UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 9, 2023

AGENUS INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**000-29089**	**06-1562417**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3 Forbes Road Lexington, MA	**02421**
(Address of principal executive offices)	**(Zip Code)**

781-674-4400
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	AGEN	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 **Results of Operations and Financial Condition**.

On May 9, 2023, Agenus Inc. announced its financial results for the quarter ended March 31, 2023. In connection with the announcement, the Company issued a press release, which is being furnished as Exhibit 99.1 to this current report on Form 8-K.

The information set forth under Item 2.02 and in Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

Item 9.01 **Financial Statements and Exhibits**.

(d) Exhibit

The following exhibit is furnished herewith:

99.1 Press Release dated May 9, 2023

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AGENUS INC.

Date: May 9, 2023

By: /s/ Christine M. Klaskin

Christine M. Klaskin
VP, Finance

Agenus Provides Corporate Update and First Quarter 2023 Financial Results

- **At a late-breaking presentation at ASCO-GI, botensilimab/balstilimab combination demonstrated a 63% 12-month overall survival rate in metastatic colorectal cancer patients who have failed a median of four prior treatments, more than double the survival rate reported for available treatments**
- **Botensilimab/balstilimab combination data update selected for late-breaking oral session at the ESMO-GI conference in June 2023**
- **FDA granted Fast Track Designation to the botensilimab/balstilimab combination in colorectal cancer in April 2023**
- **At a plenary session at SGO, botensilimab/balstilimab combination showed 33% overall response rate in platinum-resistant ovarian cancer patients**
- **Phase II ACTIVATE trials expected to fully enroll in second half of 2023**
- **AGEN2373 monotherapy data to be presented at ASCO in June 2023**
- **Balstilimab/zalifrelimab data in the treatment of sarcoma to be presented at ASCO oral session in June 2023**

LEXINGTON, Mass.--(BUSINESS WIRE)--May 9, 2023--Agenus Inc. (Nasdaq: AGEN), an immuno-oncology company with an extensive pipeline of clinical and preclinical-stage cancer treatments, today provided a corporate update and reported financial results for the first quarter 2023.

"With over 350 patients dosed with botensilimab in our Phase 1 study, we have demonstrated 20-50% response rates in 9 solid tumor cancers. These results suggest that botensilimab could provide significant benefit to patients who have not responded to or failed other available treatments," said Dr. Garo Armen, Chief Executive Officer of Agenus. "Agenus is committed to advancing our development programs to make botensilimab available to patients ASAP."

Botensilimab Combination

Unprecedented activity in 70 patients with non-MSI-H colorectal cancer and 24 patients with recurrent platinum resistant/refractory ovarian cancer:

- Agenus presented botensilimab/balstilimab combination data at a late-breaking oral session at the American Society of Clinical Oncology – Gastrointestinal Cancers Symposium (ASCO-GI) in January 2023 and at the Society of Gynecologic Oncology (SGO) 2023 Annual Meeting on Women's Cancer in March 2023
- The combination showed unprecedented responses and survival benefit in 70 patients with non-microsatellite instability-high (non-MSI-H) colorectal cancer, including:
  - 12-month overall survival of 63% (compared to 25% reported for standard of care) [1,2]
  - Overall response rate of 23% (compared to 1-2%[1,2] reported for standard of care and 1-5%[3,4] reported for other PD-(L)1 + CTLA-4 combinations)
- In April 2023, the FDA granted Fast Track Designation to the botensilimab/balstilimab combination for the treatment of non-MSI-H/deficient mismatch repair (dMMR) metastatic colorectal cancer patients without active liver involvement who are resistant or intolerant to fluoropyrimidine, oxaliplatin, or irinotecan, and have also received a VEGF inhibitor, an EGFR inhibitor, and/or a BRAF inhibitor
- Agenus is conducting a global, randomized Phase 2 trial in this patient population under its ACTIVATE trial program, and a global Phase 3 trial is expected to commence in 2023
- In 24 ovarian cancer patients who were resistant or refractory to platinum chemotherapy, the botensilimab/balstilimab combination showed a 33% response rate (compared to ~10% reported for standard of care[5] and 3-10% for other PD-(L)1 + CTLA-4 combinations[6,7])
- Agenus continues to enroll PD-(L)1 relapsed/refractory NSCLC patients in its Phase 1b study and plans to launch a randomized phase 3 study if the previously reported ~50% response rates continue

Upcoming Presentations

- Updated data on the botensilimab/balstilimab combination in non-MSI-H metastatic colorectal cancer patients selected for a late breaking oral presentation at the upcoming ESMO World Congress on Gastrointestinal Cancer (ESMO-GI), to be held June 18 – July 1, 2023 in Barcelona, Spain
- Data from a single-arm, open-label Phase 2 study of balstilimab and zalifrelimab (1st generation CTLA-4) plus doxorubicin in patients with advanced sarcomas selected for oral presentation at the ASCO 2023 Annual Meeting, to be held June 2-6 in Chicago, IL
- Complete results from the monotherapy arm of the first-in-human dose escalation study of AGEN2373 in patients with advanced solid tumors will also be presented in a poster discussion at ASCO

Clinical Pipeline and Corporate Partnerships

Additional presentation at ASCO involving Agenus's clinical pipeline involving collaborations include:

