Agenus Reports Fourth Quarter and Full Year 2013 Financial Results

March 5, 2014

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LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (NASDAQ: AGEN), a biopharmaceutical company developing a portfolio of immuno-oncology candidates, including checkpoint modulators (CPMs), heat shock protein vaccines and adjuvants, today announced its financial results and business highlights for the fourth quarter and year ended December 31, 2013.

"We began 2014 with the acquisition of an exciting new platform of fully-human checkpoint antibodies. This platform has generated six lead discovery programs in immuno-oncology," said Garo H. Armen, PhD, chairman and CEO of Agenus. "This transformative acquisition along with our strengthened balance sheet from our recent financing enables us to rigorously pursue our cancer immuno-oncology strategy with a broad portfolio of innovative products. I look forward to reporting progress from all of our platforms this year, which include QS-21 Stimulon adjuvant, heat shock protein vaccines and checkpoint modulators."

On February 12, 2014, Agenus completed the acquisition of 4-Antibody AG, a private European-based biopharmaceutical company. The 4-Antibody assets include the Retrocyte Display® technology platform which is designed to enable rapid discovery and optimization of fully human antibodies against a wide array of molecular targets. 4-Antibody has applied Retrocyte Display to create therapeutic antibodies to six checkpoint targets that regulate immune response to cancers and other diseases. 4-Antibody has multiple preclinical immune CPM programs in development including GITR and OX40 agonists and antagonists of TIM-3, LAG-3, PD-1 and CTLA-4. These programs are being pursued through a strategic collaboration with the Ludwig Cancer Research.

Fourth Quarter 2013 and Full Year Financial Update

For the fourth quarter, Agenus reported a net loss attributable to common stockholders of $5.8 million, or $0.16 per share, basic and diluted, compared with a net loss attributable to common stockholders for the fourth quarter of 2012 of $5.6 million, or $0.23 per share, basic and diluted.

For the year ended December 31, 2013, the company incurred a net loss attributable to common stockholders of $33.2 million, or $1.12 per share, basic and diluted, compared with a net loss attributable to common stockholders of $12.1 million, or $0.51 per share, basic and diluted, for the comparable period in 2012.

Cash and cash equivalents were $27.4 million as of December 31, 2013. Subsequent to year end, the company's cash position includes net proceeds of approximately $56 million from a registered public offering completed in the first quarter of 2014.

The increase in net loss attributable to common stockholders for the year ended December 31, 2013 compared to the net loss attributable to common stockholders for the same period in 2012, was 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 charge of $2.9 million. In the second quarter of 2013, the Company retired its outstanding 8.0% senior secured convertible notes due August 2014 in the principal amount of $39 million resulting in a non-cash loss of $3.3 million. In 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.

Recent and Fourth Quarter 2013 Highlights:

- Identified three CPM lead candidates that will advance into IND-enabling development. These include two GITR agonists and a CTLA-4 antagonist, which are the result of research collaboration with Ludwig Cancer Research.
- Completed an underwritten registered public offering resulting in net proceeds of approximately $56 million.
- Announced initiation of a randomized Phase 2 trial with Prophage and Yervoy® (ipilimumab) for the treatment of Stage III and IV metastatic melanoma. The combination has the potential to trigger a more effective immune response against the tumor than Yervoy alone.
- Appointed Robert B. Stein, MD, PhD, to the newly-created position of Chief Scientific Officer (CSO).
- Phase 2 data published in *Neuro-Oncology* demonstrated that over 90% of patients with recurrent glioblastoma multiforme (GBM) treated with Prophage were alive at six months after surgery and 30% were alive at twelve months.
- An independent editorial by John Sampson, MD, PhD, The Dr. Robert H. Wilkins and Gloria Wilkins Professor of Neurosurgery and Professor of Immunology and Pathology at Duke University Medical Center called the results 'impressive' and said they represent a potentially 'very promising therapy' in patients in desperate need of new treatments.
- Prophage for the treatment of brain cancer was selected as a 2013 Top Project to Watch in oncology. This selection was made through Elsevier Business Intelligence's panel of independent experts who screen hundreds of programs and weigh their potential as future products.
- Reported statistically significant top-line results from its Phase 2 randomized, double-blind, multi-center study for HerpV, a recombinant therapeutic vaccine candidate for the treatment of patients with herpes simplex virus-2 (HSV-2). HerpV contains a defined mixture of peptides representing HSV-2 antigens plus Agenus' QS-21 Stimulon® adjuvant.

