

ISOLAGEN INC
Form 8-K
December 21, 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

December 20, 2007

Date of Report (Date of earliest event reported)

ISOLAGEN, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-31564
(Commission File

Number)

87-0458888
(IRS Employer

Identification No.)

405 Eagleview Boulevard, Exton, Pennsylvania 19341
(Address of Principal Executive Offices)(Zip Code)

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(484) 713-6000

(Registrant's telephone number, including area code)

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:

- 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 8.01 Other Events.

On November 5, 2007, we reported that our 006 and 005 Nasolabial/Wrinkle trials had 191 and 168 subjects remaining, respectively. As of December 17, 2007, the number of subjects remaining in our 006 and 005 studies have remained unchanged from November 5, 2007. Patient dropouts are expected and can occur for a variety of reasons. A subject who drops out of the trial prior to the 26 week post-treatment observation would, under the current protocol, be considered a failure to respond in the results of the clinical trial. As fewer patients complete a trial, a higher positive response rate to the therapy must be obtained for the group of remaining treated subjects in order to demonstrate statistically significant benefit compared to placebo. In October 2007, we submitted a protocol amendment to the FDA which, among other things, attempted to amend our Special Protocol Assessment to redefine the intent-to-treat population to exclude subjects for whom adequate cell yields could not be obtained for treatment. In December 2007, the FDA declined the Company's protocol amendment, and as such the subject numbers remain as stated above. We continue to focus our efforts to prevent additional dropouts in both trials.

SIGNATURE

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 hereunto duly authorized.

ISOLAGEN, INC.

(Registrant)

Date: December 20, 2007

By: /s Declan Daly
Declan Daly, COO