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

August 9, 2021
Date of Report (Date of earliest event reported)

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)	(I.R.S. 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)

(Former name or former address, if changed since last report)

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:

☐ 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 August 9, 2021, Agenus Inc. announced its financial results for the quarter ended June 30, 2021. In connection with the announcement, the Company issued a press release, which is being furnished as Exhibits 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) Exhibits.

The following exhibit is furnished herewith:

99.1	Press Release dated August 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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: August 9, 2021

By: /s/ Christine M. Klaskin
Christine M. Klaskin
VP, Finance

EXHIBIT 99.1

Agenus Corporate Update and Second Quarter 2021 Financial Report

- $200M received from BMS for anti-TIGIT bispecific antibody collaboration
- FDA cleared IND for AGEN1777 clinical enrollment
- AGEN1181 rapidly advancing in the clinic; data to be presented in 2H 2021
- Cell therapy subsidiary MiNK Therapeutics filed confidential S-1 for planned IPO
- FDA accepted balstilimab BLA for Priority Review with December PDUFA date

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

“In the first half of this year, we announced a collaboration with BMS and advanced our flagship clinical candidate AGEN1181 to an important data inflection point,” said Garo Armen, PhD, Chairman and Chief Executive Officer of Agenus. “In the second half, we will disclose this data at a key cancer conference and be ready with our commercial platform in preparation for a balstilimab launch.”

AGEN1181 (Fc-enhanced anti-CTLA-4): Clinical data support superior activity in difficult-to-treat cancers

- Updated clinical data for AGEN1181 alone and in combination with balstilimab will be presented at an upcoming conference.

- Clinical responses seen in patients refractory to approved immunotherapies, including patients with microsatellite stable (MSS) tumors and melanoma, endometrial, and ovarian cancer with the low-affinity FcyRIIIA allele. No immune mediated hypophysitis, pneumonitis, or hepatitis (typically seen with first generation anti-CTLA-4s) were reported.

- Registrational trials targeted to commence by year-end 2021 with a focus on rapid path to Biologics License Application (BLA) submission.

MiNK Therapeutics: Allogeneic iNKT cell therapy company advances towards IPO

- MiNK Therapeutics (currently an Agenus company) filed a confidential S-1 to support a planned Initial Public Offering (IPO).

- Phase 1 trial of AGENT-797 in hematologic cancers dose cohorts completed with data readouts planned in the second half of 2021; Phase 1/2 expansion trials in viral acute respiratory distress syndrome (ARDS) are underway.

AGEN1777 (Fc-enhanced anti-TIGIT bispecific): Collaboration with BMS provides additional cash resources to advance Agenus’ high value drivers

- Global exclusive license with Bristol Myers Squibb for AGEN1777 provides $200 million upfront cash. In addition, Agenus to receive up to $1.36 billion in development, regulatory, and commercial milestones, and tiered double-digit royalties upon product sales.

- FDA cleared Investigational New Drug (IND) application; Phase 1 dosing with AGEN1777 alone and in combination with an anti-PD-1 in advanced solid tumors planned to begin this quarter.

Balstilimab (anti-PD-1): BLA accepted for Priority Review by U.S. FDA; data updates presented at ASCO

- Balstilimab BLA accepted for Priority Review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of December 16, 2021.

- Commercial preparation underway for a highly efficient, targeted launch to provide broad product access to physicians and patients while laying the foundation for future Agenus products.

- Clinical data presented at the American Society of Clinical Oncology (ASCO) Annual Meeting:

    - Phase 2 data for balstilimab showed a response rate of 20% in PD-L1 positive tumors, overall response rate of 15%, and median duration of response of 15.4 months.
    - Balstilimab showed superior tumor killing compared to approved anti-PD-1s such as pembrolizumab and nivolumab.

- Results from a Phase 2 trial of balstilimab plus zalifrelimab combination in recurrent or metastatic cervical cancer to be presented in a Mini Oral Session at the European Society for Medical Oncology (ESMO) Congress 2021 on September 19 from 11:35 – 11:40am ET.

