|  |  |  |  |
|  | 14.3. |  | **DISCLAIMER.**THE FOREGOING WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR ANY WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR NON-INFRINGEMENT, ALL |

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|  |  |  | OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED. | |
|  | 14.4. | |  | **LIMITATION OF LIABILITY.**EXCEPT FOR THEIR RESPECTIVE OBLIGATIONS UNDER ARTICLE 16 (INDEMNIFICATION) ARISING OUT OF THIRD PARTY CLAIMS, SUITS OR DEMANDS OR FOR ANY BREACH OF CONFIDENTIALITY OBLIGATIONS OWED UNDER THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY PUNITIVE, SPECIAL, INCIDENTAL, OR INDIRECT DAMAGES UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER. |

**ARTICLE 15. COMPLIANCE**

     Supplier agrees to comply with the applicable provisions of any Federal or State law and all executive orders, rules and regulations issued thereunder, whether now or hereafter in force, including Executive Order 11246, as amended, Chapter 60 of Title 41 of the Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex or national origin; Section 60-741.1 of Chapter 60 of 41 Code of Federal

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Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of physical or mental handicap; Section 60.250.4 of Chapter 60 of 41 Code of Federal Regulations, as amended, providing for the employment of disabled veterans and veterans of the Vietnam era; Chapter 1 of Title 48 of the Code of Federal Regulations, as Amended, Federal Acquisition Regulations; Sections 6, 7 and 12 of the Fair Labor Standards Act, as amended, and the regulations and orders of the United States Department of Labor promulgated in connection therewith. Supplier agrees that it shall comply with all present and future statutes, laws, ordinances and regulations relating to the manufacture and supply of the Product being provided hereunder, including, without limitation, those enforced by the FDA (including compliance with good manufacturing practices) and International Standards Organization Rules 9,000 et seq.

**ARTICLE 16. INDEMNIFICATION**

|  |  |  |  |
| --- | --- | --- | --- |
|  | 16.1. |  | **Generally.**Buyer and Supplier will each defend as the case may be (each an “**Indemnifying Party**”), at its own expense, indemnify and hold harmless the other Party and its Affiliates (each an “**Indemnified Party**”) from and against any and all damages, liabilities, losses, costs, and expenses, including attorneys fees (collectively, **“Liabilities”**), arising out of any claim, suit or proceeding brought against the Indemnified Party (each a “**Claim**”) to the extent such Claim is based upon a claim arising out of or relating to (i) any breach or violation of, or failure to perform, any covenant or agreement made by such Indemnifying Party in this Agreement, unless waived in writing by the Indemnified Party; (ii) any breach of the representations or warranties made by such Indemnifying Party in this Agreement; or (iii) the negligence or willful misconduct of the indemnifying Party, except, under clause (ii), to the extent arising out of the breach, violation, failure, negligence or willful misconduct of the Indemnified Party. |

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|  | 16.2. |  | **Product Liability.**Except as otherwise provided herein, Buyer (as the Indemnifying Party) will defend, at its own expense, indemnify and hold harmless Supplier and its Affiliates (as the Indemnified Parties) from and against all Liabilities arising out of any Claim to the extent such Claim is based upon a claim arising out of or relating to any personal injury or death of any Person as a result of the use of any Product sold by Buyer, its Affiliates or Sub-licensees, except to the extent such Claim is due to the manufacture of Product supplied by Supplier other than in accordance with Specifications as provided in this Agreement or the negligent, grossly negligent, or intentional act or omission of Supplier and its Affiliates. Similarly, Supplier (as the Indemnifying Party) will defend, at its own expense, indemnify and hold harmless Buyer and its Affiliates (as Indemnified Parties) from and against any and all Liabilities arising out of any Claim brought against Buyer or any such Affiliate to the extent such Claim is based upon a claim arises out of a Third Party claim or suit or demand based on bodily injury or property damage resulting from the manufacture of Product supplied by Supplier other than in accordance with Specifications as provided in this Agreement, unless such claim is due to the negligent, grossly negligent or intentional act or omission of Buyer. |
|  |  |  |  |
|  | 16.3. |  | **Claims.**If any claim is made by a Third Party (a **“Third Party Claim”**) against a party entitled to indemnification hereunder (an “**Indemnified Party”**) that, if sustained, would give rise to a Liability to a party (the **“Indemnifying Party”**) under this Agreement, the Indemnified Party shall promptly cause notice of the claim to be delivered to the Indemnifying Party along with all of the facts, |

