AGENUS INC Form 424B3 October 24, 2012

Filed Pursuant to Rule 424(b)(3) and Rule 424(c)

Registration No. 333-150326

October 24, 2012

#### PROSPECTUS SUPPLEMENT NO. 63

#### 2,333,332 SHARES OF COMMON STOCK

#### AGENUS INC.

This prospectus supplement amends the prospectus dated March 16, 2009 (as supplemented on April 15, 2009, April 17, 2009, April 22, 2009, April 27, 2009, May 4, 2009, May 11, 2009, May 27, 2009, June 4, 2009, June 8, 2009, June 9, 2009, June 11, 2009, June 15, 2009, July 7, 2009, July 15, 2009, August 3, 2009, August 5, 2009, September 11, 2009, September 18, 2009, November 12, 2009, January 5, 2010, March 1, 2010, March 25, 2010, April 26, 2010, May 11, 2010, May 18, 2010, July 23, 2010, August 9, 2010, August 25, 2010, November 3, 2010, November 10, 2010, December 30, 2010, January 7, 2011, January 14, 2011, January 28, 2011, March 1, 2011, March 8, 2011, March 8, 2011, April 18, 2011, May 5, 2011, May 9, 2011, June 8, 2011, June 17, 2011, August 8, 2011, August 16, 2011, September 7, 2011, September 30, 2011, October 11, 2011, October 20, 2011, November 7, 2011, November 17, 2011, December 12, 2011, December 21, 2011, March 5, 2012, March 6, 2012, March 13, 2012, March 21, 2012, May 9, 2012, June 19, 2012, August 2, 2012, and August 8, 2012) to allow certain stockholders or their pledgees, donees, transferees, or other successors in interest (the Selling Stockholders ), to sell, from time to time, up to 1,166,666 shares of our common stock, which they have acquired in a private placement in the United States, and up to 1,166,666 shares of our common stock issuable upon the exercise of warrants which are held by the Selling Stockholders named in the prospectus.

We would not receive any proceeds from any such sale of these shares. To the extent any of the warrants are exercised for cash, if at all, we will receive the exercise price for those warrants.

This prospectus supplement is being filed to include the information set forth in the Current Report on Form 8-K/A filed on October 23, 2012, which is set forth below. This prospectus supplement should be read in conjunction with the prospectus dated March 16, 2009, Prospectus Supplement No. 1 dated April 15, 2009, Prospectus Supplement No. 2 dated April 17, 2009, Prospectus Supplement No. 3 dated April 22, 2009, Prospectus Supplement No. 4 dated April 27, 2009, Prospectus Supplement No. 5 dated May 4, 2009, Prospectus Supplement No. 6 dated May 11, 2009, Prospectus Supplement No. 7 dated May 27, 2009, Prospectus Supplement No. 8 dated June 4, 2009, Prospectus Supplement No. 9 dated June 8, 2009, Prospectus Supplement No. 10 dated June 9, 2009, Prospectus Supplement No. 11 dated June 11, 2009, Prospectus Supplement No. 12 dated June 15, 2009, Prospectus Supplement No. 13 dated July 7, 2009, Prospectus Supplement No. 14 dated July 15, 2009, Prospectus Supplement No. 15 dated August 3, 2009, Prospectus Supplement No. 16 dated August 5, 2009, Prospectus Supplement No. 17 dated September 11, 2009, Prospectus Supplement No. 18 dated September 18, 2009, Prospectus Supplement No. 19 dated November 12, 2009, Prospectus Supplement No. 20 dated January 5, 2010, Prospectus Supplement No. 21 dated March 1, 2010, Prospectus Supplement No. 23 dated March 25, 2010, Prospectus Supplement No. 24 dated April 26, 2010, Prospectus Supplement No. 25 dated May 11, 2010, Prospectus Supplement No. 26 dated May 18, 2010, Prospectus Supplement No. 27 dated July 23, 2010, Prospectus Supplement No. 28 dated August 9, 2010, Prospectus Supplement No. 29 dated August 25, 2010, Prospectus Supplement No. 30 dated November 3, 2010, Prospectus Supplement No. 31 dated November 10, 2010, Prospectus Supplement No. 32 dated December 30, 2010, Prospectus Supplement No. 33 dated January 7, 2011, Prospectus Supplement No. 34 dated January 14, 2011, Prospectus Supplement No. 35 dated January 28, 2011, Prospectus Supplement No. 36 dated March 1, 2011, Prospectus Supplement No. 37 dated March 8, 2011, Prospectus Supplement No. 38 dated March 18, 2011, Prospectus Supplement No. 39 dated April 18, 2011, Prospectus Supplement No. 40 dated May 5, 2011, Prospectus Supplement No. 41 dated May 9, 2011, Prospectus Supplement No. 42 dated June 8, 2011, Prospectus Supplement No. 43 dated June 17, 2011, Prospectus Supplement No. 44 dated August 8, 2011, Prospectus Supplement No. 45 dated August 16, 2011, Prospectus Supplement No. 46 dated September 7, 2011, Prospectus Supplement No. 47 dated September 27, 2011, Prospectus Supplement No. 48 dated September 30, 2011, Prospectus Supplement No. 49 dated October 11, 2011, Prospectus Supplement No. 50 dated October 20, 2011, Prospectus Supplement No. 51 dated November 7, 2011, Prospectus Supplement No. 52 dated November 17, 2011, Prospectus Supplement No. 53 dated December 12, 2011, Prospectus Supplement No. 54 dated December 21, 2011, Prospectus Supplement No. 55 dated March 5, 2012, Prospectus Supplement No. 56 dated March 6, 2012, Prospectus Supplement No. 57 dated March 13, 2012, Prospectus Supplement No. 58 dated March 21, 2012, Prospectus Supplement No. 59 dated May 9, 2012, Prospectus Supplement No. 60 dated June 19, 2012, Prospectus Supplement No. 61 dated August 2, 2012, and Prospectus Supplement No. 62 dated August 8, 2012, which are to be delivered with this prospectus supplement.

