

**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): May 16, 2022

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 May 16, 2022, Acumen Pharmaceuticals, Inc. (the “**Company**”) reported financial results and business highlights for the quarter ended March 31, 2022. 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 May 16, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Acumen Pharmaceuticals, Inc.

Dated: May 16, 2022

By: /s/ Matthew Zuga

Matthew Zuga

Chief Financial Officer and Chief Business Officer



**Acumen Pharmaceuticals Reports Financial Results for
First Quarter 2022 and Business Highlights**

- **Topline results expected in the first half of 2023 from 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**
- ***Frontiers in Neuroscience* recently published a summary of preclinical evidence supporting the development of ACU193, a monoclonal antibody designed to selectively target toxic soluble amyloid-beta oligomers (A β O $_s$), for the potential treatment of early Alzheimer’s disease**
- **\$216.7 million in cash, cash equivalents and marketable securities as of March 31, 2022, which is expected to provide cash runway through 2025**
- **Company to host conference call and webcast today at 4:30 pm ET**

Charlottesville, Va. and Carmel, In., May 16, 2022 – 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 March 31, 2022 and provided a business update.

“During the first quarter, we made significant progress in advancing INTERCEPT-AD, our Phase 1 clinical trial investigating the safety, tolerability, pharmacokinetics and target engagement of ACU193 in patients with early AD. We expect to report topline results in the first half of 2023,” said Daniel O’Connell, President and Chief Executive Officer of Acumen. “Further, we expect our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through 2025 based on our current plans.”

The Acumen team is pleased with the recent publication of the *Frontiers in Neuroscience* article in which preclinical evidence characterizing ACU193’s selectivity and differentiated profile is reviewed with the rationale for targeting soluble amyloid-beta oligomers in early AD. “The *Frontiers* article is timely, as we and others in the field look at upcoming clinical and regulatory events and as we continue to position ACU193 as potentially having a best-in-class treatment profile based on its potential safety, including anticipated limited to no ARIA-E, and clinical benefits on cognitive measures,” said Eric Siemers, Acumen’s Chief Medical Officer. “Each other monoclonal antibody which is approved or is in development has a different profile targeting various forms of A β or amyloid. We believe the differences in these profiles are likely to lead to meaningful differences in the benefit-to-risk ratios of other products and product candidates and ACU193. The potential clinical significance of ACU193’s ability to selectively target toxic soluble A β O $_s$ is something we are excited to address in the clinic.”



Recent Business Highlights and Anticipated Milestones

ACU193 Clinical Development

- **INTERCEPT-AD enrollment remains ongoing.** Patient screening and enrollment is ongoing for INTERCEPT-AD. Acumen anticipates topline data from this trial in the first half of 2023, subject to the rate of site activation and patient recruitment.
- **Frontiers in Neuroscience recently published a comprehensive summary of preclinical evidence supporting ACU193 for the potential treatment of early Alzheimer's disease.** The article is titled "ACU193: An immunotherapeutic poised to test the amyloid β oligomer hypothesis of Alzheimer's disease" and can be accessed [here](#).
- **Phase 2/3 clinical trial preparation activities progressing.** Acumen plans to be ready to initiate a Phase 2/3 trial if INTERCEPT-AD results are positive. Chronic toxicology and chemistry manufacturing and controls (CMC) activities are ongoing to support readiness.

First Quarter 2022 Financial Results

- **Cash Balance.** As of March 31, 2022, cash, cash equivalents and marketable securities totaled \$216.7 million, compared to cash, cash equivalents and marketable securities of \$225.9 million as of December 31, 2021. The decrease in cash is related to funding ongoing operations.
- **Research and Development (R&D) Expenses.** R&D expenses were \$6.0 million for the three-month period ended March 31, 2022, compared to \$2.6 million for the three-month period ended March 31, 2021. The increase in research and development expenses was primarily due to increased costs related to our ongoing clinical trial which was initiated in 2021.
- **General and Administrative (G&A) Expenses.** G&A expenses were \$3.2 million for the three-month period ended March 31, 2022, compared to \$1.2 million for the three-month period ended March 31, 2021. The increase in general and administrative expenses was primarily due to increased costs related to being a public company.
- **Loss from Operations.** Losses from operations were \$9.2 million for the three-month period ended March 31, 2022, compared to \$3.8 million for the three-month period ended March 31, 2021.
- **Net Loss.** Net loss was \$9.1 million for the three-month period ended March 31, 2022, compared to \$27.0 million for the three-month period ended March 31, 2021. Net losses in the 2021 period includes a \$23.2 million non-cash expense that represents the changes in fair value of Acumen's Series B tranche liability and Series A-1 warrant liability. The remaining increase relates to increased operating expenses.