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|  |  |  | information or materials relating to such claim of which the Indemnified Party is aware; provided, however, that failure to give such notification shall not affect the indemnification provided for hereunder except to the extent that the Indemnifying Party shall have been actually prejudiced as a result of such failure. The Indemnified Party shall deliver to the Indemnifying Party, within five (5) days after the Indemnified Party’s receipt thereof, copies of all notices and documents (including court papers) received by the Indemnified Party relating to such Third Party Claim. If a Third Party Claim is made against an Indemnified Party, the Indemnifying Party will be entitled to participate in the defense thereof and, if it so chooses, to assume the defense thereof with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party. Should the Indemnifying Party so elect to assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof, unless the Third Party Claim involves potential conflicts of interest or substantially different defenses for the Indemnified Party and the Indemnifying Party. If the Indemnifying Party assumes such defense, the Indemnified Party shall have the right to participate in the defense thereof and to employ counsel, at its own expense (except as provided in the immediately preceding sentence), separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party shall control such defense. The Indemnifying Party shall be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying |

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|  |  |  | Party has not assumed the defense of any Third Party Claim that, if sustained, would give rise to a Liability of the Indemnifying Party under this Agreement. The parties shall cooperate in the defense or prosecution of any Third Party Claim. Such cooperation shall include the retention and (upon the Indemnifying Party’s request) the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim, and reasonable efforts to make employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. Whether or not the Indemnifying Party shall have assumed the defense of a Third Party Claim, the Indemnified Party shall not admit any Liability with respect to, or settle or compromise a Third Party Claim without the Indemnifying Party’s prior written consent (which consent shall not be unreasonably withheld). The Indemnifying Party may pay, settle or compromise a Third Party Claim (i) with the written consent of the Indemnified Party, not to be unreasonably withheld or delayed or (ii) without the written consent of the Indemnified Party, so long as such settlement includes (A) an unconditional release of the Indemnified Party from all Liability in respect of such Third Party Claim and (B) does not subject the Indemnified Party to any injunctive relief or other equitable remedy. In the event an Indemnified Party has a claim against an Indemnifying Party that does not involve a Third Party Claim, the Indemnified Party shall promptly cause notice of such claim to be delivered to the Indemnifying Party. If the Indemnifying Party disputes such claim, the Indemnifying Party and the Indemnified Party shall attempt in good faith for a |

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|  |  |  | period of ten (10) days to settle any such dispute. If the parties are unable to resolve such dispute, the Indemnified Party may pursue any and all courses of action available against the Indemnifying Party. |

**ARTICLE 17. MISCELLANEOUS**

|  |  |  |  |
| --- | --- | --- | --- |
|  | 17.1. |  | **Arbitration.**Any dispute, controversy or claim arising out of or relating to this Agreement or the validity, inducement, or breach thereof, shall be settled by arbitration in accordance with Article 11 (Arbitration) of the License Agreement. EXCEPT WITH RESPECT TO THEIR RESPECTIVE OBLIGATIONS UNDER ARTICLE 16 (INDEMNIFICATION) ARISING OUT OF THIRD PARTY CLAIMS, SUITS OR DEMANDS OR FOR ANY BREACH OF CONFIDENTIALITY OBLIGATIONS OWED UNDER THIS AGREEMENT, THE ARBITRATOR SHALL NOT AWARD ANY PARTY PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, AND EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT TO SEEK SUCH DAMAGES. |
|  |  |  |  |
|  | 17.2. |  | **Relationship of the Parties.**The relationship of Buyer and Supplier established by this Agreement is that of independent contractors, and nothing contained herein shall be construed to (i) give either Party any right or authority to create or assume any obligation of any kind on behalf of the other or (ii) constitute the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking. |

