



Agenus Reports Second Quarter 2023 Results

August 8, 2023

LEXINGTON, Mass.--(BUSINESS WIRE)--Aug. 8, 2023-- Agenus Inc. ("Agenus") (Nasdaq: AGEN), a leader in developing novel immunological agents to treat various cancers, today announced results for the second quarter 2023.

Key accomplishments and highlights include:

- **Botensilimab Update:** Botensilimab/balstilimab combination data presented at ESMO-GI demonstrated median overall survival (mOS) of 20.9 months and a 23% overall response rate (ORR), both surpassing data reported for standard of care in 3L+ Non-MSI-H colorectal cancer (CRC) in patients without active liver metastases.
- **Regulatory:** The U.S. FDA granted Fast Track designation for the botensilimab/balstilimab combination in 3L+ Non-MSI-H CRC in patients without active liver metastases. Agenus is exploring global accelerated approval strategies for CRC.
- **Clinical Trial Progress:** Ongoing Phase 2 ACTIVATE trials in CRC and melanoma expected to fully enroll by end of year.
- **AGEN2373 Update:** AGEN2373 Phase 1 dose escalation data presented at ASCO demonstrated promising monotherapy clinical responses in patients with advanced solid tumors.

"Botensilimab, alone or in combination with balstilimab, continues to display remarkable clinical activity in over 600 patients treated across nine late-stage, treatment resistant solid tumor cancers, demonstrating great potential to revolutionize the role of immunotherapy in cancer treatment," said Chief Executive Officer, Garo Armen, Ph.D. "Agenus is committed to advancing our diverse clinical pipeline with a focus on expediting our first regulatory submission for the botensilimab/balstilimab combination in colorectal cancer. Our data has demonstrated an unprecedented survival benefit over what has been reported for standard of care, underscoring this combination as an important potential treatment option for patients with non-MSI-high colorectal cancer, which represents 85% of the population of patients with colorectal cancer¹."

Botensilimab/Balstilimab ("Bot/Bal") Combination in 3L+ Non-MSI-H Metastatic CRC Data Presented at the ESMO-GI World Congress on Gastrointestinal Cancer in June 2023:

- In 69 evaluable patients with non-MSI-High CRC without active liver metastases, results demonstrated a meaningful improvement over standard of care in both overall response rate (ORR%) and median overall survival (mOS):
 - mOS of 20.9 months as compared to the recently reported 12.9-month benchmark with standard care.²
 - ORR of 23% as compared to the recently reported 2.8%¹ benchmark with standard care.
- In April 2023, the U.S. FDA granted Fast Track designation to the bot/bal combination for patients with non-MSI-H/dMMR metastatic CRC without active liver metastases.
- The ACTIVATE Phase 2 trial in this patient population is on target to conclude enrollment by year-end. Planning is underway for a Phase 3 CRC study; with Fast Track designation from the FDA, study design and timing will be determined as we discuss our filing approach with the agency.
- A Biologics License Application to the FDA is planned in 2024.

Botensilimab in Other Advanced Solid Tumor Cancers:

- Lung: Enrollment continues for a Phase 1b trial targeting PD-(L)1 +/- chemotherapy relapsed/refractory non-small-cell lung cancer (NSCLC); data update planned by year-end.
- Melanoma: Ongoing global enrollment in Phase 2 ACTIVATE trial with data update planned in 2024.
- Ovarian: Phase 1b trial in patients with platinum-resistant ovarian cancer (PROC) demonstrated a 33% ORR and 67% disease control rate among primarily high-grade, heavily pretreated patients (presented at SGO in March 2023).
- Sarcomas: Updated data for a Phase 1b cohort with advanced sarcomas to be presented at ESMO on October 21st 2023.

AGEN2373 Data Presented at the ASCO 2023 Annual Meeting:

- Complete results from the first-in-human monotherapy dose escalation study of AGEN2373, a CD137 agonist, in patients with advanced solid tumors:
 - Reported responses in metastatic prostate cancer, ampullary carcinoma, and vulvar squamous cell carcinoma highlight the potential impact of AGEN2373.
 - AGEN2373 is the first CD137 agonist antibody to report single-agent responses with no major toxicities.
 - Clinical data are consistent with mechanistic design intent of AGEN2373 to avoid hepatic toxicity, a typical constraint of CD137-targeted agonists.

Leadership Appointments:

In alignment with Agenus' next phase of growth and anticipated commercialization of the bot/bal combination, the company announced the following

key executive appointments:

- Robin Taylor, Ph.D., Chief Commercial Officer.
- Homa Yeganegi, Chief Product Strategy and Global Medical Affairs Officer.
- Stephanie Fagan, Chief Communications Officer.

Second Quarter 2023 Financial Results:

We ended our second quarter 2023 with a cash, cash equivalent and short-term investment balance of \$157.6 million, compared to \$193.4 million at December 31, 2022. In addition, we have raised \$20.3 million through sales of our common stock under our at market issuance sales agreement since the end of Q2 2023.

