



## Agenus Reports Second Quarter 2013 Financial Results

July 25, 2013

### Agenus to Host Conference Call Beginning at 11 a.m. ET Today

LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (Nasdaq:AGEN), a biotechnology company working to develop novel immunology based treatments for cancers and infectious diseases, today announced its financial results and business highlights for the second quarter ended June 30, 2013.

The company's net loss attributable to common stockholders for the second quarter of 2013 was \$11.2 million, or \$0.40 per share, basic and diluted, compared to a net loss attributable to common stockholders of \$7.1 million, or \$0.31 per share, basic and diluted, for the second quarter of 2012.

For the six months ended June 30, 2013, the company reported a net loss attributable to common stockholders of \$20.0 million, or \$0.76 per share, basic and diluted, compared with a net loss attributable to common stockholders of \$551,000, or \$0.02 per share, basic and diluted, for the six months ended June 30, 2012.

As a result of various corporate transactions, net loss for the six months ended June 30, 2013 increased compared to the net loss for the same period in 2012 primarily due to revenue generated in 2012 from one-time payments received and to \$6.2 million of non-recurring non-cash charges in 2013. In the first quarter of 2013, the company's preferred stock restructuring, which reduced the dividend requirements for its Series A-1 preferred securities, resulted in a non-cash deemed dividend of \$2.9 million. In the second quarter of 2013, the company retired its outstanding \$39 million 8.0% senior secured convertible notes due August 2014 resulting in a non-cash loss on extinguishment of debt of \$3.3 million. In the first quarter of 2012, revenue of \$13.4 million was generated primarily due to one-time payments received through an expanded agreement with GlaxoSmithKline (GSK) and through a license of non-core technologies. Cash and cash equivalents were \$13.4 million as of June 30, 2013.

"Building upon the company's accomplishments during the first half of 2013, we anticipate continued momentum during the second half of this year and into 2014," said Garo H. Armen, Ph.D., chairman and CEO of Agenus. "The highlights include Phase 2 results from our HerpV trial for genital herpes, updates to our Prophage Series glioblastoma program, Phase 3 results from GSK's MAGE-A3 program in melanoma and non-small cell lung cancer, and long-term efficacy data for GSK's RTS,S program for malaria. Positive data results in one or more of these areas could represent a meaningful inflection point for the company."

### Recent Highlights

- Agenus announced that enrollment began for a 222-patient, randomized Phase 2 study of Prophage Series G-200 (Heat Shock Protein Peptide Complex-96 or HSPPC-96) vaccine in combination with bevacizumab (Avastin®) to treat recurrent glioblastoma multiforme (GBM) in adult patients. The study is sponsored by a cooperative group of the National Cancer Institute (NCI) called the Alliance for Clinical Trials in Oncology. This trial is the largest brain tumor vaccine trial ever funded by the NCI and the largest vaccine study ever conducted with Avastin.
- Agenus completed enrollment of the Phase 2 randomized, double-blind, multicenter study for 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 QS-21 Stimulon®<sup>1</sup> adjuvant ("QS-21 Stimulon"). This study is testing the biological efficacy of the HerpV vaccine as measured by effect on genital viral shedding. The Phase 2 data are anticipated during the fourth quarter of 2013.
- In a plenary session presentation, Orin Bloch, MD, of the Department of Neurological Surgery, University of California San Francisco presented positive preliminary data for Prophage Series G-100 in newly diagnosed GBM at the American Association of Neurological Surgeons (AANS) Annual Scientific Meeting. Prophage Series G-100 plus the standard of care showed a 146% increase in progression free survival (PFS) and a 60% increase in overall survival (OS) as compared to historical controls using the standard of care alone.
- Agenus retired its outstanding \$39 million 8.0% senior secured convertible notes due August 2014. These Notes were exchanged for \$10 million in cash, 2.5 million shares of common stock and a twenty percent revenue interest from QS-21 Stimulon partnered programs. In addition, the company entered into debt transactions for \$10 million in notes due April 2015 plus 500,000 warrants. Following these transactions, Agenus' total debt obligation outstanding is \$10 million, which was reduced from \$39 million.