Our common stock is quoted on The NASDAQ Capital Market ( NASDAQ ) under the ticker symbol AGEN. On October 22, 2012, the last reported closing price per share of our common stock was \$4.43 per share.

Investing in our securities involves a high degree of risk. Before investing in any of our securities, you should read the discussion of material risks in investing in our common stock. See Risk Factors on page 1 of the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

THE DATE OF THIS PROSPECTUS SUPPLEMENT NO. 63 IS OCTOBER 24, 2012

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 8-K/A

#### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the

**Securities Exchange Act of 1934** 

October 23, 2012

Date of Report (Date of earliest event reported)

## **AGENUS INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE** (State or other jurisdiction

**000-29089** (Commission

06-1562417 (IRS Employer

of incorporation) File Number)

**Identification No.)** 

#### 3 Forbes Road

Lexington, MA (Address of principal executive offices)

02421 (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))

Agenus Form 8-K filed today at approximately 9:30 AM (the Prior Form 8-K ) was an incorrect version of the intended filing. This Form 8-K/A corrects and supersedes the Prior Form 8-K.

#### Item 8.01 Other events

Agenus Inc. announced today that it has initiated a Phase 2 randomized, double-blind, multicenter study of HerpV, a recombinant off-the-shelf therapeutic vaccine candidate for the treatment of genital herpes in Herpes Simplex Virus 2 (HSV-2) positive subjects. HerpV contains Agenus QS-21 Stimulon®\* adjuvant, which is currently being studied in 17 additional clinical programs. The study designated as protocol C-400-02 will enroll 75 HSV-2 positive subjects who have a history of frequent disease recurrences. The study will test the efficacy of the HerpV vaccine as measured by effect on genital viral shedding.

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.

