

ISOLAGEN INC
Form 8-K
July 19, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

JULY 19, 2007

Date of Report (date of Earliest Event Reported)

ISOLAGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation
or Organization)

001-31564

(Commission File No.)

87-0458888

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

405 EAGLEVIEW BLVD., EXTON, PA 19341

(Address of principal executive offices and zip code)

(484) 713-6000

(Registrant's telephone number, including area code)

NOT APPLICABLE

(Former name or former address, if changed from 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)).

Item 7.01 Regulation FD Disclosure.

In October 2006, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on the design of a Phase III pivotal study protocol for the treatment of nasolabial folds. The protocol was submitted to the FDA under the agency's Special Protocol Assessment, or SPA, regulations. As we have previously disclosed, we encountered certain delays related to manufacturing and scheduling in connection with the study. We conferred with the FDA regarding these issues, and based on our findings and our dialogue with the FDA, we submitted an amendment to our study protocol and chemistry, manufacturing and control submission. On July 11, 2007, the FDA notified us that our proposed changes to the protocol were acceptable and within the scope of the original SPA review.

SIGNATURE

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

ISOLAGEN, INC.

Date: July 19, 2007

By:

/s/ Declan Daly
Declan Daly,
Chief Operating Officer