

# Acumen Pharmaceuticals Reports Second Quarter 2024 Financial Results and Business Highlights

August 13, 2024

- Actively enrolling subjects in ALTITUDE-AD, a Phase 2 study to investigate sabirnetug (ACU193) for the treatment of early Alzheimer's disease
- Dosed the first subject in a Phase 1 study to support subcutaneous administration of sabirnetug in July 2024 with topline results anticipated in the first guarter of 2025
- Cash, cash equivalents and marketable securities of \$281.4 million as of Jun. 30, 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

NEWTON, Mass., Aug. 13, 2024 (GLOBE NEWSWIRE) -- <u>Acumen Pharmaceuticals. Inc.</u> (NASDAQ: ABOS) ("Acumen" or the "Company"), a clinical-stage biopharmaceutical company developing a novel therapeutic that targets toxic soluble amyloid beta oligomers ( $A\beta$ Os) for the treatment of Alzheimer's disease (AD), today reported financial results for the second quarter of 2024 and provided a business update.

"Our team is highly focused on execution in 2024, and I'm very pleased with our progress in the first half of the year. We are actively enrolling subjects in our global Phase 2 ALTITUDE-AD study that we initiated this spring. We are highly encouraged by the level of interest from investigators and patients in sabirnetug's mechanism of action which has led to enrollment progressing faster than our expectations," said Daniel O'Connell, Chief Executive Officer of Acumen. "In addition to the progress with ALTITUDE-AD, we announced in July the initiation of a Phase 1 pharmacokinetic comparison study supporting subcutaneous administration of sabirnetug. Topline results from this healthy volunteer study are expected in the first quarter of 2025. With the momentum in our clinical program and sabirnetug's distinct selectivity for toxic amyloid beta oligomers, we believe that we are positioned to deliver a potential next-generation treatment for early Alzheimer's disease."

#### **Recent Highlights and Anticipated Milestones**

- 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.
  - Currently, more than 50 sites are activated in the U.S., Canada, U.K. and EU.
- In July 2024, the Company announced the first subject had been dosed with a subcutaneous formulation of sabirnetug in a Phase 1 pharmacokinetic (PK) comparison study. The study will compare the PK profile between subcutaneous and intravenous administrations of sabirnetug in healthy volunteers.
  - Topline results are anticipated in the first quarter of 2025.
- In July 2024, the Company presented additional biomarker and target engagement analyses, as well as insight into the patient experience from the Phase 1 INTERCEPT-AD study in early AD at the Alzheimer's Association International Conference (AAIC<sup>®</sup>) annual meeting.
  - The research highlights the experiences of patients in the clinical trial to inform development of future trials, biomarker data to support sabirnetug's mechanism of action, and an ultra-sensitive method of detecting levels of sabirnetug in cerebrospinal fluid (CSF), given the small amounts of monoclonal antibodies that typically enter the brain from the blood. More details about the research are available <u>here</u>.
- The Company plans to host a virtual R&D Day on Oct. 2, 2024, providing a deep dive into the scientific rationale, Phase 1 clinical results and Phase 2 clinical plans for sabirnetug. Registration details will be communicated prior to the event.

# Second Quarter 2024 Financial Results

- Cash Balance. As of June 30, 2024, cash, cash equivalents and marketable securities totaled \$281.4 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 \$19.5 million for the three-month period ended June 30, 2024, compared to \$9.1 million for the three-month period ended June 30, 2023. The increase in R&D expenses was primarily due to increased contract research organization and other clinical trial costs related to ALTITUDE-AD, as well as

higher costs for personnel, license agreements, and shipping and packaging.

- General and Administrative (G&A) Expenses. G&A expenses were \$4.8 million for the three-month period ended June 30, 2024, compared to \$4.3 million for the three-month period ended June 30, 2023. The increase in G&A expenses was primarily due to increased costs related to personnel.
- Loss from Operations. Loss from operations was \$24.4 million for the three-month period ended June 30, 2024, compared to \$13.5 million for the three-month period ended June 30, 2023. This increase was due to the increased R&D and G&A expenses over the prior year period.
- Net Loss. Net loss was \$20.5 million for the three-month period ended June 30, 2024, compared to \$11.6 million for the three-month period ended June 30, 2023.

#### **Conference Call Details**

Acumen will host a conference call and live audio webcast today, August 13, 2024, at 8:00 a.m. ET.

To participate in the live conference call, please register using this <u>link</u>. 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 $\beta$ Os), which are a highly toxic and pathogenic form of A $\beta$ , relative to A $\beta$  monomers and amyloid plaques. Soluble A $\beta$ Os have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble A $\beta$ Os, sabirnetug aims to address the hypothesis that soluble A $\beta$ Os 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 is currently being evaluated in a Phase 2 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. Results showed sabirnetug to be well-tolerated with a favorable overall safety profile. The trial showed amyloid plaque reduction, effects on synaptic biomarkers, low overall rates of ARIA-E, and evidence of target engagement that validated proof of mechanism. More information can be found on <u>www.clinicaltrials.gov</u>, NCT identifier NCT04931459.

