## **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 7, 2021

# Acumen Pharmaceuticals, Inc.

(Exact name of registrant as specified in its Charter)

Delaware		
(State or Other Jurisdiction		
of Incorporation)		

001-40551 (Commission File Number)

36-4108129 (IRS Employer Identification No.)

427 Park St., Charlottesville, Virginia (Address of Principal Executive Offices)

22902 (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	
5	check mark whether the registrant is an eme Rule 12b-2 of the Securities Exchange Act o		of the Securities Act of 1933 (§230.405 of this	

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.  $\ \Box$ 

#### Item 7.01 Regulation FD Disclosure.

On October 7, 2021, Acumen Pharmaceuticals, Inc. issued a press release announcing the dosing of the first patient in INTERCEPT-AD, the Phase 1 placebo-controlled, single- and multiple-dose clinical trial of ACU193, a monoclonal antibody that selectively targets toxic amyloid-beta oligomers for the treatment of early Alzheimer's disease. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information contained in this Item 7.01 of this Current Report on Form 8-K, including the exhibits attached hereto, is being furnished and shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	
No.	Description

99.1 <u>Press release issued by Acumen Pharmaceuticals, Inc. on October 7, 2021.</u>

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 7, 2021

By: /s/ Matthew Zuga

Matthew Zuga

Chief Financial Officer and Chief Business Officer



# Acumen Announces First Patient Dosed in a Phase 1 Clinical Trial of ACU193, a Monoclonal Antibody that Selectively Targets Toxic Aß Oligomers for the Treatment of Early Alzheimer's Disease.

ACU193 is the first monoclonal antibody to enter a clinical trial that was discovered and is being developed to selectively target toxic amyloid-beta oligomers (ABOs).

Enrollment of early Alzheimer's patients is ongoing in INTERCEPT-AD, the Phase 1 placebo-controlled, single- and multiple-dose clinical trial of ACU193.

Charlottesville, VA and Carmel, IN, (October 7, 2021) – Acumen Pharmaceuticals, Inc., a clinical stage biopharmaceutical company focused on the development of novel targeted therapeutics for Alzheimer's disease (AD), today announced dosing of the first patient in INTERCEPT-AD, the Phase 1 placebo-controlled, single- and multiple-dose clinical trial of ACU193, a monoclonal antibody that selectively targets toxic amyloid-beta oligomers (AßOs) for the treatment of early AD.

"We are very pleased to report this first clinical development milestone for ACU193," said Daniel O'Connell, President and CEO of Acumen. "We are encouraged by recent momentum and the breadth of scientific innovation that is being applied to Alzheimer's research. We believe ACU193 has distinct potential to address the continued unmet medical needs of people living with Alzheimer's disease."

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

"We are all very excited about evaluating ACU193 in the INTERCEPT-AD trial," said Eric Siemers MD, Chief Medical Officer for Acumen. "Our goal for this Phase 1 clinical trial is to establish proof of mechanism for ACU193, including overall safety and tolerability, pharmacokinetics and target engagement. We have also incorporated standard clinical outcomes for AD as well as exploratory assessments. Based on ACU193's unique mechanism of action, we believe it has the potential for improved efficacy and for improved safety compared to other monoclonal antibodies in development."

#### **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 <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>, <a href="https://www.nctioncentrolled">NCT04931459</a>.

#### 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 A&Os, which a growing body of evidence indicates are primary triggers of Alzheimer's disease pathology. Acumen is currently focused on advancing its investigational immunotherapy drug, ACU193, a humanized monoclonal antibody that selectively targets toxic A&Os in a Phase I clinical trial involving early Alzheimer's disease patients.

#### **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, as well as the expectations concerning the INTERCEPT-AD trial. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 16, 2021, which is available on the SEC's website at www.sec.gov. 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 otherwi

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For more information, visit www.acumenpharm.com.