Agenus Corporate Update and Third Quarter 2021 Financial Report

November 9, 2021

- Clinical results presented at SITC show that AGEN1181, as a monotherapy and in combination with balstilimab, shows durable responses in 9 cancer types, including patients whose cancers have recurred following PD-1 therapy
- Agenus will commence Phase 2/3 trials of AGEN1181 and balstilimab in colorectal and several gynecological cancers
- Agenus' cell therapy affiliate, MiNK Therapeutics (NASDAQ: INKT), launched as a publicly traded company with >$40 million raised to accelerate clinical development
- AGEN1777, an Fc-enhanced TIGIT bispecific antibody, entered Phase 1 development, triggering a $20M milestone payment from Bristol Myers Squibb
- After successfully achieving clinical milestones and passing FDA inspections, Agenus withdrew its BLA for balstilimab based on FDA guidance; given the clinical benefit demonstrated by balstilimab, Agenus plans to launch an expanded access program in several countries

LEXINGTON, Mass., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of checkpoint antibodies, adjuvants, and vaccines designed to activate immune response to cancers and infections, today provided a corporate update and reported financial results for the third quarter of 2021.

"With more than 100 patients treated with our Fc-enhanced CTLA-4 antibody, AGEN1181, we are very encouraged by the clinical responses achieved across tumor types. Of note, we are seeing responses in patients who have failed to respond to all other treatment, including PD-1 inhibitors," said Garo Armen, PhD, Chairman and Chief Executive Officer of Agenus. "We will be presenting detailed trial results at the SITC conference this week. We have also successfully completed an initial public offering for MiNK Therapeutics, and have launched our adjuvant business, SaponiQx."

AGEN1181 (Fc-enhanced CTLA-4), as a monotherapy and in combination with balstilimab (anti PD-1), shows clinical benefit in 9 cold and treatment-resistant tumor types; data to be presented at SITC

- First presentation of clinical data from 100+ patients who represent a heavily pre-treated population, and were administered AGEN1181 as a monotherapy or in combination with balstilimab
- Evidence of AGEN1181 monotherapy activity with multiple confirmed responses: microsatellite stable (MSS) - endometrial cancer (CR), melanoma (PR), cervical cancer (PR), and pancreatic cancer (PR), with the former three responses occurring in tumors which failed to respond to anti-PD-1 therapy
- Additional responses in patients treated with AGEN1181 in combination with balstilimab, including in cold, poorly immunogenic tumors. These include:
    - Microsatellite stable colorectal cancer (MSS-CRC): 2 confirmed PRs, 2 unconfirmed PRs, and 7 stable disease (SD) among 17 evaluable patients for a disease control rate of 65%
    - Gynecological malignancies: 2 PRs, 3 SDs among 6 evaluable ovarian cancer patients; 1 PR and 1 unconfirmed PR in MSS-endometrial cancer
    - Other tumors: 2 unconfirmed responses in visceral angiosarcoma, and one unconfirmed response in PD-1-relapsed/refractory NSCLC
- Majority of responses are durable and ongoing, with additional data to be presented at SITC on November 12th (Abstract # 479)
- Both monotherapy and combination therapy were well tolerated, with no cases of hypophysitis or pneumonitis
- Based on these data, Agenus will commence Phase 2/3 trials evaluating AGEN1181, as a monotherapy and in combination with balstilimab, in colorectal and gynecological cancers

MiNK Therapeutics launched an IPO; its stock is trading on NASDAQ

- MiNK Therapeutics launched a successful IPO, raising >$40M to support the rapid clinical development of its allogeneic cell therapies
- MiNK has three presentations planned at SITC, which will showcase data on clinical-stage, allogeneic, iNKT cell therapy (AgenT-797), including clinical persistence and activity, preclinical anti-tumor activity and tissue distribution, as well as the tumor killing potential of engineered iNKT cells generated by leveraging a proprietary CAR platform

SaponiQx launch to accelerate development of proven and novel adjuvants, as well as optimized antigen-adjuvant constructs

- Will address global need for vaccines offering long-lasting efficacy with secure production, which has been amplified by the current pandemic
- QS-21 Stimulon™ adjuvant is proven to drive durable immunity - SHINGRIX® (GSK zoster vaccine, recombinant) offers protection of >9 years
- Collaborating with Phyton Biotech and Ginkgo Bioworks to develop and optimize a plant cell culture method of manufacturing QS-21 and next-generation saponin- based adjuvants for a secure and sustainable adjuvant supply

First patients dosed in multiple collaborator programs

- First patient dosed with AGEN1777, our Fc-enhanced TIGIT bispecific antibody licensed to BMS, triggering a $20 million milestone payment. BMS intends to advance AGEN1777 in high-priority indications, such as non-small cell lung cancer
- First patient dosed in clinical collaboration with Nelum, evaluating our first-generation CTLA-4, zalifrelimab, in combination with Nelum's hedgehog inhibitor and chemotherapy in first-line pancreatic cancer

Planning underway to launch expanded access programs for balstilimab

- BLA for balstilimab in second-line cervical cancer was withdrawn after full approval of pembrolizumab, four months ahead of the FDA goal date, based on data for pembrolizumab plus chemotherapy in first-line setting
- Agenus will discontinue the confirmatory trial, resulting in a >$100M expense reduction
- As balstilimab met trial endpoints with ORR of 20% in PD-L1 positive tumors and 8% in PD-L1 negative tumors, Agenus plans to launch an expanded access program in several countries, including the US, pending regulatory processes
- Combination of balstilimab and zalifrelimab resulted in a near doubling of responses (33% vs. what has been reported with pembrolizumab in PD-L1+ cervical cancer patients); data was presented at this year's ESMO Conference

Third Quarter 2021 Financial Results

We ended the third quarter of 2021 with a cash and short-term investment balance of $262 million as compared to $100 million at December 31, 2020.