#### About Acumen Pharmaceuticals, Inc.

Acumen Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic that targets toxic soluble amyloid beta oligomers (AβOs) for the treatment of Alzheimer's disease (AD). Acumen's scientific founders pioneered research on AβOs, 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 AβOs, in its ongoing Phase 2 clinical trial ALTITUDE-AD (NCT06335173) in early symptomatic Alzheimer's disease patients, following positive results in its Phase 1 trial INTERCEPT-AD. The company is headquartered in Newton, Mass. 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 enrollment progression of ALTITUDE-AD, and the anticipated timeline for results from the Phase 1 trial to support a subcutaneous dosing option of sabirnetug. 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)

		June 30, 2024	December 31, 2023			
400570		(unaudited)				
ASSETS						
Current assets	\$	67.055	¢	66.006		
Cash and cash equivalents	Ф	67,955	\$	66,886		
Marketable securities, short-term		192,517		176,636		
Prepaid expenses and other current assets		6,443		3,093		
Total current assets		266,915		246,615		
Marketable securities, long-term		20,908		62,553		
Right-of-use asset		325		381		
Restricted cash		235 105		233 122		
Property and equipment, net		425		221		
Other assets	<u>_</u>	_	¢			
Total assets	\$	288,913	\$	310,125		
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities						
Accounts payable	\$	4,211	\$	1,379		
Accrued clinical trial expenses		7,027		4,387		
Accrued expenses and other current liabilities		4,004		6,339		
Finance lease liability, short-term		-		756		
Operating lease liability, short-term		125		110		
Total current liabilities		15,367		12,971		
Operating lease liability, long-term		219		284		
Debt, long-term		29,380		29,897		
Total liabilities		44,966		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 June 30, 2024 and December 31, 2023		-		-		
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 60,079,778 and 57,910,461 shares issued and outstanding						
as of June 30, 2024 and December 31, 2023, respectively		6		6		
Additional paid-in capital		502,313		489,453		
Accumulated deficit		(258,208)		(222,798)		
Accumulated other comprehensive income (loss)		(164)		312		
Total stockholders' equity	_	243,947	_	266,973		
Total liabilities and stockholders' equity	\$	288,913	\$	310,125		

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

Three Months Ended June 30,

	 2024	 2023		2024	 2023
Operating expenses					
Research and development	\$ 19,533	\$ 9,133	\$	31,982	\$ 17,846
General and administrative	 4,848	 4,345		10,173	 8,767
Total operating expenses	 24,381	 13,478		42,155	 26,613
Loss from operations	(24,381)	(13,478)		(42,155)	(26,613)
Other income (expense)					
Interest income	3,816	1,884		7,821	3,716
Interest expense	(1,004)	-		(2,004)	-
Change in fair value of embedded derivatives	1,100	-		1,050	-
Other expense, net	 (68)	 (16)		(122)	 (20)
Total other income	 3,844	 1,868		6,745	 3,696
Net loss	 (20,537)	 (11,610)		(35,410)	 (22,917)
Other comprehensive gain (loss)					
Unrealized gain (loss) on marketable securities	(20)	(122)		(476)	105
Comprehensive loss	\$ (20,557)	\$ (11,732)	\$	(35,886)	\$ (22,812)
Net loss per common share, basic and diluted	\$ (0.34)	\$ (0.28)	\$	(0.59)	\$ (0.56)
Weighted-average shares outstanding, basic and diluted	 60,079,778	 41,025,062	_	59,945,889	 41,025,062

# Condensed Statements of Cash Flows (in thousands)

(unaudited)

	Six Months Ended June 30,			
	2024	2023		
Cash flows from operating activities				
Net loss	\$ (35,410)	\$ (22,917)		
Adjustments to reconcile net loss to net cash used in operating activities:	• (22, 22)	· (,,		
Depreciation	33	29		
Stock-based compensation expense	4,954	2,911		
Amortization of premiums and accretion of discounts on				
marketable securities, net	(3,222)	(634)		
Change in fair value of embedded derivatives	(1,050)	-		
Amortization of right-of-use asset	56	76		
Realized gain on marketable securities	(2)	-		
Non-cash interest expense	539	-		
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(3,350)	(1,933)		
Other assets	(7)	(57)		
Accounts payable	2,823	384		
Accrued clinical trial expenses	2,640	1,385		
Accrued expenses and other current liabilities	(2,335)	(1,013)		
Finance lease liability	(23)	-		
Operating lease liability	(50)	(76)		
Net cash used in operating activities	(34,404)	(21,845)		
Cash flows from investing activities				
Purchases of marketable securities	(57,093)	(52,131)		
Proceeds from maturities and sales of marketable securities	85,605	21,268		
Purchases of property and equipment	(16)	-		
Net cash provided by (used in) investing activities	28,496	(30,863)		
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	(188)	(145)		
Repurchase of common shares to pay employee withholding		. ,		
taxes	(32)			
Net cash provided by (used in) financing activities	6,979	(145)		

Net change in cash and cash equivalents and restricted cash		1,071	(52,853)
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	\$	68,190	\$ 77,248