**Item 9.01** Financial Statements and Exhibits (d) Exhibits

The following exhibit is filed herewith:

99.1 Press Release dated October 23, 2012

#### **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: October 23, 2012 By: /s/ Garo H. Armen

Garo H. Armen Chief Executive Officer

#### EXHIBIT INDEX

Exhibit

No. Description of Exhibit

99.1 Press Release dated October 23, 2012

#### **Media and Investor Contact:**

Jonae R. Barnes

Vice President

Investor Relations and

Corporate Communications

jonae.barnes@agenusbio.com

617-818-2985

#### AGENUS COMMENCES PHASE 2 STUDY OF HERPV VACCINE FOR THE TREATMENT OF GENITAL HERPES

HerpV is the most clinically advanced therapeutic vaccine candidate for the treatment of genital herpes

Contains Agenus QS-21 Stimulon® adjuvant currently being studied in 17 clinical programs

Lexington, MA Oct. 23, 2012 Agenus Inc. (Nasdaq: AGEN), a developer of therapeutic vaccines for cancer and infectious diseases, today announced that it has initiated a Phase 2 randomized, double-blind, multicenter study of HerpV, a recombinant off-the-shelf therapeutic vaccine candidate for the treatment of genital herpes in Herpes Simplex Virus 2 (HSV-2) positive subjects. HerpV contains Agenus QS-21 Stimulon\* adjuvant, which is currently being studied in 17 additional clinical programs.

The study designated as protocol C-400-02 will enroll 75 HSV-2 positive subjects who have a history of frequent disease recurrences. The study will test the efficacy of the HerpV vaccine as measured by effect on genital viral shedding. In the study, 65 participants will receive the active treatment, HerpV and QS-21, and a control group of 10 participants will receive placebo. A booster injection will be given at six months after treatment to evaluate the durability of treatment effect.

The HerpV Phase 2 study design has been defined by key opinion leaders in the field. Experts in HSV-2 clinical research believe that a reduction in viral shedding, the driving force behind the spread of genital herpes, is an important surrogate for clinical benefit in potentially reducing recurrent outbreaks.

Our earlier clinical experience demonstrated an unprecedented immune response with both arms of the immune system (CD8+ and CD4+ T cells) being activated in subjects vaccinated with HerpV and QS-21, but not in subjects receiving placebo, said Garo H. Armen, Ph.D., chairman and CEO of Agenus Inc. Incorporating a broad spectrum of herpes antigens along with QS-21 has the potential enable the immune system sability to recognize and destroy HSV-2 infected cells.

QS-21 is a key component of many vaccines in clinical development. Over the next 15 months additional data from multiple important clinical programs that contain QS-21 are expected to be disclosed. QS-21 is incorporated in several vaccines currently in clinical development, including four GlaxoSmithKline (GSK) Phase 3 programs.

#### About Heat Shock Protein Platform (HSP) and Recombinant Series HerpV

HerpV is a recombinant therapeutic vaccine for the treatment of genital herpes, which is caused by the herpes simplex virus-2 (HSV-2). The vaccine is based on Agenus HSP platform technology, and is administered with Agenus proprietary adjuvant QS-21 Stimulondjuvant. HerpV consists of recombinant human heat shock protein-70 complexed with 32 distinct 35-mer synthetic peptides from the HSV-2 proteome. This broad spectrum of herpes antigens is intended to allow for more accurate immune targeting and surveillance, reducing the likelihood of immune escape. Further, the diversity of antigens in HerpV is designed to increase the chance of providing efficacy for a wide segment of the patient population.

In a four-arm, Phase 1 study, 35 HSV-2 seropositive patients received HerpV (designated in the study as AG-707 plus QS-21), AG-707, QS-21 alone, or placebo. Patients received three treatments at two-week intervals. The vaccine was generally well tolerated, with injection site pain as the most common reported adverse event. All patients who received HerpV and were evaluable for immune response showed a statistically significant CD4+ T cell response (100%; 7/7) to HSV-2 antigens as detected by IFNg Elispot, and the majority of those patients demonstrated a CD8+ T cell response (75%; 6/8). This study was published in the scientific journal *Vaccine*.

#### **About HSV-2**

According to the Centers for Disease Control, genital herpes affects more than 60 million Americans or 1 in 6 people between ages 14 and 49 with an additional 1.5 million new cases each year<sup>(1)</sup>. This disease often results in recurrent painful sores in the genital area<sup>(2)</sup>. The emotional consequences of genital herpes are quite significant, as 82 percent of people in the study reported depression, 75 percent experienced fear of rejection, 69 percent cited feelings of isolation and 55 percent reported fear of discovery all due to infection. Current therapies involve taking a daily medication that only partly suppresses the virus.