For the third quarter ended September 30, 2021, our cash provided by operations was $131 million and we reported a net income of $177 million or $0.76 per share basic and $0.72 per share diluted. This compares to cash used in operations for the same period in 2020 of $32 million and a net loss of $52 million or $0.28 per share basic and diluted.

Our cash provided by operations for the nine-months ended September 30, 2021 was $33 million with net income of $39 million or $0.19 per share basic and $0.18 per share diluted, compared to cash used in operations of $104 million and a net loss for the same period in 2020 of $145 million or $0.87 per share, basic and diluted. Non-cash operating expenses for the nine-months ended September 30, 2021 were $46 million compared to $35 million for the same period of 2020.

We recognized revenue of $275 million and $57 million for the nine-months ended September 30, 2021 and 2020, respectively, which includes revenue related to upfront license fees received and milestones earned, non-cash royalties, and revenue recognized under our collaboration agreements.

Financial Highlights
(in thousands, except per share data)
(unaudited)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 261,528	$ 99,871

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues, research and development	$ 238,986	$ 4,286	$ 242,265	$ 24,283
Revenues, non-cash royalty	12,593	8,947	28,903	29,950
Revenues, other	1,375	1,599	4,236	2,673
Total Revenue	252,954	14,832	275,404	56,906

Research and development expenses	42,937	32,134	125,122	107,048
General and administrative expenses	21,385	14,380	54,388	39,188
Cost of service revenue	817	911	2,589	1,545
Other expense (income)	162	939	(1,207)	2,805
Non-cash interest expense	16,298	15,918	48,295	44,109
(Gain) loss related to debt	(6,197)	-	(6,197)	2,720
Non-cash contingent consideration fair value adjustment	275	2,196	13,531	4,652
Net income (loss)	$ 177,277	$ (51,646)	$ 38,883	$ (145,161)
Net income (loss) per share attributable to Agenus Inc. common stockholders, basic	$ 0.76	$ (0.28)	$ 0.19	$ (0.87)
Net income (loss) per share attributable to Agenus Inc. common stockholders, diluted	$ 0.72	$ (0.28)	$ 0.18	$ (0.87)
Cash provided by (used in) operations	**$ 131,373**	**$ (31,626)**	**$ 33,072**	**$ (103,506)**
Non-cash operating expenses	$ 4,337	$ 14,375	$ 46,321	$ 35,181

Conference Call
Tuesday, November 9, 2021, 8:30am ET
Dial-in numbers: (833) 614-1394 (US) or (914) 987-7115 (International); Conference ID: 8585893.

Webcast
A live webcast and replay of the conference call will be accessible from the Events & Presentations page of the Company's website at https://investor.agenusbio.com/events-and-presentations and via https://edge.media-server.com/mmc/p/mr7ep4vu.

About Agenus
Agenus is a clinical-stage immuno-oncology company focused on the discovery and development of therapies that engage the body's immune system to fight cancer. The Company's vision is to expand the patient populations benefiting from cancer immunotherapy by pursuing combination approaches that leverage a broad repertoire of antibody therapeutics, adoptive cell therapies (through its affiliate MiNK Therapeutics), adjuvants, and proprietary cancer vaccine platforms. The Company is equipped with a suite of antibody discovery platforms and a state-of-the-art GMP manufacturing facility with the capacity to support clinical programs. Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com and our Twitter handle @agenus_bio. Information that may be important to investors will be routinely posted on our website and Twitter.

Forward-Looking Statements
This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements relating to the use of therapeutic candidates AGEN1181, zalifrelimab, balstilimab AGEN1777, and iNKT cell therapy (AgenT-797) , for instance, statements regarding therapeutic benefit and efficacy, mechanism of action, potency, durability, and safety profile of the therapeutic candidates, both alone and in combination with each other and/or other agents (e.g., AGEN1181 in combination with balstilimab); statements relating to future clinical and regulatory development plans for therapeutic candidates alone and in combination with other agents, including AGEN1181 in combination with balstilimab; statements relating to our ability to obtain regulatory approval for our therapeutic candidates, including the timing (including the possibility of accelerated review) and scope of any such regulatory approval; statements relating to our ability to launch expanded access programs; statements relating to future commercial plans, including those related to the receipt of future milestone payments and collaboration and license arrangements; statements relating to our ability to develop novel adjuvants and accelerate the development of adjuvants, as well as statements relating to our ability to develop optimized antigen-adjuvant constructs and develop and optimize manufacturing methods for QS-21 and other adjuvants; statements relating to planned savings; ; and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will" and similar expressions are intended to identify forward-looking statements. 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 most recent Quarterly Report on Form 10-Q or Annual Report on Form 10-K 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 press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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