

# Agenus Reports First Quarter 2024 Results

5/7/2024

\$100M royalty financing agreement with Ligand announced, bringing in capital via non-equity means to support critical botensilimab/balstilimab (BOT/BAL) development and launch readiness activities

Company has reestablished its market compliance with Nasdaq Listing

Notable clinical results observed in Phase 1 and Phase 2 studies of BOT/BAL in metastatic relapsed/refractory colorectal cancer setting (r/r MSS CRC NLM)

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. ("Agenus") (Nasdaq: AGEN), a leader in discovering and developing novel immunological agents to treat various cancers, today announced results for the first quarter 2024. In a concurrent press release accompanying Agenus' earnings announcement, a \$100M royalty financing agreement between Ligand and Agenus was reported. This pivotal, minimally dilutive capital infusion will support the key development and launch readiness initiatives needed to advance the company's lead program, BOT/BAL, in relapsed/refractory non-MSI high colorectal cancer without liver metastases (r/r MSS CRC NLM).

"We are thrilled to announce a significant \$100 million royalty financing agreement with Ligand, a milestone that investors have eagerly anticipated. This capital infusion is pivotal for advancing the development and market readiness of our BOT/BAL treatment," said Garo Armen, CEO of Agenus. He continued, "The BOT/BAL combination has consistently demonstrated deep and durable responses in 'cold' solid tumors, especially in our advanced studies of relapsed/refractory MSS CRC. With the promising results we have seen, and additional data from our ongoing Phase 2 study, we plan to engage with the FDA in the second half of 2024. Pending the outcomes of these discussions, we aim to commence the submission of a Biologics License Application under the accelerated approval provision for BOT/BAL in refractory MSS CRC NLM."

In parallel, Agenus has successfully reduced its cash burn rate. The company successfully executed a 20:1 reverse stock split during Q1 2024. This reverse stock split was implemented to achieve multiple key objectives, including satisfying the eligibility criteria for inclusion in the Russell Indices, regaining compliance with Nasdaq listing requirements, and maintaining a stock price above \$5 per share, enabling investment by certain institutional investors. Regaining of compliance with NASDAQ listing requirements was **confirmed in a press release** on April 30<sup>th</sup>, 2024. This reverse stock split comes as part of a series of strategic initiatives meant to lower Agenus' cost of capital and to broaden its investor base, benefitting both shareholders and patients.

## Q1 2024 Highlights on Botensilimab:

### Colorectal cancer:

- Data presented from the company's lead BOT/BAL program included an update of the Phase 1b trial in patients with relapsed-refractory MSS CRC NLM.
- This updated dataset (n=77) demonstrated a minimum of 23% RECIST-confirmed overall response rate (ORR) with a median overall survival (mOS) of 21.2 months, a 12-month overall survival (OS) estimate of 71%, and an 18-month OS estimate of 62% in 77 patients after a median follow up of 13.6 months. As of the data cutoff of March 1, 2024, the median duration of response was not yet reached.
- These data, which continue to mature, stand in stark contrast to standard of care therapies in this treatment setting with standard of care therapies ranging from 1% to 6.1% with a median OS of 12.9 months<sup>1, 2</sup>.
- The most common safety observations are immune-related diarrhea and colitis, which are managed in accordance with standard therapies. Grade 3+ treatment related diarrhea/colitis occurred in approximately 16% of patients.
- A **poster presentation** at the upcoming ASCO Annual Meeting in June on this same r/r MSS CRC cohort from the Phase 1b includes results from a sub-analysis conducted to determine whether treatment outcomes are correlated with specific sites of metastatic disease in patients with non-active liver metastases.

### Neoadjuvant CRC:

- Clinical data from an ongoing Investigator Sponsored Study (IST) at Weill-Cornell testing BOT/BAL in the neoadjuvant CRC population were presented at ASCO-GI in January 2024.
- In this IST (NEST-1) led by Dr. Pashtoon Kasi, patients diagnosed with resectable localized colon or rectal cancer were treated with one dose of BOT and two doses of BAL approximately 4 weeks prior to planned surgery.
- After surgery, pathologic analysis reported significant tumor shrinkage: 3/3 patients (100%) with microsatellite instability-high (MSI-H) CRC experienced major pathological responses (>90% tumor shrinkage) in less than 4 weeks, while 6/9 (67%) MSS CRC patients had tumor shrinkage of 50% or more.