Conference Call Details

Acumen will host a conference call and live audio webcast today, May 16, at 4:30 pm ET. The live webcast may be accessed from the Investors section of the Company's website at www.acumenpharm.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 877 311-0573 in the U.S., or +1 470 495-9505 outside the U.S., and entering passcode 2586595.



An archived version of the webcast will be available for at least 30 days in the Investors section of the Company's website at www.acumenpharm.com.

About ACU193

ACU193 is a humanized 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 and Acumen's planned Phase 2/3 clinical trial, including the anticipated number of trial sites, enrollment objectives and 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and future filings and reports by Acumen, including Acumen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. 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.

Investor & Media Contact:

investors@acumenpharm.com



Acumen Pharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)

	<u>March 31, 2022</u> (unaudited)	<u>December 31, 2021</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 108,764	\$ 122,162
Marketable securities, short-term	80,326	72,075
Prepaid expenses and other current assets	3,008	4,424
Total current assets	192,098	198,661
Marketable securities, long-term	27,658	31,619
Property and equipment, net	51	36
Right-of-use asset	201	—
Other assets	79	14
Total assets	<u>\$ 220,087</u>	<u>\$ 230,330</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,219	\$ 1,088
Accrued expenses and other current liabilities	2,578	4,059
Operating lease liability, current portion	139	—
Total current liabilities	3,936	5,147
Operating lease liability, net of current portion	62	—
Total liabilities	3,998	5,147
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized and 40,473,270 shares issued and outstanding as of March 31, 2022 and December 31, 2021	4	4
Additional paid-in capital	353,599	352,981
Accumulated deficit	(136,700)	(127,571)
Accumulated other comprehensive loss	(814)	(231)
Total stockholders' equity	216,089	225,183
Total liabilities and stockholders' equity	<u>\$ 220,087</u>	<u>\$ 230,330</u>



Acumen Pharmaceuticals, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses		
Research and development	\$ 5,985	\$ 2,578
General and administrative	3,221	1,215
Total operating expenses	<u>9,206</u>	<u>3,793</u>
Loss from operations	(9,206)	(3,793)
Other income (expense)		
Interest income, net	76	4
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	—	(23,217)
Other income, net	1	9
Total other income (expense)	<u>77</u>	<u>(23,204)</u>
Net loss	(9,129)	(26,997)
Other comprehensive loss		
Unrealized loss on marketable securities	(583)	—
Comprehensive loss	<u>\$ (9,712)</u>	<u>\$ (26,997)</u>
Net loss per common share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (64.41)</u>
Weighted-average shares outstanding, basic and diluted	<u>40,473,270</u>	<u>419,124</u>



Acumen Pharmaceuticals, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (9,129)	\$ (26,997)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4	—
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	—	23,217
Stock-based compensation expense	618	126
Amortization of premiums and accretion of discounts on marketable securities, net	216	—
Amortization of right-of-use asset	33	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,416	(44)
Other assets	(65)	(13)
Accounts payable	121	387
Operating lease liability	(32)	—
Accrued expenses and other current liabilities	(1,481)	954
Net cash used in operating activities	<u>(8,299)</u>	<u>(2,370)</u>
Cash flows from investing activities		
Purchases of marketable securities	(9,090)	—
Proceeds from maturities and sales of marketable securities	4,000	—
Purchases of property and equipment	(9)	—
Net cash used in investing activities	<u>(5,099)</u>	<u>—</u>
Net change in cash and cash equivalents	(13,398)	(2,370)
Cash and cash equivalents at the beginning of the period	122,162	43,777
Cash and cash equivalents at the end of the period	<u>\$ 108,764</u>	<u>\$ 41,407</u>
Supplemental disclosure of cash flow information		
Cash paid for income taxes	<u>\$ —</u>	<u>\$ —</u>
Cash paid for interest	<u>\$ —</u>	<u>\$ —</u>
Supplemental disclosure of noncash investing and financing activities		
Purchases of property and equipment in accounts payable	<u>\$ 10</u>	<u>\$ —</u>
Deferred offering costs in accrued expenses and other current liabilities	<u>\$ —</u>	<u>\$ 257</u>