For the three and six months ended June 30, 2023, we recognized revenue of \$25.3 million and \$48.2 million and incurred a net loss of \$73.4 million and \$144.3 million, respectively. Our net loss includes non-cash expenses of \$28.9 million for the three months ended, and \$53.8 million for the six months ended, June 30, 2023.

Select Financial Information

(in thousands, except per share data)

(unaudited)

	June 30, 2023		December 31, 2022	
Cash, cash equivalents and short-term investments	\$ 157,852		\$ 193,358	
Cash raised since quarter end	\$ 20,281			
	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenues, royalty sales milestone	\$ -	\$ 17,316	\$ -	\$ 17,316
Revenues, non-cash royalty	22,068	144	41,174	17,778
Revenues, research and development	2,489	1,907	5,101	8,647
Revenues, other	739	1,559	1,923	3,126
Total Revenue	25,296	20,926	48,198	46,867
Research and development expenses	59,285	44,960	116,402	87,404
General and administrative expenses	20,415	18,914	38,653	37,866
Cost of service revenue	254	2,024	2,548	2,567
Other income	(883)	(8,966)	(1,604)	(8,776)
Non-cash interest expense	19,647	13,636	36,920	28,588
Non-cash contingent consideration fair value adjustment	8	(407)	(398)	(943)
Net loss*	\$ (73,430)	\$ (49,235)	\$ (144,323)	\$ (99,839)
Net loss per share attributable to Agenus Inc. common stockholders:	\$ (0.20)	\$ (0.17)	\$ (0.41)	\$ (0.35)

*Includes non-cash expenses

Adjusted Net loss for non-cash expenses:

Net loss as reported	\$ (73,430)	\$ (49,235)	\$ (144,323)	\$ (99,839)
Non-cash expenses				
Depreciation and amortization	2,973	1,690	5,535	3,350
Share based compensation	6,042	4,634	11,527	9,625
Non-cash interest expense	19,647	13,636	36,920	28,588
Other	285	(409)	(100)	(943)
Total non-cash expenses	28,947	19,551	53,882	40,620
Net loss excluding non-cash expenses	\$ (44,483)	\$ (29,684)	\$ (90,441)	\$ (59,219)

References

1 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037515/>

2 Cohen et al. ASCO Annual Meeting 2023

About Botensilimab

Botensilimab, an investigational multifunctional CTLA-4 antibody, is designed to extend immunotherapy benefits to “cold” tumors, which have not historically responded to standard of care or other investigational therapies. Besides binding to the CTLA-4 receptor, its Fc-enhanced structure induces a memory immune response, downregulates regulatory T cells, and activates T cells, thereby enhancing immune responses. Approximately 600 patients have been treated with botensilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus’ 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 AGEN2373

AGEN2373 is a novel anti-CD137 agonist that has been designed to activate T and NK cells while mitigating liver toxicities common to the CD137 target class. CD137 (4-1BB) is an activating receptor expressed on T and NK cells. Upon binding to CD137, AGEN2373 is designed to stimulate the growth and activation of cytotoxic T and NK cells, triggering a lasting memory response to cancer. AGEN2373 binds to a unique epitope designed to achieve this response specifically within the tumor microenvironment. This selective binding is designed to avoid serious side effects associated with CD137 activation in the liver that have been reported by competitor molecules. AGEN2373 has demonstrated preliminary clinical activity and has been well tolerated by patients without signs of liver toxicity (Barve et al. ASCO 2023).

About Agenus

Agenus is a leading immuno-oncology company targeting cancer and infectious diseases with a comprehensive pipeline of immunological agents. The company’s 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 is headquartered in Lexington, MA. For more information, visit www.agenusbio.com or follow us on [LinkedIn](#) and [Twitter](#) @agenus_bio.

Non-GAAP Financial Measures

To supplement our financial disclosures that are prepared and presented in accordance with generally accepted accounting principles in the United States (“GAAP”), this press release includes Adjusted Net Loss, which is a non-GAAP financial measure that we believe is helpful to our investors. We use these non-GAAP financial measures for financial and operational decision-making purposes. We believe these measures provide investors with meaningful period-to-period comparisons of our underlying performance.

Adjusted Net Loss is a supplemental measure of our operating performance and excludes the impacts of certain costs required to be recorded under GAAP. We calculate Adjusted Net Loss as net loss adjusted to exclude non-cash expenses of depreciation and amortization, share based compensation, non-cash interest expense and certain other non-cash expenses. Accordingly, Adjusted Net Loss should not be considered in isolation or as a substitute for net loss, which is the most directly comparable financial measure presented in accordance with GAAP.

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 our technologies, therapeutic candidates, and capabilities, for instance, statements regarding therapeutic benefit and efficacy, mechanism of action, potency, durability, and safety and tolerability profile of our therapeutic candidates, both alone and in combination with each other and/or other agents; statements regarding future plans, including research, clinical, regulatory, and commercialization plans; and any other statements containing the words “may,” “believes,” “expects,” “anticipates,” “hopes,” “intends,” “plans,” “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 and available on our website: www.agenusbio.com. 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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