Between Agenus and its partners, a total of 23 vaccine programs are in clinical development of which 21 contain QS-21 Stimulon. They include, but are not limited to:

- Phase 3: GSK's RTS,S for malaria<sup>2</sup>
- Phase 3: GSK's MAGE-A3 cancer immunotherapy for selected patients with resected melanoma<sup>2</sup>
- Phase 3: GSK's MAGE-A3 cancer immunotherapy for selected patients with resected non-small cell lung cancer<sup>2</sup>
- Phase 3: GSK's HZ/su for shingles<sup>2</sup>
- Phase 2: Janssen's ACC-001 for Alzheimer's disease

Agenus' pipeline programs include:

- Phase 2: HerpV (contains QS-21 Stimulon) for genital herpes
- Phase 2: Prophage Series G-100 for newly diagnosed GBM
- Phase 2: Prophage Series G-200 for recurrent GBM

#### **Saponin Platform: QS-21 Stimulon® Adjuvant**

Agenus' QS-21 Stimulon adjuvant is one of the most widely tested vaccine adjuvants under development. QS-21 Stimulon is designed to strengthen the body's immune response to a vaccine's antigen, thus making it more effective. QS-21 Stimulon is a key component in the development of investigational preventive vaccine formulations across a wide variety of infectious diseases, and appears to play an important role in several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. Licensees of QS-21 Stimulon include GSK and Janssen Alzheimer Immunotherapy. Agenus is generally entitled to receive milestone payments as QS-21 Stimulon-containing programs advance, as well as royalties for 10 years after commercial launch, with some exceptions.

#### **Heat Shock Protein Platform (HSP): Recombinant Series HerpV**

HerpV is a recombinant therapeutic vaccine candidate for the treatment of genital herpes, which is caused by the herpes simplex virus-2 (HSV-2). HerpV is the most clinically advanced HSV-2 therapeutic vaccine and is currently in a Phase 2 randomized, double-blind, multicenter study. The Phase 2 data are anticipated during the fourth quarter of 2013. The vaccine is based on Agenus' HSP platform technology, and contains Agenus' proprietary QS-21 Stimulon adjuvant.

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 increases 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 IFN $\gamma$  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*.

#### **Heat Shock Protein Platform (HSP): Prophage Series Cancer Vaccines**

Derived from each individual's tumor, Prophage Series vaccines contain the 'antigenic fingerprint' of the patient's particular cancer and are designed to reprogram the body's immune system to target only cancer cells bearing this fingerprint. Prophage Series vaccines, based on our HSP platform technology, are intended to leave healthy tissue unaffected and limit the debilitating side effects typically associated with traditional cancer treatments such as chemotherapy and radiation therapy. The Prophage Series vaccines are currently being studied in both newly diagnosed and recurrent GBM.

Patient enrollment is underway for the large-scale, randomized Phase 2 trial of Prophage Series G-200 in combination with Avastin in patients with surgically resectable recurrent GBM. This trial is investigating the combination of G-200 and Avastin in a three-arm randomized study of 222 patients with surgically resectable recurrent GBM. The study will compare efficacy of G-200 given with Avastin either concomitantly or at progression, versus Avastin alone.

For additional information please refer to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or click on the following link <http://www.clinicaltrials.gov/ct2/show/NCT01814813?term=HSPPC-96&rank=6>.

In addition to the recurrent GBM study, a Phase 2 trial testing the Prophage Series G-100 vaccine in patients with newly diagnosed GBM is ongoing. In this trial, G-100 is being used with the standard of care, which includes Temodar® (Merck; temozolomide) and radiation. It is believed that the efficacy of G-100 could potentially be enhanced through this combination regimen.

