AGENUS INC
Form 8-K
September 05, 2013

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

September 5, 2013
Date of Report (Date of earliest event reported)

AGENUS INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**000-29089**	**06-1562417**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3 Forbes Road

Lexington, MA	**02421**
(Address of principal executive offices)	(Zip Code)

781-674-4400
(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 (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 8.01 Other events

Agenus Inc. announced today that GlaxoSmithKline's (NYSE: GSK) DERMA[i] study, a Phase 3 randomized, blinded, placebo-controlled MAGE-A3 cancer immunotherapeutic[ii] (CI) trial, which contains Agenus' QS-21 Stimulon® adjuvant[iii], a component of GSK's novel adjuvant system AS15, did not meet its first co-primary endpoint. In an independent analysis, the study did not significantly extend the disease-free survival (DFS)[iv] period when compared to placebo in the overall MAGE-A3 positive trial population.

In line with the Independent Data Monitoring Committee's (IDMC) unanimous recommendation, GSK will continue the study until the second co-primary endpoint is assessed. This co-primary endpoint is based on predefined criterion that was agreed upon by regulatory authorities. This analysis, which is based on gene signature, is designed to prospectively identify patients who may have the capability to be more immunologically responsive and therefore can potentially benefit from treatment. If further analysis shows that the predefined gene signature subset data are successful, there is the potential that a regulatory filing could be considered. GSK anticipates that these data will be available in 2015. Until then, GSK will remain blinded to all safety and efficacy data.

The full text of the press release issued in connection with the announcement is being filed as Exhibit 99.1 to this current report on Form 8-K.

i Adjuvant immunotherapy with MAGE-A3 in melanoma GSK 2132231A Antigen-Specific Cancer Immunotherapeutic in patients with resected melanoma.
ii MAGE-A3 cancer immunotherapeutic consists of recombinant MAGE-A3 protein and a novel immunostimulant AS15 (a combination of QS-21 Stimulon® adjuvant, monophosphoryl lipid A, and CpG7909, a TLR-9 agonist, in a liposomal formulation).
iii QS-21 Stimulon® adjuvant and the related agreements, and HerpV are assets of Antigenics Inc., a wholly owned subsidiary of Agenus Inc.
iv DFS is defined as the time from randomization to the date of first recurrence of the disease or of death, whichever comes first.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

The following exhibit is filed herewith:

99.1 Press Release dated September 5, 2013

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 hereunto duly authorized.

AGENUS INC.

Date: September 5, 2013 By: /s/ Garo H. Armen

Garo H. Armen
Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
99.1	Press Release dated September 5, 2013