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|  | 17.3. |  | **Entire Agreement**. It is the mutual desire and intent of the parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. The parties have, in this Agreement, incorporated all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, neither Party makes any covenant or other commitment to the other concerning its future action. Accordingly, this Agreement and the License Agreement (i) constitute the entire agreement and understanding between the parties with respect to the subject matter hereof and there are no promises, representations, conditions, provisions or Terms related thereto other than those set forth in this Agreement and (ii) supersede all previous understandings, agreements and representations between the parties, written or oral. No modification, change or amendment to this Agreement shall be effective unless in writing signed by each of the parties hereto. |
|  |  |  |  |
|  | 17.4. |  | **Construction.**Unless otherwise expressly provided for herein (i) financial and accounting terms will have the meaning ascribed to such terms in accordance with U.S. generally accepted accounting principles, consistently applied, (ii) the word, **“**including**”**, will mean **“**including but not limited to**”**and the word **“**day**”**will mean **“**calendar day**”**, (iii) references to the singular will include the plural and vice versa, (iv) the use of any pronoun will include the neuter and both genders, and (v) references to Sections, Articles, Schedules and Exhibits will be references to Sections, Articles, Schedules and Exhibits to this Agreement and the word, **“**herein**”**and words of similar import will be construed to refer to this Agreement, |

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|  |  |  | and (vi) headings and titles of Sections and Articles herein will be construed to be descriptive only and without any substantive or interpretive effect. | |
|  | 17.5. | |  | **Notices.**All notices and other communications hereunder shall be in writing. All notices hereunder of an Indemnity Claim, a Force Majeure Event, default or breach hereunder, or, if applicable, Termination or renewal of the Term hereof, or any other notice of any event or development material to this Agreement taken as a whole, shall be delivered personally, or sent by national overnight delivery service or postage pre-paid registered or certified U.S. mail, and shall be deemed given: when delivered, if by personal delivery or overnight delivery service; or if so sent by U.S. mail, three business days after deposit in the mail, and shall be addressed: |

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|  |  | If to Supplier: | | |  | Attention: Chief Executive Officer |
|  |  |  |  |  |  | NOVAVAX, Inc. |
|  |  |  |  |  |  | 508 Lapp Road |
|  |  |  |  |  |  | Malvern, PA 19355 |
|  |  |  |  |  |  |  |
|  |  |  |  | With a copy to: |  | Attention: Legal Department |
|  |  |  |  |  |  | NOVAVAX, Inc. |
|  |  |  |  |  |  | 508 Lapp Road |
|  |  |  |  |  |  | Malvern, PA 19355 |
|  |  |  |  |  |  |  |
|  |  | If to Buyer: | | |  | Attention: Chief Executive Officer |
|  |  |  |  |  |  | ESPRIT Pharma, Inc. |
|  |  |  |  |  |  | Two Tower Blvd. |
|  |  |  |  |  |  | East Brunswick, NJ 08816 |
|  |  |  |  |  |  |  |
|  |  |  |  | With a copy to: |  | Attention: Steven M. Bosacki, General Counsel |
|  |  |  |  |  |  | ESPRIT Pharma, Inc. |
|  |  |  |  |  |  | Two Tower Blvd. |
|  |  |  |  |  |  | East Brunswick, NJ 08816 |

or to such other place as either Party may designate by written notice to the other in accordance with the Terms hereof.

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|  | 17.6. |  | **Failure to Exercise.**The failure of either Party to enforce at any time for any period any provision hereof shall not be construed to be a waiver of such provision or of the right of such Party thereafter to enforce each such provision, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy. Remedies provided herein are cumulative and not exclusive of any remedies provided at law. |
|  |  |  |  |
|  | 17.7. |  | **Assignment.**This Agreement may not be assigned by either Party without the prior written consent of the other which will not be unreasonably withheld or |

