



Acumen Pharmaceuticals Reports First Quarter 2024 Financial Results and Business Highlights

May 14, 2024

- Announced initiation of ALTITUDE-AD, a Phase 2 study to investigate sabirnetug (ACU193) for the treatment of early Alzheimer's disease, in May 2024
- Initiation of a Phase 1 study to support a subcutaneous dosing option of sabirnetug expected in mid-2024
- Cash, cash equivalents and marketable securities of \$296.6 million as of Mar. 31, 2024, expected to support current clinical and operational activities into the first half of 2027
- Company to host conference call and webcast today at 8:00 a.m. ET

CHARLOTTESVILLE, Va., May 14, 2024 (GLOBE NEWSWIRE) -- [Acumen Pharmaceuticals, Inc.](#) (NASDAQ: ABOS) ("Acumen" or the "Company"), a clinical-stage biopharmaceutical company developing a novel therapeutic that targets toxic soluble amyloid beta oligomers (A β Os) for the treatment of Alzheimer's disease (AD), today reported financial results for the first quarter of 2024 and provided a business update.

"In the first quarter, our team remained laser-focused on the initiation of ALTITUDE-AD, our Phase 2 study investigating the efficacy and safety of sabirnetug for the treatment of early AD. We announced the first patient dosed in this study just last week. We are encouraged by the level of investigator interest in the potential of sabirnetug to offer a best-in-class therapeutic profile for patients, which is a testament to our strong Phase 1 data package and the relationships our team has built with clinical sites," Daniel O'Connell, Chief Executive Officer of Acumen. "We continue to expect to initiate a Phase 1 study with a subcutaneous form of sabirnetug in mid-2024 in an effort to extend the product profile and offer administration optionality for patients. We remain committed to delivering on our strategic priority to advance the clinical development of sabirnetug efficiently and thoughtfully."

Recent Highlights and Anticipated Milestones

Sabirnetug (ACU193) Clinical Development

- **In May 2024, the Company announced the first patient dosed in ALTITUDE-AD, a Phase 2 study to investigate the clinical efficacy and safety of sabirnetug for the treatment of early AD.**
- **In April 2024, the Company presented biomarker, safety and target engagement analyses from the Phase 1 INTERCEPT-AD study in AD at the American Academy of Neurology Annual Meeting.**
 - The results build upon Acumen's prior presentations at the [AD/PD™ 2024 Annual Meeting](#) and [positive topline data](#) first announced in July 2023, highlighting sabirnetug as the first humanized monoclonal antibody to clinically demonstrate selective target engagement of synaptotoxic A β Os. Additional information can be found [here](#).
- **In April 2024, the Company announced a collaboration agreement with Lonza, a global partner to the pharmaceutical, biotech and nutraceutical markets.**
 - The agreement covers the manufacture of sabirnetug for clinical development and commercialization, if approved. Acumen will leverage Lonza's regulatory expertise, extensive experience in antibody manufacturing, and global manufacturing network from 2,000L to 20,000L.
- **The Company expects to initiate a Phase 1 study to support a subcutaneous dosing option of sabirnetug in mid-2024.**

First Quarter 2024 Financial Results

- **Cash Balance.** As of March 31, 2024, cash, cash equivalents and marketable securities totaled \$296.6 million, compared to cash, cash equivalents and marketable securities of \$306.1 million as of December 31, 2023. The decrease in cash is related to funding ongoing operations. Cash is expected to support current clinical and operational activities into the first half of 2027.
- **Research and Development (R&D) Expenses.** R&D expenses were \$12.4 million for the three month period ended March 31, 2024, compared to \$8.7 million for the three month period ended March 31, 2023. The increase in R&D

expenses was primarily due to increased costs related to personnel, manufacturing and materials costs, consulting, and other costs.

- **General and Administrative (G&A) Expenses.** G&A were \$5.3 million for the three month period ended March 31, 2024, compared to \$4.4 million for the three month period ended March 31, 2023. The increase in G&A expenses was primarily due to increased costs related to personnel.
- **Loss from Operations.** Losses from operations were \$17.8 million for the three month period ended March 31, 2024, compared to \$13.1 million for the three month period ended March 31, 2023. This increase was due to the increased R&D and G&A expenses over the prior year period.
- **Net Loss.** Net loss was \$14.9 million for the three-month period ended March 31, 2024, compared to \$11.3 million for the three month period ended March 31, 2023.

Conference Call Details

Acumen will host a conference call and live audio webcast today, May 14, 2024, at 8:00 a.m. 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 webcast 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 Sabirnetug (ACU193)

Sabirnetug (ACU193) is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble amyloid beta oligomers (A β O_s), which are a highly toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques. Soluble A β O_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_s, sabirnetug aims to address the hypothesis that soluble A β O_s are an early and persistent underlying cause of the neurodegenerative process in Alzheimer's disease (AD). Sabirnetug has been granted Fast Track designation for the treatment of early AD by the U.S. Food and Drug Administration and was previously evaluated in a Phase 1 study in patients with early AD.

About ALTITUDE-AD (Phase 2)

Initiated in 2024, ALTITUDE-AD is a Phase 2, multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy and safety of sabirnetug (ACU193) infusions administered once every four weeks in slowing cognitive and functional decline as compared to placebo in participants with early Alzheimer's disease. The study will enroll approximately 540 individuals with early Alzheimer's disease (mild cognitive impairment or mild dementia due to AD). The global study is currently enrolling at multiple investigative sites located in the United States and Canada with plans for additional sites in Europe and the UK. More information can be found on www.clinicaltrials.gov, NCT identifier NCT06335173.