- Abstract #424868: Targeting minimal residual disease (MRD) in resected RAS mutated pancreatic cancer with vaccine TG01/QS-21 +/- PD-1 inhibitor, balstilimab: A randomized phase II study (TESLA)
- Abstract # TPS6104: Phase 2 Trial of Retifanlimab (anti–PD-1) in Combination With INCAGN02385 (anti–LAG-3) and INCAGN02390 (anti–TIM-3) as First-Line Treatment in Patients With PD-L1–Positive Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck
- Abstract #2599: A Phase 1/2 Study of retifanlimab (INCMGA00012, Anti–PD-1), INCAGN02385 (Anti–LAG-3), and INCAGN02390 (Anti–TIM-3) Combination Therapy in Patients (Pts) With Advanced Solid Tumors
- Abstract #2541: A phase 1/2 study of the safety, tolerability, and preliminary efficacy of the anti-GITR monoclonal antibody, INCAGN01876, combined with immunotherapies (IO) in patients (Pts) with advanced cancers

Agenus shareholders received dividend of shares in MiNK Therapeutics (NASDAQ: INKT)

On May 1st, 2023, Agenus distributed a dividend of approximately 5,000,000 shares it owned of its subsidiary MiNK Therapeutics' common stock to shareholders who held Agenus shares as of April 17, 2023, with a ratio of 0.0146 shares of MiNK (NASDAQ: INKT) per share of Agenus. The announced dividend distribution preceded MiNK's presentation of its lead product, agenT-797, an allo-INKT cell therapy, showing clinical and biomarker responses in solid tumor cancers at AACR in April 2023. This distribution allows Agenus shareholders to benefit from future growth of MiNK through direct ownership. The shares that were distributed as part of this dividend were not part of a new stock offering.

First Quarter 2023 Financial Results:

We ended our first quarter 2023 with a cash, cash equivalent and short-term investment balance of $189.2 million, compared to $193.4 million at December 31, 2022. Since quarter end we have raised $13.6 million through sales under our at market issuance sales agreement.

For the first quarter ended March 31, 2023, we recognized revenue of $22.9 million and incurred a net loss of $70.9 million (including non-cash expenses of $24.9 million) or $0.22 per share.

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 189,233	$ 193,358

	Three months ended March 31,	
	2023	2022
Revenues, research and development	$ 2,612	$ 6,740
Revenues, non-cash royalty	19,106	17,634
Revenues, other	1,184	1,567
Total Revenue	22,902	25,941
Research and development expenses	57,118	42,442
General and administrative expenses	18,237	18,953
Cost of service revenue	2,294	543
Other (income) loss	(721)	191
Non-cash interest expense	17,273	14,952
Non-cash contingent consideration fair value adjustment	(406)	(536)
Net loss	$ (70,893)	$ (50,604)
Net loss per share attributable to Agenus Inc. common stockholders	$ (0.22)	$ (0.19)
Cash used in operations	**$ 58,526**	**$ 52,391**
Non-cash operating expenses	$ 24,935	$ 21,069

Conference Call

Date: May 9, 2023, 8:30am ET
Dial-in numbers: 646-307-1963 (US-NY) & 800-715-9871 (Ex-US)
Event ID: 9144113

Webcast

A 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/v54y2wy9.

References

1 Mayer et al. NEJM 2015
2 Grothey et al. Lancet 2013
3 Chen et al. JAMA Oncol. 2020
4 Overman et al. ASCO 2016
5 Mutch DG, et al. J Clin Oncol. 2007;25(19): 2811-2818
6 https://clinicaltrials.gov/ct2/show/results/NCT01928394
7 Hinchcliff et al. Gynecologic Oncology 2021

About Botensilimab

Botensilimab is a novel, multifunctional CTLA-4 investigational antibody that has been designed to extend clinical benefits to "cold" tumors that have not historically responded to standard of care or investigational therapies, as well as to expand clinical benefit in "hot" tumors, where immunotherapies are approved but benefit only a minority of patients. In addition to binding to the CTLA-4 receptor, its Fc-enhanced structure induces a memory immune response, downregulates regulatory T cells, activates existing T cells, as well as primes and expands new T cells, thereby promoting a more effective and durable immune response to cancer.

In a Phase 1 clinical study of more than 350 patients, botensilimab has demonstrated clinical responses in nine different cold and treatment-refractory solid tumor cancers, either alone or in combination with Agenus' PD-1 antibody, balstilimab (data presented at ASCO GI 2023, SGO 2023, SITC 2022, and CTOS 2022). Agenus is conducting global, randomized Phase 2 trials in non-MSI-H colorectal cancer, melanoma, and pancreatic cancer as part of its ACTIVATE trial programs. Additional information about these botensilimab trials can be found at www.clinicaltrials.gov under the identifiers NCT05608044, NCT05630183, and NCT05529316, respectively. A global Phase 3 trial in non-MSI-H colorectal cancer is expected to launch in 2023.

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 binging 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 (Tolcher et al. ASCO 2021).

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 and infections. 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 subsidiary MiNK Therapeutics), and adjuvants (through its subsidiary SaponiQx). 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.

About MiNK Therapeutics

MiNK Therapeutics is a clinical-stage biopharmaceutical company pioneering the discovery, development, and commercialization of allogeneic invariant natural killer T (iNKT) cell therapies to treat cancer and other immune-mediated diseases. MiNK is advancing a pipeline of both native and next-generation engineered iNKT programs, with a platform designed to facilitate scalable and reproducible manufacturing for off-the-shelf delivery. The company is headquartered in New York, NY. For more information, visit https://minktherapeutics.com/ and Twitter handle @MiNK_iNKT.

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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