

**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): August 12, 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 August 15, 2022, Acumen Pharmaceuticals, Inc. (the “**Company**”) reported financial results and business highlights for the quarter ended June 30, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 12, 2022, Dr. Jeffrey Sevigny notified the Board of Directors of his resignation from the Board of Directors, effective immediately. Dr. Sevigny’s departure was due to requirements of his current employment and not due to any disagreement with the Company. The Company thanks Dr. Sevigny for his service and wishes him well in his future endeavors.

Item 9.01 Financial Statements and Exhibits.**(d). Exhibits**

Exhibit No.	Description
99.1	Earnings Press Release, dated August 15, 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: August 15, 2022

By: /s/ Matthew Zuga

Matthew Zuga

Chief Financial Officer and Chief Business Officer



Acumen Pharmaceuticals Reports Financial Results for Second 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 (AD)**
- **Key methods and assay model developed to potentially standardize the study of soluble amyloid-beta oligomers (A β O) presented in a poster at the recent Alzheimer’s Association International Conference (AAIC)**
- **\$209.9 million in cash, cash equivalents and marketable securities as of June 30, 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., August 15, 2022 – Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), a clinical-stage biopharmaceutical company focused on the development of novel targeted therapeutics for Alzheimer’s disease, today reported financial results for the quarter ended June 30, 2022 and provided a business update.

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

Recent Business Highlights and Anticipated Milestones

ACU193 Clinical Development

- **INTERCEPT-AD enrollment remains ongoing.** Patient screening and enrollment is continuing for INTERCEPT-AD. At present, we have 15 active clinical trial sites recruiting patients for INTERCEPT-AD. Acumen anticipates topline data from this trial in the first half of 2023.
- **Presentation of methodology for synthetic model assay to potentially standardize the study of soluble A β O.** Methodology was recently presented in a poster, “Preparation and qualification of soluble amyloid beta oligomers for use in bioanalytic assays supporting Alzheimer’s disease therapeutics” (P4-178), at the 2022 Alzheimer’s Association International Conference. This presentation discussed utilizing A β -derived diffusible ligands (ADDLs) as a synthetic A β O model reagent to aid in standardization of A β O assays, including the use of ADDLs as a potential quantitative reference standard in potency and PK assays, and possibly to better understand the A β O specificity and selectivity of A β -targeting antibodies.



- **Phase 2/3 clinical trial preparation activities progressing.** Acumen anticipates initiating a Phase 2/3 trial for ACU193 following completion of INTERCEPT-AD, if successful, and subsequent consultation and feedback from the FDA. Chronic toxicology and chemistry manufacturing and controls (CMC) activities are ongoing to support readiness.

Corporate and Board

- **Acumen continues to expand its team with new appointments.** In Q2 2022, we hired Liean Schenck, MS as our VP, Head of Chemistry, Manufacturing and Controls (CMC). Ms. Schenck brings over 25 years of pharmaceutical industry experience in biologics process development, manufacturing, and CMC program management and has been responsible for CMC delivery of three commercial products since 2016 in her prior experience with other companies. Ms. Schenck started her career at Lonza Biologics in fermentation development before spending more than 20 years at Eli Lilly and Company in various CMC roles. In her most recent position, she served as Head of CMC program management at Novavax.
- Dr. Jeffrey Sevigny, the Chief Medical Officer of Prevail Therapeutics, Inc., a wholly owned subsidiary of Eli Lilly and Company, has departed from the Board effective August 12, 2022. Dr. Sevigny's departure was due to requirements of his current employment and not due to any disagreement with the Company. Dr. Sevigny joined Acumen's Board in 2019 and has made valuable contributions to the company. "We thank Jeff for his service and support of Acumen over the last three years," said Dan O'Connell, Chief Executive Officer of Acumen. "His extensive experience and detailed knowledge of clinical translation and neuroscience have been highly valued at Acumen as we have grown, and his early commitment and support of our program and team are greatly appreciated."

Second Quarter 2022 Financial Results

- **Cash Balance.** As of June 30, 2022, cash, cash equivalents and marketable securities totaled \$209.9 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 \$7.3 million for the three-month period ended June 30, 2022, compared to \$2.3 million for the three-month period ended June 30, 2021. The increase in research and development expenses was due to increased costs related to our ongoing clinical trial, which was initiated in 2021 and started enrolling patients in the second half of 2021, as well as nonclinical research and development activity.
- **General and Administrative (G&A) Expenses.** G&A expenses were \$3.1 million for the three-month period ended June 30, 2022, compared to \$1.2 million for the three-month period ended June 30, 2021. The increase in general and administrative expenses was primarily due to increased costs related to personnel, insurance, legal, marketing and recruiting expenses.



- **Loss from Operations.** Losses from operations were \$10.4 million for the three-month period ended June 30, 2022, compared to \$3.4 million for the three-month period ended June 30, 2021. This increase was due to the increased R&D and G&A expenses over the prior year period.
- **Net Loss.** Net loss was \$10.2 million for the three-month period ended June 30, 2022, compared to \$61.4 million for the three-month period ended June 30, 2021. Net losses in the 2021 period includes a \$57.9 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, August 15, 2022, at 4:30 pm ET.

To participate in the live conference call, please register using this [link](#). After registration, you will be informed of the dial-in numbers including PIN. Please register at least one day in advance.

The presentation with audio will be available via this [link](#).