About INTERCEPT-AD (Phase 1)

Completed in 2023, INTERCEPT-AD was a Phase 1, U.S.-based, multi-center, randomized, double-blind, placebo-controlled clinical trial evaluating the safety and tolerability, and establishing clinical proof of mechanism, of sabirnetug in patients with early Alzheimer's disease (AD). Sixty-five individuals with early AD (mild cognitive impairment or mild dementia due to AD) enrolled in this first-in-human study of sabirnetug. The INTERCEPT-AD study consisted of single-ascending-dose (SAD) and multiple-ascending-dose (MAD) cohorts and was designed to evaluate the safety, tolerability, pharmacokinetics (PK), and target engagement of intravenous doses of sabirnetug. More information can be found on www.clinicaltrials.gov, NCT identifier NCT04931459.

About Acumen Pharmaceuticals, Inc.

Acumen, headquartered in Charlottesville, VA, with additional offices in Indianapolis, IN and Newton, MA, is a clinical-stage biopharmaceutical company developing a novel therapeutic that targets toxic soluble amyloid beta oligomers (A β O_s) for the treatment of Alzheimer's disease (AD). Acumen's scientific founders pioneered research on A β O_s, which a growing body of evidence indicates are early and persistent triggers of Alzheimer's disease pathology. Acumen is currently focused on advancing its investigational product candidate, sabirnetug (ACU193), a humanized monoclonal antibody that selectively targets toxic soluble A β O_s, following positive results 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," "should," "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, and Acumen's ability to achieve its strategic and financial goals, including its projected use of cash, cash equivalents and marketable securities and the expected sufficiency of its cash resources into the first half of 2027, the therapeutic potential of Acumen's product candidate, sabirnetug (ACU193), including against other antibodies, the anticipated timeline for initiating a Phase 1 trial to support a subcutaneous dosing option of sabirnetug, and the expected use of proceeds from a credit facility. 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 geopolitical events and macroeconomic conditions, such as rising inflation and interest rates, supply disruptions and uncertainty of credit and financial markets. 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 most recent Annual Report on Form 10-K, and in subsequent filings with 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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Acumen Pharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)

	March 31, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 46,930	\$ 66,886
Marketable securities, short-term	205,582	176,636
Prepaid expenses and other current assets	3,319	3,093
Total current assets	255,831	246,615
Marketable securities, long-term	44,108	62,553
Right-of-use asset	353	381
Restricted cash	234	233
Property and equipment, net	117	122
Other assets	324	221
Total assets	<u>\$ 300,967</u>	<u>\$ 310,125</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,079	\$ 1,379
Accrued clinical trial expenses	2,367	4,387
Accrued expenses and other current liabilities	2,905	6,339
Finance lease liability, short-term	-	756
Operating lease liability, short-term	121	110
Total current liabilities	8,472	12,971
Operating lease liability, long-term	252	284
Debt, long-term	30,209	29,897
Total liabilities	38,933	43,152
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, 2024 and December 31, 2023	-	-
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 60,079,778 and 57,910,461 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	6	6
Additional paid-in capital	499,843	489,453
Accumulated deficit	(237,671)	(222,798)
Accumulated other comprehensive income (loss)	(144)	312
Total stockholders' equity	262,034	266,973
Total liabilities and stockholders' equity	<u>\$ 300,967</u>	<u>\$ 310,125</u>

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

Three Months Ended March 31,

	2024	2023
Operating expenses		
Research and development	\$ 12,449	\$ 8,713
General and administrative	5,325	4,422
Total operating expenses	17,774	13,135
Loss from operations	(17,774)	(13,135)
Other income (expense)		
Interest income	4,005	1,832
Interest expense	(1,000)	-
Change in fair value of embedded derivatives	(50)	-
Other expense, net	(54)	(4)
Total other income	2,901	1,828
Net loss	(14,873)	(11,307)
Other comprehensive gain (loss)		
Unrealized gain (loss) on marketable securities	(456)	227
Comprehensive loss	\$ (15,329)	\$ (11,080)
Net loss per common share, basic and diluted	\$ (0.25)	\$ (0.28)
Weighted-average shares outstanding, basic and diluted	59,812,000	41,025,062

Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (14,873)	\$ (11,307)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	16	14
Stock-based compensation expense	2,484	1,390
Amortization of premiums and accretion of discounts on marketable securities, net	(1,763)	(334)
Change in fair value of embedded derivatives	50	-
Amortization of right-of-use asset	28	38
Realized gain on marketable securities	(2)	-
Non-cash interest expense	268	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(226)	(899)
Other assets	35	(44)
Accounts payable	1,700	(878)
Accrued clinical trial expenses	(2,020)	2,486
Accrued expenses and other current liabilities	(3,512)	(38)
Finance lease liability	(23)	-
Operating lease liability	(21)	(603)
Net cash used in operating activities	(17,859)	(10,175)
Cash flows from investing activities		
Purchases of marketable securities	(45,292)	(52,131)
Proceeds from maturities and sales of marketable securities	36,100	10,204
Purchases of property and equipment	(11)	-
Net cash used in investing activities	(9,203)	(41,927)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	7,938	-
Payment for financing lease	(739)	-
Payments for deferred offering costs	(60)	-
Repurchase of common shares to pay employee withholding taxes	(32)	-
Net cash provided by financing activities	7,107	-
Net change in cash and cash equivalents and restricted cash	(19,955)	(52,102)
Cash and cash equivalents and restricted cash at the beginning of the period	67,119	130,101
Cash and cash equivalents and restricted cash at the end of the period	\$ 47,164	\$ 77,999

