

NOVAVAX INC
Form 8-K
October 20, 2009

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 8-K
CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
Date of Report (Date of earliest event reported) October 19, 2009
NOVAVAX, INC.**

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or
organization)

0-26770
(Commission File Number)

22-2816046
(I.R.S. Employer
Identification No.)

9920 Belward Campus Drive
Rockville, Maryland
(Address of principal executive offices)

20850
(Zip Code)

Registrant's telephone number, including area code: (240) 268-2000
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01 Entry into a Material Definitive Agreement.

On October 19, 2009, Novavax, Inc. ("Novavax") entered into a Materials Transfer Agreement (the "MTA") with Laboratorio Avi-Mex S.A. de C.V. ("Avimex"). Pursuant to the MTA, Novavax will transfer certain amounts of 2009 H1N1 influenza vaccine (the "Vaccine") to Avimex. Avimex made a fixed non-refundable milestone payment to Novavax upon execution of the MTA and will pay Novavax a transfer fee for the Vaccine based on Novavax's production costs. Avimex will use the Vaccine to conduct clinical trials in Mexico. Avimex will pay for all passthrough and site costs for the first 1,000 subjects in the clinical trials, plus other development and regulatory costs, up to an agreed maximum amount. Novavax is responsible for all passthrough and site costs for additional subjects, as well as all CRO costs associated with the clinical trials. While Avimex is required to use commercially reasonable efforts to obtain regulatory approval for the Vaccine in Mexico in a timely manner, all decisions regarding regulatory strategy must be approved in advance by Novavax. Unless earlier terminated, the MTA expires on December 31, 2009, unless the option (as described below) is exercised, in which case the MTA expires on December 31, 2010. The MTA may be terminated by either party due to a material uncured breach by the other party, by Novavax if Avimex is convicted of a felony for violating, or a final, non-appealable order is issued finding that Avimex has violated, any applicable laws, by either party if notice of a bankruptcy proceeding is given to the other party, or upon the mutual agreement of the parties. If the parties agree to terminate the MTA, Avimex must provide reasonable assistance to Novavax for 90 days following termination to enable Novavax to continue the clinical trials.

Pursuant to the MTA, Novavax granted Avimex an irrevocable right and option to enter into a non-exclusive distribution agreement to distribute the Vaccine in Mexico (the "Distribution Agreement"), the form of which is attached to the MTA as an Exhibit. Avimex may exercise this option at any time during the term of the MTA, provided it is in compliance with the terms of the MTA. Upon receipt of regulatory approval, Avimex must decide whether to exercise or decline the option. The option terminates if Avimex does not exercise the option before December 31, 2009 or if Novavax desires to seek regulatory approval of the Vaccine and Avimex does not cooperate. If the option terminates because Novavax desires to seek regulatory approval and Avimex does not cooperate, and Novavax enters into a distribution agreement with another party in Mexico and that distributor sells a specified number of doses, Novavax will be required to pay Avimex a fee.

If Avimex exercises the option, Avimex may use the results of the clinical trial in Mexico exclusively and Novavax may use the results in any regulatory submission outside of Mexico. In addition, Novavax may not authorize any third party to distribute the Vaccine in Mexico under the sanitary registration obtained in Novavax's name with Avimex's assistance pursuant to the MTA, but may seek separate registration. If Avimex does not exercise the option, the option terminates, or the MTA is terminated for certain reasons, Novavax may, and may authorize third parties to, use the results (and data) from the clinical trials conducted by Avimex anywhere in the world and may distribute and sell the Vaccine in Mexico under the sanitary registration obtained in Novavax's name with Avimex's assistance pursuant to the MTA.

The Distribution Agreement provides that, as of the effective date of the Distribution Agreement, Avimex will be deemed to have ordered all doses of the Vaccine currently contemplated by the Distribution Agreement. As consideration for entering into the Distribution Agreement, Avimex will pay Novavax fixed non-refundable, non-creditable milestone payments upon certain developmental milestones. Payment for the Vaccine is based on a per dose transfer price (20% of which shall be pre-paid), as adjusted by Avimex's net sales and certain prepayments made by Avimex. The Distribution Agreement will expire on December 31, 2010, unless earlier terminated. The Distribution Agreement may be terminated by either party due to a material uncured breach by the other party, by Novavax if Avimex is convicted of a felony for violating, or a final, non-appealable order is issued finding that Avimex has

violated, any applicable laws, by either party if notice of a bankruptcy proceeding is given to the other party, or upon the mutual agreement of the parties.

On October 20, 2009, Novavax issued a press release regarding the transactions described herein and the clinical trial to be conducted pursuant to the MTA. The foregoing is a brief description of the material terms of the MTA and Distribution Agreement and does not purport to be a complete description of the rights and obligations of the parties thereunder.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibits

99.1 Press Release of Novavax, Inc. dated October 20, 2009.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novavax, Inc.
(Registrant)

October 20, 2009

By: /s/ Frederick W. Driscoll
Name: Frederick W. Driscoll
Title: Vice President, Chief Financial
Officer and Treasurer