Additional programs

- Phase 1 data for AGEN2373, a CD137 agonist antibody, in patients with advanced solid tumors were presented at ASCO 2021.
    - No dose limiting toxicities were seen at doses up to 3 mg/kg, including no liver toxicity. Combination trials are in planning.
- Process for scale up of QS-21 manufacturing continues to advance.
- VISION platform knowledge base expanding to support AGEN1181 response prediction and combination discovery.

Management appointments

- Steven O'Day, MD appointed to Chief Medical Officer.
- Andy Hurley appointed to Chief Commercial Officer.
- Marc Wiles, PhD appointed to Vice President of Regulatory Affairs.
- Julie DeSander promoted to Chief Business Officer.
- Joseph Grossman, MD, appointed to Vice President of Exploratory Medicine.
- Jason Paragas appointed to Vice President of Data Sciences.
- Jennifer Buell, PhD, appointed to Chief Executive Officer of MiNK Therapeutics. Dr. Buell will continue as a member of the Agenus Executive Committee.

Second Quarter Financial Results

We ended the second quarter of 2021 with a cash balance of $74 million as compared to $100 million at December 31, 2020. Subsequent to the quarter end we received $200 million related to our BMS partnership.

For the second quarter ended June 30, 2021, our cash used in operations was $56 million and we reported a net loss of $84 million or $0.37 per share which included a number of non-cash items. This compares to cash used in operations for the same period in 2020 of $37 million and a net loss of $48 million or $0.28 per share. Non-cash operating expenses for the second quarter ended June 30, 2021 were $30 million compared to $18 million for the second quarter of 2020.

Our cash used in operations for the six months ended June 30, 2021 was $98 million with a net loss of $138 million or $0.65 per share compared to cash used in operations of $72 million and a net loss for the same period in 2020 of $94 million or $0.59 per share.

We recognized revenue of $22 million and $42 million for the six-months ended June 30, 2021 and 2020, respectively, which includes revenue related to non-cash royalties earned, revenue recognized under our collaboration agreements, and in 2020, $14 million from an upfront license fee received.

Select Financial Information
(in thousands, except per share data)
(unaudited)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 73,543 *	$ 99,871

*Excludes $200 million received in July 2021 from BMS

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenues, research and development	$ 1,708	$ 18,068	$ 3,279	$ 19,996
Revenues, non-cash royalty	7,826	7,846	16,310	21,002
Revenues, other	1,196	1,031	2,860	1,075
Total Revenue	10,730	26,945	22,449	42,073

Research and development expenses	45,508	38,550	82,184	74,913
General and administrative expenses	16,650	14,195	33,003	24,809
Cost of service revenue	667	634	1,772	634
Other expense (income)	1,210	623	(1,369)	1,865
Non-cash interest expense	16,386	14,347	31,997	28,191
Loss on modification of debt	-	-	-	2,720
Non-cash contingent consideration fair value adjustment	14,300	6,840	13,256	2,456
Net loss	$ (83,991)	$ (48,244)	$ (138,394)	$ (93,515)
Net loss per share attributable to Agenus Inc. common stockholders	$ (0.37)	$ (0.28)	$ (0.65)	$ (0.59)
Cash used in operations	**$ (55,557)**	**$ (37,375)**	**$ (98,301)**	**$ (71,880)**
Non-cash operating expenses	$ 30,171	$ 17,685	$ 41,984	$ 20,806

Conference Call
Monday August 9, 2021, 8:30am ET
Dial-in numbers: (833) 614-1394 (US) or (914) 987-7115 (International).
Conference ID number: 3686849.

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/gsbikqz2.

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 MiNK Therapeutics subsidiary), 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 regarding clinical development and regulatory plans and timelines, anticipated corporate milestones, new clinical data and program updates to be presented, and the anticipated commercial launch of balstilimab. 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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