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NEWS RELEASE

Agenus Reports Second Quarter 2024 Operational and Financial Results

8/8/2024

- Robust Phase 2 Data Validate Consistent Clinical Activity of BOT/BAL in Metastatic MSS CRC
- Maturing Data Across BOT/BAL Program Demonstrate Broad Solid Tumor Activity in the Late Stage, First-Line with Chemo Combinations, and Neoadjuvant disease
- Commenced Interactions with Global Regulatory Authorities for BOT/BAL Approval Pathways
- Data from ESMO GI Demonstrate Pathologic Complete Responses with BOT/BAL Therapy in Neoadjuvant CRC Patients

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. (“Agenus”) (Nasdaq: AGEN), a leader in discovering and developing novel immunological agents to treat various cancers, today provided a corporate update and reported financial results for the second quarter of 2024.

“Agenus milestones this quarter include the release of interim data from our global randomized Phase 2 trial of BOT/BAL in relapsed/refractory MSS colorectal cancer, consistent with our Phase 1 results,” said Garo Armen, PhD, Chairman and CEO of Agenus. “The robust responses in this trial and across various solid tumors validate BOT/BAL’s potential to address challenging cancer cases. Our data show significant and durable tumor reductions in patients who have exhausted other treatments. We are continuing to work with global health authorities and are dedicated to ensuring swift access to these life-saving therapies. We are deeply moved by the strong support from the patient advocacy and clinical communities and remain committed to accelerating the BOT/BAL program and delivering innovative therapies to patients.”

Key Highlights:

- Maturing Data Demonstrate Activity in Multiple Cancers and Stages of Disease: Data from our BOT/BAL

clinical program in ~1,100 patients have demonstrated robust activity across 10 different cancers and across early and late-stage disease, including refractory metastatic and neoadjuvant settings. This includes durable tumor reductions and, in some cases, complete responses in patients who have failed approved therapies. Some of these data have already been presented and published, with new data to be presented at upcoming conferences and published in top tier scientific publications.

- Promising Interim Data: Topline interim data from the randomized Phase 2 trial in r/r MSS CRC show trends consistent with the more mature data from the Phase 1 study at a similar follow up timepoint. This includes a now RECIST confirmed overall response rate (ORR) of 19.4% and a 6-month overall survival (OS) rate of 90% in the selected BOT 75mg/BAL combination cohort. BOT/BAL's safety profile continues to be manageable, with no new signals observed.
- Nature Medicine and Cancer Discovery Publications: Recent publications in **Nature Medicine** and **Cancer Discovery** highlighted the promising results of the BOT/BAL combination in metastatic MSS CRC, the most prevalent form of CRC, affecting 95% of metastatic CRC patients.
- NEST Study Results: Updated results from the NEST study in neoadjuvant CRC presented at ESMO GI in June demonstrated unprecedented activity of BOT/BAL in MSS CRC that has historically been poorly responsive to IO therapies. In the NEST-2 cohort of extended treatment (8 weeks), 78% (7/9) of MSS CRC patients achieved pathologic responses of at least 50% tumor reduction, with 56% (5/9) achieving complete pathologic responses (cPR). Toxicities were well managed, and no surgeries were delayed due to adverse events.
- ASCO Annual Meeting: New analyses presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June highlighted BOT/BAL activity in metastatic CRC across challenging sites of metastatic disease, including peritoneal metastases, soft tissue, bone, and brain. The ORR was consistent across favorable and unfavorable sites of disease and ranged from 18-33%, with disease control rates (DCR) ranging from 67-82%. Median OS remained consistent and ranged from 20.7 months to not reached.
- National Cancer Institute Collaboration: The National Cancer Institute's Cancer Therapy Evaluation Program (CTEP) began accepting Letters of Intent to conduct clinical studies using BOT during Q2. CTEP is also considering requests to supply BOT for nonclinical studies.
- Global Regulatory Engagements: Agenus initiated engagement with the European Medicines Authority (EMA) and has subsequent meetings planned for this fall. In addition, Agenus will explore registration paths for BOT/BAL in r/r MSS CRC with regulatory authorities in other geographies, including the UK, Canada, Australia, Israel, and Brazil.
- Upcoming Data: Agenus anticipates releasing further data later this year across the BOT/BAL program beyond MSS CRC that will continue to demonstrate the uniquely differentiated clinical activity of this combination therapy.
- Phase 3 Study in r/r MSS CRC: Agenus has gained alignment with the FDA on the proposed design and dosing regimen for its upcoming Phase 3 study in the r/r MSS CRC treatment setting and intends to initiate this study soon.

- FDA Interaction: While the FDA discouraged the submission of interim results for Accelerated Approval based on the dataset shared with them during the July End-of-Phase 2 meeting, Agenus plans to further engage the FDA with more mature data to support its AA strategy.

