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): October 22, 2021

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)**

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

N/A
(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 (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 8.01 Other Events.

Agenus Inc. (the “Company”) announced today a strategic decision to voluntarily withdraw its Biologics License Application (BLA) for balstilimab, its PD-1 inhibitor. The decision comes after consultation with the FDA following early full approval of pembrolizumab in second-line cervical cancer. The decision to withdraw the BLA does not change the Company’s development plans for use of balstilimab in combination with other therapeutic agents.

The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press Release dated October 22, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: October 22, 2021

AGENUS INC.

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

Exhibit 99.1

Agenus Provides Update on Balstilimab Development

- Company voluntarily withdraws BLA at FDA's recommendation following full approval of pembrolizumab, which came four months earlier than FDA goal date
- Balstilimab achieved trial endpoints with 20% response rates in PD-L1 positive patients, versus 14% reported in pembrolizumab's label; Agenus successfully completed 3 FDA pre-approval inspections for the PDUFA date of Dec. 16, 2021
- Agenus plans to launch expanded access programs to give patients access to balstilimab in several countries, including the US
- Agenus will discontinue its ongoing confirmatory trial (BRAVA) in this population, which is expected to reduce R&D expenses by over $100M
- Accelerated development of balstilimab in combination with AGEN1181 will be launched in multiple tumor types; clinical update at SITC

LEXINGTON, Mass., October 22, 2021 /GLOBENEWSWIRE/ — Agenus (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 announced a strategic decision to withdraw its Biologics License Application (BLA) for balstilimab, its PD-1 inhibitor. The decision to withdraw the BLA does not change the development plans for balstilimab combinations.

Following the full approval of pembrolizumab, announced four months earlier than the FDA goal date, the U.S. Food and Drug Administration (FDA) no longer considered it appropriate to review the BLA for accelerated approval and recommended Agenus withdraw. The BLA submission for balstilimab received Fast Track and Priority Review designation from the FDA, with a target action date of December 16, 2021. As part of the BLA review process, Agenus successfully completed 3 FDA inspections with no cited issues, concerns, or Form-483s.

As previously reported, in the largest single-arm trial to date in this population (140 evaluable patients), balstilimab demonstrated objective responses in both PD-L1 positive and negative patients, with an objective response rate (ORR) of 20% and 8% respectively[1]. Pembrolizumab has demonstrated an ORR of 14% and 0% in PD-L1 positive and negative patients respectively, which led to its accelerated approval in 2018. Balstilimab has shown superior killing of PD-L1 negative tumors compared to other anti PD-1 therapies, including pembrolizumab, suggesting a broader mechanism consistent with balstilimab's clinical activity in both PD-L1 positive and negative cervical cancer[2].

Concurrent with the withdrawal, Agenus will discontinue its ongoing confirmatory trial (BRAVA) in this population, which is expected to reduce R&D expenses by over $100M. However, given the clinical benefit demonstrated by balstilimab, Agenus plans to launch expanded access programs to give patients and doctors access to balstilimab in several countries, including the US, pending regulatory processes.

“While the commercial market for balstilimab monotherapy in second line cervical cancer was always anticipated to be small, Agenus’ priority remains developing balstilimab as a necessary component of highly effective and affordable combination therapies, both with its own portfolio and with partners, including in combination with Agenus’ next-generation CTLA-4, AGEN1181,” said Garo Armen, CEO and Chairman of Agenus.

“Balstilimab has demonstrated meaningful clinical activity and an excellent safety profile in second-line cervical cancer, including in PD-L1 negative patients, who are ineligible to receive standard of care anti-PD-1 therapy, which makes the decision to withdraw so difficult for us,” said Steven O’Day, MD, Chief Medical Officer of Agenus. “Balstilimab remains a critical component of our combination regimens, including with our next-generation CTLA-4 agent, AGEN1181. Concomitant with presentation of new data at SITC next month, we continue to accelerate development of AGEN1181 in combination with balstilimab in trials designed to rapidly support full or accelerated approval in multiple tumor types.”

Agenus executives will host a conference call to discuss this update at 8:30AM ET today.

Conference Call

Dial-in numbers: (833) 614-1394 (US) or (914) 987-7115 (International); Conference ID: 5399638.

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/2p8yio6u.

References

1. D.M. O’Malley, A. Oaknin, B.J. Monk, et al., Phase II study of the safety and efficacy of the anti-PD-1 antibody balstilimab inpatients with rec..., Gynecologic Oncology, https://doi.org/10.1016/j.ygyno.2021.08.018

2. C. Joyce, D. Chand et al., Differentiated activity profile for the PD-1 inhibitor balstilimab. Journal of Clinical Oncology 39, no. 15_suppl (May 20, 2021) 5529-5529.

About Balstilimab

Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. PD-1 is a negative regulator of immune activation that is considered a foundational target within the immuno-oncology market.

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 affiliate MiNK Therapeutics), 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 relating to the use of therapeutic candidates balstilimab and AGEN 1181, for instance, statements regarding therapeutic benefit and efficacy, mechanism of action, potency, durability, and safety profile of the therapeutic candidates, both alone and in combination with each other and/or other agents; future clinical and regulatory development plans for balstilimab alone and in combination with other agents, including AGEN1181; our ability to obtain regulatory approval for balstilimab, alone and in combination with other agents, including AGEN1181, including the timing (including the possibility of accelerated review) and scope of any such regulatory approval; future commercial plans, including pricing, for balstilimab, alone and in combination with other agents; and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "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. 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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