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|  |  |  | delayed, except that either Party may assign its rights and/or obligations hereunder to any of its wholly-owned Affiliates or to a successor to its business in a sale of all or substantially all of the assets of such Party. Subject to the foregoing sentence, this Agreement shall bind and inure to the benefit of the parties hereto and their respective successors and assigns. This Section 17.07 shall not be deemed to prohibit or otherwise apply to a change in control of Supplier (whether by merger of sale of capital stock or otherwise) at the shareholder or Board of Director levels or otherwise. |
|  |  |  |  |
|  | 17.8. |  | **Severability.**In the event that any one or more of the provisions (or any part thereof) contained in this Agreement or in any other instrument referred to herein, shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, then to the maximum extent permitted by law, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any other such instrument. Any Term or provision of this Agreement which is invalid, illegal or unenforceable in any jurisdiction shall, to the extent the economic benefits conferred by this Agreement to both parties remain substantially unimpaired, not affect the validity, legality or enforceability of any of the Terms or provisions of this Agreement in any other jurisdiction. |
|  |  |  |  |
|  | 17.9. |  | **Further Assurances.**Upon reasonable request from Buyer, Supplier shall provide to Buyer, promptly, any product samples, manufacturing information and other information as is necessary for Buyer to complete or obtain U.S. or foreign |

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|  |  |  | registration (including reimbursement arrangements) or approval in any territory where Buyer is allowed to sell product or use technology. | |
|  | 17.10. | |  | **Counterparts.**This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. |
|  |  | |  |  |
|  | 17.11. | |  | **Expenses.**Each Party shall pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement and the arrangements contemplated hereby. |
|  |  | |  |  |
|  | 17.12. | |  | **Survival.**Sections 7.4 (Effect of Termination) and 11.2 (Failure to Supply) and ARTICLE 12 (Labeling; Artwork; Proprietary Rights), ARTICLE 13 (Confidentiality), ARTICLE 16 (Indemnification) and ARTICLE 17 (Miscellaneous) shall survive the termination of this Agreement in accordance with the respective Terms thereof. |

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     IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized respective representatives as of the day and year first above written.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |
| ESPRIT PHARMA, INC. | | |  |  |  | NOVAVAX, INC. | | |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| By: |  |  |  |  |  | By: |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| Name: |  |  |  |  |  | Name: |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| Title: |  |  |  |  |  | Title: |  |  |  |  |
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**SUPPLY AGREEMENT**

**Schedule A – Product**

A topically- or transdermally-administered product developed under Seller’s IND No. 63957 of sold under a trademark upon which Supplier and Buyer shall mutually agree, of the following formulation:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Ingredient Description** |  | **Percent w/w** |
| Testosterone USP/Ph. Eur. |  | \*\*\* |
|  |  |  |
| Soybean Oil USP |  | \*\*\* |
|  |  |  |
| Polysorbate 80 NF |  | \*\*\* |
|  |  |  |
| 190 Proof Ethyl Alcohol USP |  | \*\*\* |
|  |  |  |
| Purified Water USP |  | \*\*\* |
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**SUPPLY AGREEMENT**

**Schedule B – Specifications**

**1. Formula**

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| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Ingredient Description** |  | **Percent w/w** |  | **Theoretical Weight** |
| **Testosterone USP/EP** |  | **\*\*\*** |  | **\*\*\*** |
| **Soybean Oil USP** |  | **\*\*\*** |  | **\*\*\*** |
| **Polysorbate 80 NF** |  | **\*\*\*** |  | **\*\*\*** |
| **190 Proof Ethyl Alcohol USP** |  | **\*\*\*** |  | **\*\*\*** |
| **Purified Water USP** |  | **\*\*\*** |  | **\*\*\*** |
| **TOTAL** |  | **\*\*\*** |  | **\*\*\*** |

**2. Specifications**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Test** |  | **Test Method** |  | **Specification** |
| Appearance |  | Visual observation |  | \*\*\* |
| Testosterone Identity |  | HPLC |  | \*\*\* |
| Testosterone Assay |  | HPLC |  | \*\*\* |
| Particle Size |  | Coulter Laser |  | \*\*\* |
| Viscosity |  | Viscometer |  | \*\*\* |
| pH |  | pH Meter |  | \*\*\* |
| Microbial Limits Test |  | USP |  | \*\*\* |
| Related Substances |  | HPLC |  | \*\*\* |
| Crystal Count Analysis |  | Polarized light microscopy |  | \*\*\* |
| Quantitative Crystal Analysis |  | HPLC |  | \*\*\* |
| Ethanol assay |  | GC |  | \*\*\* |
| *In vitro*release |  | VanKel diffusion cell |  | \*\*\* |