Partnerships and Financing

Agenus closed the first tranche of its $75 million royalty financing led by Ligand Pharmaceuticals, as announced in May. The company is continuing its efforts for a second closing of this financing. Additionally, Agenus is pursuing potential out-licensing transactions for several of its pipeline assets. This includes assets such as AGEN1777, previously licensed to Bristol Myers Squibb (BMS), and AGEN2373, for which Gilead's (GILD) option period has expired. Agenus' clinical and R&D teams are currently assessing the rich datasets generated in these programs.

"To support our efforts to deliver BOT/BAL to individuals living with colorectal cancer and other solid tumors, our strategic focus includes securing a global partnership for BOT/BAL. We are in discussions with several major biopharma companies that share our belief in the therapeutic regimen's potential to provide meaningful clinical benefit to patients. The recent FDA interactions have provided additional clarity on the selection of dose and design of our phase 3 trial, which have been helpful in our partnership discussions," said Robin Taylor, Agenus' Chief Commercial Officer.

Agenus has also received recent interest in partnerships for its wholly owned Chemistry, Manufacturing, and Controls (CMC) infrastructure in Northern California, including the newly launched 83,000 sq. ft. cGMP facility in Emeryville, California.

As part of its commitment to patient care, Agenus is launching a Named Patient Program for BOT/BAL. This program will provide a framework for physicians to prescribe this investigational combination to eligible patients before it becomes commercially available. The program aims to offer early access to botensilimab for patients with critical needs, particularly those with colorectal cancer and other solid tumors that have not responded to standard treatments.

"Patients can't wait, which is why Agenus is putting this Named Patient Program in place, a program that reflects our dedication to patients who need promising new therapies," said Dr. Nils Eckardt, Global Head of Medical Affairs at Agenus. "By providing this early access pathway, we're offering hope to patients with limited options while we continue to advance BOT/BAL through clinical development. This program underscores our commitment to patients and our confidence in BOT/BAL's potential to transform cancer treatment."

Second Quarter 2024 Financial Overview

We ended the second quarter 2024 with a consolidated cash balance of $93.7 million compared to $76.1 million on

December 31, 2023.

For the three and six months ended June 30, 2024, we recognized revenue, which includes non-cash revenue, of $23.5 million and $51.5 million respectively. This compares to $25.3 million and $48.2 million, for the same periods in 2023. Our cash used in operations for the first half of 2024 was $76.4 million, reduced from $118.6 million for the first half of 2023. Our net loss for the three and six months ended June 30, 2024, is $54.8 million and $118.3 million; these include non-cash operating expenses of $33.5 million and $71.8 million, respectively.

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 93,723	$ 76,110

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenues, non-cash royalty	$ 22,582	$ 22,068	$ 50,349	$ 41,174
Revenues, research and development	267	2,489	267	5,101
Revenues, other	660	739	898	1,923
Total Revenue	23,509	25,296	51,514	48,198
Research and development expenses	36,771	59,285	80,696	116,402
General and administrative expenses	16,816	20,415	33,672	38,653
Cost of service revenue	115	254	222	2,548
Other income	(7,064)	(883)	(6,088)	(1,604)
Non-cash interest expense	31,668	19,647	61,263	36,920
Non-cash contingent consideration fair value adjustment	-	8	-	(398)
Net loss	$ (54,797)	$ (73,430)	$(118,251)	$ (144,323)
Net loss per share attributable to Agenus Inc. common stockholders:	$ (2.52)	$ (3.93)	$ (5.56)	$ (8.22)
Cash used in operations	$38,180	$43,453	$76,371	$118,569
Non-cash operating expenses	$ 33,520	$ 28,947	$ 71,775	$ 53,882

Conference Call

Date: August 8th, 2024, 8:30 a.m. ET

To access dial-in numbers, please register **here** .

Conference ID: 73242

Webcast

A live webcast and replay of the conference call will be accessible on the company's website at **https://investor.agenusbio.com/events-and-presentations** .

About Botensilimab

Botensilimab is a human Fc enhanced CTLA-4 blocking antibody designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend immunotherapy benefits to “cold” tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. Botensilimab augments immune responses across a wide range of tumor types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Approximately 1,100 patients have been treated with botensilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus’ investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. For more information about botensilimab trials, visit **www.clinicaltrials.gov** with the identifiers NCT03860272, NCT05608044, NCT05630183, and NCT05529316.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer with a comprehensive pipeline of immunological agents. The company was founded in 1994 with a mission is to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants (through SaponiQx). Agenus has robust end-to-end development capabilities, across commercial and clinical cGMP manufacturing facilities, research and discovery, and a global clinical operations footprint. Agenus is headquartered in Lexington, MA. For more information, visit **www.agenusbio.com** or @agenus_bio. Information that may be important to investors will be routinely posted on our website and social media channels.

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 regarding its botensilimab and balstilimab programs, expected regulatory timelines and filings, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will," “establish,” “potential,” “superiority,” “best in class,” 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 Annual Report on Form 10-K for 2023, and subsequent Quarterly Reports on Form 10-Q 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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Source: Agenus Inc.