- Longer follow-up on these initial 12 patients (NEST-1) will be presented at an upcoming medical meeting.
  - Part 2 of this IST is rapidly enrolling and allows a total of four BAL doses with one dose of BOT followed by surgery at 8 weeks (compared to surgery at 4 weeks in Part 1)
- Based upon these early encouraging data, Agenus plans to prioritize clinical development activities in the neoadjuvant MSS CRC treatment setting and is evaluating study designs for subsequent pivotal trials.

Outside of CRC, Agenus expects to release updated Phase 1 and 2 data in melanoma, lung cancer, sarcoma and pancreatic cancer later this year.

In parallel with these ongoing BOT/BAL development and regulatory activities around the company's planned BLA submission, Agenus has prioritized resources and efforts towards advancing critical commercial launch readiness activities. This includes ensuring quality and availability of BOT/BAL supply, through both third-party CMO partners and Agenus' wholly owned cGMP-grade facility in Emeryville, and the hiring of an established and seasoned commercial leadership team with extensive experience in launching oncology therapeutics. "We are partnering closely with our Global Medical Affairs and Clinical Team to gather insights from the world's experts in GI oncology and have conducted market research with over 150 US-based GI oncologists, both in the academic and community hospital settings. It is clear to us that there is significant anticipation for BOT/BAL, which underscores the urgency we feel to deliver this important treatment option to patients," said Robin Taylor, Chief Commercial Officer of Agenus.

### First Quarter 2024 Financial Overview:

We ended our first quarter 2024 with a cash and cash equivalent balance of \$52.9 million, compared to \$76.1 million on December 31, 2023. This morning, we announced a \$100 million agreement with Ligand Pharmaceuticals, consisting of an initial investment of \$75 million with an option to invest an additional \$25 million. Our cash used in operations for this first quarter was \$38.2 million, compared to \$40.6 million during the fourth quarter ended December 31, 2023.

For the first quarter ended March 31, 2024, we recognized revenue of \$28 million and incurred a net loss of \$63.5 million (including non-cash expenses of \$38.3 million) or \$3.04 per share. This compares to a net loss of \$70.9 million (including non-cash expenses of \$24.9 million) or \$4.31 per share for the same period in 2023.

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

March 31,

December 31,

|                                                                    | 2024                         | 2023        |
|--------------------------------------------------------------------|------------------------------|-------------|
| Cash and cash equivalents                                          | \$ 52,856                    | \$ 76,110   |
|                                                                    | Three months ended March 31, |             |
|                                                                    | 2024                         | 2023        |
| Revenues, research and development                                 | \$ -                         | \$ 2,612    |
| Revenues, non-cash royalty                                         | 27,767                       | 19,106      |
| Revenues, other                                                    | 238                          | 1,184       |
| Total Revenue                                                      | 28,005                       | 22,902      |
| Research and development expenses                                  | 43,925                       | 57,118      |
| General and administrative expenses                                | 16,855                       | 18,237      |
| Cost of service revenue                                            | 107                          | 2,294       |
| Other (income) loss                                                | 977                          | (721)       |
| Non-cash interest expense                                          | 29,595                       | 17,273      |
| Non-cash contingent consideration fair value adjustment            | -                            | (406)       |
| Net loss                                                           | \$ (63,454)                  | \$ (70,893) |
| Net loss per share attributable to Agenus Inc. common stockholders | \$ (3.04)                    | \$ (4.31)   |
| Cash used in operations                                            | \$ 38,191                    | \$ 58,526   |
| Non-cash operating expenses                                        | \$ 38,255                    | \$ 24,935   |

## Conference Call

Date: May 7<sup>th</sup>, 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> and via <https://events.q4inc.com/attendee/928123199>.

## References

<sup>1</sup> Prager et al. NEJM 2023

<sup>2</sup> Grothey et al. Lancet 2013

## About Botensilimab

Botensilimab is an investigational multifunctional anti-CTLA-4 immune activator (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 900 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](http://www.clinicaltrials.gov) with the identifiers NCT03860272, NCT05608044, NCT05630183, and NCT05529316.

## 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](http://www.agenusbio.com) or [@agenus\\_bio](https://twitter.com/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 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 at [www.agenusbio.com](http://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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