

**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): November 15, 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

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 November 15, 2021, Acumen Pharmaceuticals, Inc. (the “*Company*”) reported financial results and business highlights for the quarter ended September 30, 2021. A copy of this press release (the “*Earnings Press Release*”) is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference.

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Earnings Press Release, dated November 15, 2021
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: November 15, 2021

By: /s/ Matthew Zuga
Matthew Zuga
Chief Financial Officer and Chief Business Officer



Acumen Pharmaceuticals Reports Financial Results for Third Quarter 2021 and Business Highlights

- **Acumen’s investigational product candidate, ACU193, is the first humanized monoclonal antibody discovered and developed to selectively target toxic amyloid-beta oligomers (ABOs) to enter clinical trials**
- **Enrolled first patients in INTERCEPT-AD, a multi-center, randomized, double-blind, placebo-controlled, single- and multiple-ascending dose Phase 1 clinical trial of ACU193 in patients with early Alzheimer’s disease**
- **Closed initial public offering in July 2021, with aggregate net proceeds of \$168.6 million**

Charlottesville, Va, and Carmel, In., November 15, 2021 – Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), a clinical stage biopharmaceutical company focused on the development of novel targeted therapeutics for Alzheimer’s disease (AD), today reported financial results for the quarter ended September 30, 2021 and provided recent business highlights.

“Starting with our successful IPO in early July, the third quarter of 2021 marked the beginning of the next phase of life for our company. In October 2021, we announced the screening and initial dosing of our first patient in INTERCEPT-AD,” said Daniel O’Connell, President and Chief Executive Officer at Acumen. “INTERCEPT-AD is investigating the safety, tolerability, pharmacokinetics and target engagement of our product candidate ACU193 in a Phase 1 clinical trial involving early Alzheimer’s patients. ACU193 is differentiated as the first humanized monoclonal antibody discovered and developed to selectively target toxic amyloid-beta oligomers (ABOs) to enter a clinical trial. We have cleared our sentinel safety review and are continuing to recruit patients in INTERCEPT-AD. We believe we have the resources to execute against our current strategic plan with our existing cash and cash equivalents and marketable securities, which we believe will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least through 2024.”

Recent Business Highlights and Anticipated Milestones

ACU193 Clinical Development

- **INTERCEPT-AD is recruiting; sentinel safety review complete and Cohort 1 is enrolling.** Patient screening and enrollment is ongoing for INTERCEPT-AD. Although Acumen has experienced delays in clinical site activation and patient enrollment in INTERCEPT-AD, which Acumen believes is a result of the rise of the Delta variant of COVID-19 early in the third quarter of 2021, Acumen continues to anticipate topline data from this trial by the end of 2022, subject to the rate of site activation and patient recruitment.



Corporate

- **Closing of Initial Public Offering.** In July 2021, Acumen issued an aggregate of 11,499,998 shares of common stock, including shares pursuant to the underwriters' exercise of their full over-allotment option, in an initial public offering, resulting in aggregate net proceeds of \$168.6 million.

Third Quarter 2021 Financial Results

- **Cash Balance.** As of September 30, 2021, our cash and cash equivalents totaled \$135.8 million and our marketable securities totaled \$94.1 million, compared to cash and cash equivalents of \$43.8 million and no marketable securities as of December 31, 2020.
- **Research and Development (R&D) Expenses.** R&D expenses were \$1.8 million and \$6.6 million for the three- and nine-month periods ended September 30, 2021, respectively, compared to \$3.0 million and \$7.0 million for the three- and nine-month periods ended September 30, 2020, respectively.
- **General and Administrative (G&A) Expenses.** G&A expenses were \$2.1 million and \$4.5 million for the three- and nine-month periods ended September 30, 2021, respectively, compared to \$0.2 million and \$0.7 million for the three- and nine-month periods ended September 30, 2020, respectively.
- **Loss from Operations.** Losses from Operations were \$3.9 million and \$11.2 million for the three- and nine-month periods ended September 30, 2021, respectively, compared to \$2.5 million and \$6.6 million for the three- and nine-month periods ended September 30, 2020, respectively.
- **Net Loss.** Net Losses were \$3.9 million and \$92.3 million for the three- and nine-month periods ended September 30, 2021, respectively, compared to \$2.5 million and \$6.6 million for the three- and nine-month periods ended September 30, 2020, respectively. Net losses in 2021 include a non-cash expense that represents the changes in fair value of Acumen's Series B tranche liability and Series A-1 warrant liability. The tranche liability and warrant liability were initially recorded at fair value as a liability on Acumen's balance sheet and were subsequently re-measured at fair value at the end of each reporting period. The increases in the fair value of these instruments were recognized as a component of other expense. The second tranche of the Series B Preferred Stock financing round closed in June 2021 and, as a result, the remaining value of the tranche liability was reclassified to convertible preferred stock on Acumen's condensed balance sheet. Additionally, the Series A-1 warrant was exercised in June 2021, and the remaining value of the warrant liability was reclassified to convertible preferred stock on Acumen's condensed balance sheet. Upon the closing of the initial public offering, all outstanding share of convertible preferred stock converted into equivalent shares of common stock.



About ACU193

ACU193 is a monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble A β Os, which Acumen believes are the most toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques. Soluble A β Os have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble A β Os, 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 Pharmaceuticals, 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 toxic soluble A β Os, 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 A β Os in 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, Acumen's ability to achieve its strategic and financial goals, including its projected use of cash, cash equivalents and marketable securities and the sufficiency of its cash resources, 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, including the expected timing of reporting data, and risks and uncertainties relating to the progression and duration of the COVID-19 pandemic and responsive measures thereto and related effects on Acumen. 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, and future filings and reports by Acumen, including Acumen’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. 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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