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 O $_2$ s, which Acumen believes are the most toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques. Soluble A β O $_2$ s have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble A β O $_2$ s, 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 A β O $_2$ s, 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 O 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," "milestone" 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, rate of site activation, rate of enrollment, enrollment objectives and the expected timing of reporting data, the potential utility of ADDLs as a synthetic A β O model reagent to aid in standardization of A β O assays, including the use of ADDLs as a potential quantitative reference standard in potency and PK assays and the potential to better understand the A β O specificity and selectivity of A β -targeting antibodies, and risks and uncertainties relating to the progression and duration of the COVID-19 pandemic and responsive measures, geopolitical events such as the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions such as rising inflation, supply disruptions, and uncertainty of credit and financial markets, 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, geopolitical events and macroeconomic conditions. 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, Acumen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, and future filings and reports by Acumen, including Acumen's Quarterly Report on Form 10-Q for the quarter ended and June 30, 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>June 30, 2022</u> (unaudited)	<u>December 31, 2021</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 111,067	\$ 122,162
Marketable securities, short-term	78,844	72,075
Prepaid expenses and other current assets	1,142	4,424
Total current assets	191,053	198,661
Marketable securities, long-term	20,001	31,619
Property and equipment, net	113	36
Deferred offering costs	238	—
Right-of-use asset	167	—
Other assets	106	14
Total assets	<u>\$ 211,678</u>	<u>\$ 230,330</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,710	\$ 1,088
Accrued expenses and other current liabilities	3,282	4,059
Operating lease liability, current portion	142	—
Total current liabilities	5,134	5,147
Operating lease liability, net of current portion	25	—
Total liabilities	5,159	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 June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized and 40,501,258 shares and 40,473,270 issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	354,331	352,981
Accumulated deficit	(146,851)	(127,571)
Accumulated other comprehensive loss	(965)	(231)
Total stockholders' equity	206,519	225,183
Total liabilities and stockholders' equity	<u>\$ 211,678</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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 7,321	\$ 2,254	\$ 13,306	\$ 4,832
General and administrative	3,090	1,187	6,312	2,402
Total operating expenses	<u>10,411</u>	<u>3,441</u>	<u>19,618</u>	<u>7,234</u>
Loss from operations	(10,411)	(3,441)	(19,618)	(7,234)
Other income (expense)				
Interest income, net	260	4	337	8
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	—	(57,940)	—	(81,157)
Other income, net	—	19	1	28
Total other income (expense)	<u>260</u>	<u>(57,917)</u>	<u>338</u>	<u>(81,121)</u>
Net loss	<u>(10,151)</u>	<u>(61,358)</u>	<u>(19,280)</u>	<u>(88,355)</u>
Other comprehensive loss				
Unrealized loss on marketable securities	(151)	—	(734)	—
Comprehensive loss	<u>\$ (10,302)</u>	<u>\$ (61,358)</u>	<u>\$ (20,014)</u>	<u>\$ (88,355)</u>
Net loss per common share, basic and diluted	<u>\$ (0.25)</u>	<u>\$ (141.93)</u>	<u>\$ (0.48)</u>	<u>\$ (207.52)</u>
Weighted-average shares outstanding, basic and diluted	<u>40,497,087</u>	<u>432,325</u>	<u>40,485,244</u>	<u>425,761</u>



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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (19,280)	\$(88,355)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10	—
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	—	81,157
Stock-based compensation expense	1,333	253
Amortization of premiums and accretion of discounts on marketable securities, net	384	—
Amortization of right-of-use asset	66	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,282	(1,108)
Other assets	(92)	(13)
Accounts payable	580	741
Operating lease liability	(66)	—
Accrued expenses and other current liabilities	(984)	691
Net cash used in operating activities	<u>(14,767)</u>	<u>(6,634)</u>
Cash flows from investing activities		
Purchases of marketable securities	(12,129)	—
Proceeds from maturities and sales of marketable securities	15,860	—
Purchases of property and equipment	(45)	(6)
Net cash provided by (used in) investing activities	<u>3,686</u>	<u>(6)</u>
Cash flows from financing activities		
Proceeds from issuance of Series B milestone shares, net of issuance costs	—	30,031
Proceeds from exercise of Series A-1 warrant	—	1,250
Proceeds from exercise of common stock warrants	—	614
Payments for deferred offering costs	(31)	(220)
Proceeds from the exercise of stock options	17	—
Net cash provided by (used in) financing activities	<u>(14)</u>	<u>31,675</u>
Net change in cash and cash equivalents	<u>(11,095)</u>	<u>25,035</u>
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>\$ 111,067</u>	<u>\$ 68,812</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		
Right-of-use asset obtained in exchange for operating lease liabilities	<u>\$ 233</u>	<u>\$ —</u>
Deferred offering costs in accrued expenses and other current liabilities	<u>\$ 207</u>	<u>\$ 497</u>
Purchases of property and equipment in accounts payable	<u>\$ 42</u>	<u>\$ —</u>
Reclassification of preferred stock tranche rights liability upon share issuance	<u>\$ —</u>	<u>\$ 81,190</u>
Reclassification of warrant liability upon exercise of preferred stock warrant	<u>\$ —</u>	<u>\$ 5,380</u>
Deferred offering costs in accounts payable	<u>\$ —</u>	<u>\$ 1,635</u>