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 24, 2022

Acumen Pharmaceuticals, Inc.
(Exact name of registrant as specified in its Charter)

Delaware	**001-40551**	**36-4108129**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

427 Park St., Charlottesville, Virginia	**22902**
(Address of Principal Executive Offices)	**(Zip Code)**

(434) 297-1000
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(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 Instructions 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, $0.0001 par value	**ABOS**	**The Nasdaq Global Select 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.

On October 24, 2022, Acumen Pharmaceuticals, Inc. (the "***Company***") issued a press release announcing that the U.S. Food and Drug Administration has granted it Fast Track designation for ACU193, a humanized monoclonal antibody that selectively targets toxic soluble amyloid-beta oligomers, for the treatment of early Alzheimer's disease. A copy of that press release is attached as Exhibit 99.1 to this Current Report on Form 8-K (this "***Report***") and is incorporated herein by reference.

This Report and Exhibit 99.1 hereto contain forward looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 24, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

SIGNATURES

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

Acumen Pharmaceuticals, Inc.

Dated: October 24, 2022

By: /s/ Derek Meisner
Derek Meisner
Chief Legal Officer and Corporate Secretary

Acumen's ACU193, an Anti-Amyloid Beta Oligomer Antibody, Granted FDA Fast Track Designation for Alzheimer's Disease

Charlottesville, Va. and Carmel, Ind. (October 24, 2022) – Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS) today announced that ACU193, the first clinical-stage monoclonal antibody that selectively targets toxic soluble amyloid beta oligomers (AßOs), has been granted Fast Track designation for the treatment of early Alzheimer's disease by the U.S. Food and Drug Administration (FDA). ACU193 is currently being studied in the Phase 1 INTERCEPT-AD trial designed to assess safety and proof of mechanism of ACU193.

ACU193 is a humanized monoclonal antibody discovered and developed based on its selectivity for soluble AßOs, which scientific evidence shows are the most toxic and pathogenic form of Aß, relative to Aß monomers and amyloid plaques. Some types of toxic soluble AßOs have been found to interact within synapses which leads to altered neuronal function, and can initiate and perpetuate the process of neurodegeneration, ultimately leading to cell death. ACU193 binds AßOs that bind to synapses, and due to its unique binding profile, ACU193 has potential to provide therapeutic benefit with low risk of amyloid-related imaging abnormalities (ARIA), because ACU193 blocks the toxic effects of AßOs without directly targeting amyloid plaques.

"We are encouraged to receive Fast Track designation for ACU193, reflecting its potential clinical utility to treat Alzheimer's disease," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "We look forward to collaborating with the FDA to advance the development of ACU193. Treating Alzheimer's disease ultimately requires therapies that target different components of the disease pathway, and we are developing ACU193 with the goal of providing patients with more treatment options."

The FDA Fast Track program is designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening conditions with the potential to fill an unmet medical need. The Fast Track designation allows Acumen to have more frequent engagement with the FDA to discuss development plans and clinical study design for ACU193 to ensure collection of appropriate data to support evaluation for approval.

About ACU193

ACU193 is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble AßOs, which Acumen believes are the most toxic and pathogenic form of Aß, relative to Aß monomers and amyloid plaques. Soluble AßOs have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble AßOs, ACU193 aims to directly address what a growing body of evidence indicates is a primary underlying cause of the neurodegenerative process in AD.

About INTERCEPT-AD

Approximately 62 individuals with early AD (mild cognitive impairment or mild dementia due to AD) are expected to be randomized into this double-blind, placebo-controlled, first-in-human study of ACU193.

INTERCEPT-AD is designed to establish safety and proof of mechanism. It consists of single-ascending-dose (SAD) and multiple-ascending-dose (MAD) cohorts and is designed to evaluate the safety, tolerability, pharmacokinetics (PK), and target engagement of intravenous doses of ACU193. The study is enrolling at multiple investigative sites located in the United States. More information can be found on www.clinicaltrials.gov, NCT identifier NCT04931459.

About Acumen Pharmaceuticals, Inc.

Acumen, headquartered in Charlottesville, VA, with clinical operations based in Carmel, IN, is a clinical stage biopharmaceutical company developing a novel disease-modifying approach to treat Alzheimer's disease. Acumen's scientific founders pioneered research on AßOs, which a growing body of evidence indicates are primary triggers of Alzheimer's disease pathology. Acumen is currently focused on advancing its investigational product candidate, ACU193, a humanized monoclonal antibody that selectively targets toxic soluble AßOs in INTERCEPT-AD, a Phase 1 clinical trial involving early Alzheimer's disease patients. For more information, visit www.acumenpharm.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Any statement describing Acumen's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Words such as "believes," "expects," "anticipates," "could," "would," "seeks," "aims," "plans," "potential," "will" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements include statements concerning Acumen's business and the therapeutic potential of Acumen's product candidate, ACU193, including its potential for improved safety and efficacy as compared to other monoclonal antibodies in development, and expectations with respect to the role of toxic soluble AßOs in the potential treatment of Alzheimer's disease. These statements are based upon the current beliefs and expectations of Acumen management, and are subject to certain factors, risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing safe and effective human therapeutics. Such risks may be amplified by the impacts of the COVID-19 pandemic. These and other risks concerning Acumen's programs are described in additional detail in Acumen's filings with the Securities and Exchange Commission ("SEC"), including in Acumen's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 28, 2022, which is available on the SEC's website at www.sec.gov, and its other documents subsequently filed with or furnished to the SEC. Copies of these and other documents are available from Acumen. Additional information will be made available in other filings that Acumen makes from time to time with the SEC. These forward-looking statements speak only as of the date hereof, and Acumen expressly disclaims any obligation to update or revise any forward-looking statement, except as otherwise required by law, whether, as a result of new information, future events or otherwise.

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