Agenus Reports Third Quarter 2013 Financial Results

October 24, 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 third quarter ended September 30, 2013.

“Recently, we achieved important milestones in both QS-21 Stimulon ®[1] adjuvant-containing programs as well as our Prophage Phase 2 newly diagnosed brain cancer trial. We are gratified to have contributed to the clinical success of the world’s most advanced malaria vaccine candidate with QS-21 Stimulon. We believe this important proof of efficacy could potentially lead to a string of clinical successes in coming years,” said Garo H. Armen, Ph.D., chairman and CEO of Agenus. “Through our own efforts and those of our partners, we remain committed to advancing our heat shock protein platform, QS-21 Stimulon programs, and additional immunotherapy product candidates over the next several years. In the near-term, we look forward to reporting Phase 2 data for HerpV, a therapeutic vaccine for the treatment of genital herpes, and Phase 3 results from GSK’s MAGE-A3 non-small cell lung cancer trial.”

The company’s net loss attributable to common stockholders for the third quarter of 2013 was $7.4 million, or $0.24 per share, basic and diluted, compared to a net loss attributable to common stockholders of $5.9 million, or $0.24 per share, basic and diluted, for the third quarter of 2012.

For the nine months ended September 30, 2013, the company reported a net loss attributable to common stockholders of $27.4 million, or $0.99 per share, basic and diluted, compared with a net loss attributable to common stockholders of $6.5 million, or $0.28 per share, basic and diluted, for the nine months ended September 30, 2012.

As a result of various corporate transactions, net loss for the nine months ended September 30, 2013 increased compared to the net loss for the same period in 2012 primarily due to $6.2 million of non-recurring non-cash charges incurred during 2013 and one-time payments of $13.4 million received during 2012. 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 $30.2 million as of September 30, 2013.

Recent and Third Quarter 2013 Highlights

- New Phase 3 data for GSK’s RTS,S malaria vaccine candidate, which contains Agenus’ QS-21 Stimulon adjuvant, were presented at a Multilateral Initiative on Malaria Pan African Conference in Durban, South Africa. The new data show that RTS,S helped protect young children and infants from clinical malaria up to 18 months post vaccination.
- GSK initiated a Phase 3 study to evaluate the immunogenicity and safety of the herpes zoster vaccine candidate HZ/su when co-administered with GSK's seasonal influenza vaccine GSK2321138A in adults aged 50 years and older. GSK’s HZ/su vaccine candidate for the prevention of shingles contains Agenus’ QS-21 Stimulon adjuvant. GSK currently has 9 active Phase 3 studies underway for the HZ/su vaccine candidate.
- Agenus entered into a non-exclusive license agreement with VaxLogic for the use of QS-21 Stimulon adjuvant in the development of select addiction, allergy and respiratory disease vaccine candidates.
- Agenus completed a registered direct offering of $10 million. Agenus issued an aggregate of 3,333,333 shares of its common stock at a price of $3.00 per share along with 1,000,000 warrants to purchase its common stock at an exercise price of $3.75 per share. Separately, Agenus received $11.4 million from the sale of our common stock in at-the-market offerings.
- A recent analysis from a Phase 2 trial in patients with newly diagnosed glioblastoma multiforme (GBM) treated with Prophage Series G-100 (HSPPC-96) in combination with the current standard of care (radiation and temozolomide) showed an almost 18 month median progression free survival, which represents a 160% increase versus current standard of care alone.[2] Median overall survival (OS), the primary endpoint of the trial, is 23.3 months and remains durable in patients treated with HSPPC-96 versus the standard of care alone, which is 14.6 months.[2] Based on these findings, Agenus plans to hold an end of Phase 2 meeting with the US Food and Drug Administration to discuss a Phase 3 trial that could potentially lead to marketing approval of the HSPPC-96 vaccine as a treatment for patients with newly diagnosed GBM.
- GSK’s Phase 3 MAGE-A3 cancer immunotherapeutic trial, which contains Agenus’QS-21 Stimulon adjuvant, did not meet its first co-primary endpoint. 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. 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.

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 [3]
- Phase 3: GSK's MAGE-A3 cancer immunotherapy for selected patients with resected melanoma [3]
- Phase 3: GSK's MAGE-A3 cancer immunotherapy for selected patients with resected non-small cell lung cancer [3]
- Phase 3: GSK's HZ/su for shingles [3]
- 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 in clinical development. QS-21Stimulon 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-21Stimulon-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, one of the most clinically advanced HSV-2 therapeutic vaccine candidates in development, 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 IFNγ 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 or click on the following linkhttp://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.

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/. A replay will be available approximately two hours after the call through midnight Eastern Time on December 23, 2013. The replay number is 416-915-1035 and the access code is **402191**. 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.

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 June 30, 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® adjuvant and the related agreements, and HerpV are assets of Antigenics Inc., a wholly owned subsidiary of Agenus Inc.

2. Stupp, R., et al., Radiotherapy plus concomitant and adjuvant temozolomide for glioblastoma. N Engl J Med, 2005. 352(10): p. 987-96.

3. QS-21 Stimulon is a component of certain GSK adjuvant systems.

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 September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Revenue	$ 736	$ 869	$ 2,653	$ 14,871
Operating expenses:				
Cost of sales	80	217	529	369
Research and development	3,893	2,606	9,764	8,194
General and administrative	3,578	2,587	11,112	8,820
Operating (loss) income	(6,815)	(4,541)	(18,752)	(2,512)
Other expense, net	504	1,188	5,543	3,373
Net loss	(7,319)	(5,729)	(24,295)	(5,885)
Dividends on Series A convertible preferred stock	(51)	(198)	(3,109)	(593)
Net loss attributable to common stockholders	$ (7,370)	$ (5,927)	$ (27,404)	$ (6,478)
Per common share data, basic and diluted:				
Net loss attributable to common stockholders	$ (0.24)	$ (0.24)	$ (0.99)	$ (0.28)
Weighted average number of common shares outstanding, basic and diluted	30,345	24,529	27,774	23,275

Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	September 30, 2013	December 31, 2012

Cash and cash equivalents	$ 30,205	$ 21,468
Total assets	37,670	29,093
Total stockholders' deficit	(2,877)	(17,600)

Contact:

Media and Investor Contact:
Agenus Inc.
Jonae R. Barnes, 617-818-2985
Vice President
Investor Relations and
Corporate Communications
jonae.barnes@agenusbio.com