Positive preliminary data presented at this year's AANS meeting showed a median PFS of 17 months with Prophage G-100; these results compare favorably to the PFS reported with the standard of care alone, which is 6.9 months.<sup>3</sup> Median OS, which is the primary endpoint for the trial, in patients treated with G-100 is currently 23.3 months. For the standard of care alone, median OS survival is 14.6 months.<sup>3</sup> The majority of enrolled patients in the trial are still being followed and it is expected that PFS and OS will continue to mature as more data are collected.

#### **Conference Call and Web Cast Information**

Agenus executives will host a conference call at 11:00 a.m. Eastern Time today. To access the live call, dial 647-426-1845. The call will also be webcast and will be accessible from the company's website at [www.agenusbio.com/webcast/](http://www.agenusbio.com/webcast/). A replay will be available approximately two hours after the call through midnight Eastern Time on August 25, 2013. The replay number is 416-915-1035 and the access code is **102913**. The replay will also be available on the company's website approximately two hours after the live call.

#### **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 [www.agenusbio.com](http://www.agenusbio.com).

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

*This earnings release contains forward-looking statements, including statements regarding development and clinical trial activities, data read-outs and timelines of the company and its licensees and collaborators; potential benefit of product candidates in development, and potential revenue streams from our partnering and licensing arrangements. 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, decisions by regulatory authorities, physicians, patients, and our existing and potential licensees and collaborators; the possibility that clinical trial results will not be favorable; the inability to secure favorable partnering arrangements; the ability to raise capital; and the factors described under the Risk Factors section of our Annual Report on Form 10-Q filed for the period ended March 31, 2013, and other reports filed with the Securities and Exchange Commission. 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.

1. QS-21 Stimulon<sup>®</sup> adjuvant and the related agreements, and HerpV are assets of Antigenics Inc., a wholly owned subsidiary of Agenus Inc.
  2. QS-21 Stimulon is a component of certain GSK adjuvant systems.
  3. Stupp, R., et al., Radiotherapy plus concomitant and adjuvant temozolomide for glioblastoma. N Engl J Med, 2005. 352(10): p. 987-96.
- Stimulon is a registered trademark of Agenus Inc. and its subsidiaries. Avastin is a registered trademark of Genentech.

## Summary Consolidated Financial Information

### Condensed Consolidated Statements of Operations Data

(in thousands, except per share data)

(unaudited)

|   | Three months ended June 30, |            | Six months ended June 30, |           |
|---|-----------------------------|------------|---------------------------|-----------|
|   | 2013                        | 2012       | 2013                      | 2012      |
| Revenue   | \$ 807                      | \$ 627     | \$ 1,917                  | \$ 14,002 |
| Operating expenses:   |                             |            |                           |           |
| Cost of sales   | 177                         | 128        | 449                       | 152       |
| Research and development  | 3,317                       | 2,911      | 5,871                     | 5,588     |
| General and administrative  | 4,642                       | 3,359      | 7,534                     | 6,233     |
| Operating (loss) income   | (7,329)                     | (5,771)    | (11,937)                  | 2,029     |
| Other expense, net  | 3,813                       | 1,152      | 5,040                     | 2,185     |
| Net loss  | (11,142)                    | (6,923)    | (16,977)                  | (156)     |
| Dividends on Series A convertible preferred stock                       | (51)                        | (198)      | (3,058)                   | (395)     |
| Net loss attributable to common stockholders                            | \$ (11,193)                 | \$ (7,121) | \$ (20,035)               | \$ (551)  |
| Per common share data, basic and diluted:                               |                             |            |                           |           |
| Net loss attributable to common stockholders                            | \$ (0.40)                   | \$ (0.31)  | \$ (0.76)                 | \$ (0.02) |
| Weighted average number of common shares outstanding, basic and diluted | 27,846                      | 22,947     | 26,466                    | 22,641    |

### Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

June 30, 2013 December 31, 2012

|                             |           |           |
|-----------------------------|-----------|-----------|
| Cash and cash equivalents   | \$ 13,445 | \$ 21,468 |
| Total assets                | 21,371    | 29,093    |
| Total stockholders' deficit | (17,263)  | (17,600)  |

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