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**3. Packaging Specifications**

**Component Specifications**

**Current Master Label**

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**Schedule C**

**CMC Support from Novavax, Inc.**

**Novavax Activities:**

Novavax will provide full chemistry and manufacturing controls support for development and commercialization of Product (testosterone topical emulsion for female sexual dysfunction). The activities include:

|  |  |  |  |
| --- | --- | --- | --- |
|  | 1. |  | \*\*\* |
|  |  |  |  |
|  | 2. |  | \*\*\* |
|  |  |  |  |
|  | 3. |  | \*\*\* |
|  |  |  |  |
|  | 4. |  | \*\*\* |

Description of Activities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 1. |  | \*\*\* | | |
|  | | | 1.1. |  | Assumptions are as follows: |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | 1.1.1.\*\*\* |
|  |  |  |  |
|  |  |  | 1.1.2.\*\*\* |
|  |  |  |  |
|  |  |  | 1.1.3.\*\*\* |
|  |  |  |  |
|  |  |  | 1.1.4.\*\*\* |
|  |  |  |  |
|  |  |  | 1.1.5.\*\*\* |
|  | 1.2. |  | Analytical testing will consist of the following: |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | 1.2.1.\*\*\* |
|  |  |  | 1.2.2.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.3.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.4.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.5.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.6.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.7.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.8.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.9.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.10.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.11.\*\*\* |
|  |  |  |  |
|  |  |  | 1.2.12.\*\*\* |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | 1.2.13.\*\*\* |

|  |
| --- |
|  |

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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 1.3. |  | Stability testing | | |
|  | | | 1.3.1. |  | \*\*\* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | 1.3.1.1. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 1.3.1.2. | |  | \*\*\* |
|  | 1.3.2. |  | \*\*\* | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | 1.3.2.1. |  | \*\*\* |
|  | | | |  |  |  |
|  | | | | 1.3.2.2. |  | \*\*\* |
|  | 1.4. |  | Cost: \*\*\* | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2. |  | \*\*\* | | |
|  | | | 2.1. |  | Assumptions are as follows: |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | 2.1.1. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.1.2. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.1.3. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.1.4. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.1.5. |  | \*\*\* |
|  | 2.2. |  | Analytical testing will consist of the following [analytical tests will be validated as required]: | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | 2.2.1. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.2. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.3. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.4. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.5. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.6. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.7. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.8. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.9. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.10. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.11. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.12. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.2.13. | |  | \*\*\* |
|  | 2.3. |  | Stability testing | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | 2.3.1. |  | \*\*\* |

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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | 2.3.1.1. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.3.1.2. | |  | \*\*\* |
|  | 2.3.2. |  | \*\*\* | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | 2.3.2.1. |  | \*\*\* |
|  | | | |  |  |  |
|  | | | | 2.3.2.2. |  | \*\*\* |
|  | 2.4. |  | Additional analytical testing | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | 2.4.1. |  | \*\*\*testing |
|  | 2.5. |  | Cost: | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2.5.1. |  | \*\*\* | | |
|  | | 2.5.1.1. | |  | \*\*\* |
|  | |  | |  |  |
|  | | 2.5.1.2. | |  | \*\*\* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | 2.5.2. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.5.3. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.5.4. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.5.5. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.5.6. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.5.7. |  | \*\*\* |
|  | | |  |  |  |
|  | | | 2.5.8. |  | \*\*\* |
|  | 3. |  | Documentation | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | 3.1. |  | \*\*\* |
|  |  |  |  |
|  | 3.2. |  | \*\*\* |
|  |  |  |  |
|  | 3.3. |  | \*\*\* |
|  |  |  |  |
|  | 3.4. |  | \*\*\* |
|  |  |  |  |
|  | 3.5. |  | \*\*\* |
|  |  |  |  |
|  | 3.6. |  | \*\*\* |

Total cost of CMC support summary:

1. \*\*\*  
2. \*\*\*  
3. \*\*\*  
**4. TOTAL:**\*\*\*

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**Schedule D**

\*\*\*

**Confidential Treatment**