#### About Agenus QS-21 Stimulon Adjuvant

Agenus flagship adjuvant, QS-21 Stimulon adjuvant, is a saponin extracted from the bark of the *Quillaja saponaria* tree, also known as the soap bark tree or Soapbark, an evergreen tree native to warm temperate central Chile. Agenus QS-21 has become a key component in the development of investigational preventive vaccine formulations across a wide variety of infectious diseases, and appears to be essential for several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. QS-21 Stimulon adjuvant has been widely studied in clinical development and tens of thousands of patients have received vaccines containing the adjuvant. QS-21 Stimulon adjuvant is being studied in clinical trials for approximately 17 vaccine programs and include GSK s Phase 3 vaccine programs for RTS,S for malaria, MAGE-A3 cancer immunotherapeutic for non-small cell lung cancer and melanoma and HZ/su for shingles. In addition, Janssen s QS-21 Stimulon adjuvant-containing vaccine candidate is in Phase 2 trials for the treatment of Alzheimer s disease.

#### **About Agenus**

Agenus Inc. is a biotechnology company working to develop treatments for cancers and infectious diseases. The company is focused on immunotherapeutic products based on strong platform technologies with multiple product candidates advancing through the clinic, including several product candidates that have advanced into late-stage clinical trials through corporate partners. For more information, please visit <a href="https://www.agenusbio.com">www.agenusbio.com</a>.

For more details about the HerpV C-400-02 study, please visit <u>www.clinicaltrials.gov</u> using the identifier NCT01687595. The HerpV C-400-02 study participating centers include the following:

University of Washington Virology Research Clinic

Seattle, WA 98104

Principal Investigator: Anna Wald, MD

Contact: Kirsten Hauge, 206-720-4340

vrc@u.washington.edu

Westover Heights Clinic

Portland, OR 97210

Principal Investigator: Terri Warren, ANP

Contact: Annie Turner, 503-226-6678

info@westoverheights.com

Center for Clinical Studies Texas Medical Center

Houston, TX 77030

Principal Investigator: Stephen K. Tyring, MD

Contact: Marigdalia Ramirez-Fort, MD, 713-528-8818

info@ccstexas.com

Center for Clinical Studies Webster

Houston, TX 77598

Principal Investigator: Patricia C. Lee, MD

Contact: Farhan Khan, MD, 281-333-2288

info@ccstexas.com

Center for Clinical Studies Cypress

Houston, TX 77065

Principal Investigator: Vandana Madkan, MD

Contact: Deborah Yetman, 713-554-4688

info@ccstexas.com

#### **Forward-Looking Statement**

This press release contains forward-looking statements, including statements regarding clinical trial activities, the publication of data, and the potential application of the Company's technologies and product candidates in the prevention and treatment of diseases. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the ability to recruit patients, sources of funding, decisions of doctors, patients and our collaborations partners, the potential for viral shedding to act as a surrogate for clinical benefit, and the factors described under the Risk Factors section of our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission for the period ended June 30, 2012. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this document, and Agenus undertakes no obligation to update or revise the statements. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. Agenus business is subject to substantial risks and uncertainties, including those identified above. When evaluating Agenus business and securities, investors should give careful consideration to these risks and uncertainties.

- \* QS-21 Stimulon® adjuvant is an asset of Antigenics, Inc., a wholly owned subsidiary of Agenus Inc. Stimulon is a registered trademark of Agenus Inc. and its subsidiaries.
- 1. Genital Herpes CDC Fact Sheet; http://www.cdc.gov/std/Herpes/STDFact-Herpes.htm
- 2. Herpes Virus; <a href="http://www.herpesonline.org/articles/herpes-virus.html">http://www.herpesonline.org/articles/herpes-virus.html</a>
- 3. Clinical Management of Herpes Viruses by Stephen L. Sacks 1995

Contact:

Media and Investors:

Jonae R. Barnes

Vice President

Investor Relations &

Corporate Communications

617-818-2985

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