Additional milestones anticipated in 2014 include:

- Phase 3 data from GlaxoSmithKlines's (GSK) MAGE-A3 cancer immunotherapy trial in non-small cell lung cancer. This vaccine is formulated with Agenus' QS-21 Stimulon.
- Regulatory submission for GSK's RTS,S malaria vaccine formulated with Agenus' QS-21 Stimulon
- Phase 2 booster data for HerpV, Agenus' therapeutic vaccine for HSV-2
- Data presentations on Prophage Series vaccine for GBM
- At least one corporate collaboration with the 4-Antibody platform

Checkpoint Antibody Platform

The company's proprietary discovery engine Retrocyte Display ® is capable of rapidly generating high quality therapeutic antibody drug candidates using a high-throughput approach incorporating full-length IgG format human antibody libraries expressed in mammalian B-lineage cells.

Heat Shock Protein Platform(HSP): Prophage Anti-Cancer Vaccines

The company's individualized cancer vaccine platform produces therapeutic cancer vaccine candidates from each patient's own tumor tissue. As a result of its individualized nature, each Prophage vaccine intends to contain the precise signals (antigenic fingerprint) of the patient's particular cancer which is meant to engage the body's immune system to target only cancer cells bearing this specific fingerprint. Such high precision in immunological targeting represents a distinctly different method for treating cancer compared to conventional anti-cancer treatments such as chemotherapy or radiation therapy without many of the side effects seen in conventional therapy.

Prophage is currently being studied in both newly diagnosed and recurrent GBM. Patient enrollment is underway for the large-scale, randomized Phase 2 trial of Prophage in combination with Avastin® in patients with surgically resectable recurrent GBM. This three-arm study of 222 patients will compare efficacy of Prophage 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 link http://www.clinicaltrials.gov/ct2/show/NCT01814813?term=HSPPC-96&rank=6

Heat Shock Protein Platform (HSP): 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). Positive preliminary results were reported from a Phase 2 randomized study during the fourth quarter of 2013 and post-booster results, along with immune response data, are anticipated in the first half of 2014. HerpV consists of recombinant human heat shock protein-70 complexed with 32 distinct 35-mer synthetic peptides from the HSV-2 proteome and contains QS-21 Stimulon.

Saponin Platform: QS-21 Stimulon Adjuvant

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 of 21 investigational vaccines for infectious diseases, cancers and degenerative disorders. Licensees include GSK and Janssen Alzheimer Immunotherapy. Agenus is generally entitled to receive milestone payments as well as royalties for 10 years after commercial launch.

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 May 5, 2014. The replay number is 416-915-1035 and the access code is 498676. The replay will also be available on the company's website approximately two hours after the live call.

About Agenus

Agenus is a biopharmaceutical company developing a portfolio of immuno-oncology candidates, including checkpoint modulators (CPMs), heat shock protein vaccines and adjuvants. The company's proprietary discovery engine Retrocyte Display ® is designed to rapidly generate high quality therapeutic antibody drug candidates using a high-throughput approach incorporating full-length IgG format human antibody libraries expressed in mammalian B-lineage cells. A portfolio of checkpoint modulator programs is advancing in preclinical development. The company's heat shock protein vaccines for cancer and infectious disease are in Phase 2 studies. Agenus' QS-21 Stimulon adjuvant platform is extensively partnered with GlaxoSmithKline and Janssen and includes several candidates in Phase 3 trials. Among Agenus and its partners, 23 programs are in clinical development. For more information, please visit www.agenusbio.com, or connect with the company on Facebook, LinkedIn, Twitter and Google+.

Forward-Looking Statement

This press release contains forward-looking statements, including statements regarding the potential impact of the 4-Antibody acquisition on the company's business, preclinical and 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 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 September 30, 2013. 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.

Summary Consolidated Financial Information

Condensed Consolidated Statements of Operations Data
(in thousands, except per share data)
(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2013	2012	2013	2012
Revenue	$ 393	$ 1,090	$ 3,045	$ 15,961
Operating expenses:				
Cost of revenue	7	303	536	672
Research and development	3,241	2,371	13,005	10,565
General and administrative	3,372	2,645	14,484	11,465
Operating loss	(6,227)	(4,229)	(24,980)	(6,741)
Other expense, net	(450)	1,211	5,093	4,584
Net loss	(5,777)	(5,440)	(30,073)	(11,325)
Dividends on Series A convertible preferred stock	(50)	(199)	(3,159)	(792)
Net loss attributable to common stockholders	$ (5,827)	$ (5,639)	$ (33,232)	$ (12,117)
Per common share data, basic and diluted:				
Net loss attributable to common stockholders	$ (0.16)	$ (0.23)	$ (1.12)	$ (0.51)
Weighted average number of common shares outstanding, basic and diluted	35,676	24,682	29,766	23,629

Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	December 31, 2013	December 31, 2012
Cash and cash equivalents	$ 27,352	$ 21,468
Total assets	34,835	29,093
Total stockholders' deficit	(4,481)	(17,600)

Contacts

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