Acumen Pharmaceuticals Reports Third Quarter 2024 Financial Results and Business Highlights

November 12, 2024

- Expect ALTITUDE-AD, a Phase 2 study to investigate sabirnetug (ACU193) for the treatment of early Alzheimer's disease, to complete enrollment in the first half of 2025
- Expect to announce topline results of Phase 1 study to support subcutaneous administration of sabirnetug in the first quarter of 2025
- Cash, cash equivalents and marketable securities of $258.9 million as of Sept. 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., Nov. 12, 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 (AβOs) for the treatment of Alzheimer's disease (AD), today reported financial results for the third quarter of 2024 and provided a business update.

"Our team remains deeply committed to executing our plans in 2024, and I'm proud of the strides we've made in the third quarter. We expect enrollment completion of our Phase 2 ALTITUDE-AD study in the first half of 2025," said Daniel O'Connell, Chief Executive Officer of Acumen. "Additionally, we anticipate topline results from our Phase 1 healthy volunteer study investigating subcutaneous sabirnetug in the first quarter of 2025. With our clinical program gaining momentum and sabirnetug's unique selectivity for toxic amyloid beta oligomers, we are excited about the potential to offer a next-generation treatment for early Alzheimer's disease."

Recent Highlights

- **In September 2024, the Company announced it had extended its collaboration with Lonza to enable the potential future commercial launch of sabirnetug (ACU193).** The extended collaboration builds upon an existing successful relationship, in which Lonza provides drug substance manufacturing for the ALTITUDE-AD study. Under the terms of the extended agreement, Lonza will manufacture cGMP drug product of sabirnetug for the ongoing and future clinical phases and support the potential commercial launch of sabirnetug.
- **In October 2024, the Company hosted a virtual investor event to provide a deep dive into the scientific rationale, Phase 1 clinical results and Phase 2 clinical plans for sabirnetug.** A replay is available on the Investors section of Acumen's website.
- **In October 2024, the Company presented a late-breaking presentation featuring insights from its participant screening approach used in the ongoing Phase 2 ALTITUDE-AD clinical trial evaluating sabirnetug at the 17th Annual Clinical Trials on Alzheimer's Disease (CTAD) conference.**
    - The presentation detailed the use of a validated research-use plasma phosphorylated tau 217 (pTau217) assay to screen potential participants in ALTITUDE-AD. The plasma pTau217 assay is being used as an initial screening tool to identify people who qualify for additional amyloid testing to determine eligibility for the ALTITUDE-AD trial. More details about the research are available here.
- **In November 2024, the Company announced the appointment of Amy Schacterle, PhD as Chief Regulatory Officer & Head of Quality.** Dr. Schacterle brings over 30 years of experience in regulatory affairs, quality assurance, and therapeutic development to Acumen, with a focus on central nervous system disorders.

Anticipated Milestones

- The Company expects ALTITUDE-AD, a Phase 2 study to investigate sabirnetug for the treatment of early Alzheimer's disease, to complete enrollment in the first half of 2025.
- The Company expects to announce topline results of a Phase 1 study to support subcutaneous administration of sabirnetug in the first quarter of 2025.

Third Quarter 2024 Financial Results

- **Cash Balance.** As of Sept. 30, 2024, cash, cash equivalents and marketable securities totaled $258.9 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 $27.2 million for the three-month period ended Sept. 30, 2024, compared to $11.2 million for the three-month period ended Sept. 30, 2023. The increase in R&D expenses was

primarily due to increased clinical trial costs related to ALTITUDE-AD and license expenses.

- **General and Administrative (G&A) Expenses.** G&A expenses were $5.0 million for the three-month period ended Sept. 30, 2024, compared to $4.9 million for the three-month period ended Sept. 30, 2023. The increase in G&A expenses was primarily due to increased costs related to personnel.
- **Loss from Operations.** Loss from operations was $32.3 million for the three-month period ended Sept. 30, 2024, compared to $16.0 million for the three-month period ended Sept. 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 $29.8 million for the three-month period ended Sept. 30, 2024, compared to $13.0 million for the three-month period ended Sept. 30, 2023.

Participation in Upcoming Investor Conferences

- UBS Global Healthcare Conference, November 11-14
- Stifel 2024 Healthcare Conference, November 18-19
- 7th Annual Evercore ISI HealthCONx Conference, December 3-5

Conference Call Details

Acumen will host a conference call and live audio webcast today, Nov. 12, 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 (AβOs), which are a highly toxic and pathogenic form of Aβ, relative to Aβ monomers and amyloid plaques. Soluble AβOs have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble AβOs, sabirnetug aims to address the hypothesis that soluble AβOs 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 www.clinicaltrials.gov, 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 completion date of enrollment 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)

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 33,184	$ 66,886
Marketable securities, short-term	167,159	176,636
Prepaid expenses and other current assets	7,289	3,093
Total current assets	207,632	246,615
Marketable securities, long-term	58,552	62,553
Right-of-use asset	296	381
Restricted cash	236	233
Property and equipment, net	89	122
Other assets	170	221
Total assets	$ 266,975	$ 310,125
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,342	$ 1,379
Accrued clinical trial expenses	12,517	4,387
Accrued expenses and other current liabilities	4,926	6,339
Finance lease liability, short-term	-	756
Operating lease liability, short-term	129	110
Total current liabilities	19,914	12,971
Operating lease liability, long-term	185	284
Debt, long-term	29,674	29,897
Total liabilities	49,773	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 September 30, 2024 and December 31, 2023	-	-
Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 60,079,778 and 57,910,461 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	6	6
Additional paid-in capital	504,651	489,453
Accumulated deficit	(287,973)	(222,798)
Accumulated other comprehensive income	518	312
Total stockholders' equity	217,202	266,973
Total liabilities and stockholders' equity	$ 266,975	$ 310,125

Acumen Pharmaceuticals, Inc.
Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	$ 27,247	$ 11,179	$ 59,229	$ 29,025
General and administrative	5,018	4,860	15,191	13,627
Total operating expenses	32,265	16,039	74,420	42,652
Loss from operations	(32,265)	(16,039)	(74,420)	(42,652)
Other income (expense)				
Interest income	3,504	3,124	11,325	6,840
Interest expense	(1,027)	-	(3,031)	-
Change in fair value of embedded derivatives	(10)	-	1,040	-
Other income (expense), net	33	(42)	(89)	(62)
Total other income	2,500	3,082	9,245	6,778
Net loss	(29,765)	(12,957)	(65,175)	(35,874)
Other comprehensive gain (loss)				
Unrealized gain on marketable securities	682	137	206	242
Comprehensive loss	$ (29,083)	$ (12,820)	$ (64,969)	$ (35,632)
Net loss per common share, basic and diluted	$ (0.50)	$ (0.24)	$ (1.09)	$ (0.79)
Weighted-average shares outstanding, basic and diluted	60,079,778	54,229,630	59,990,844	45,474,953

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

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (65,175)	$ (35,874)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	49	42
Stock-based compensation expense	7,292	4,511
Amortization of premiums and accretion of discounts on marketable securities, net	(4,599)	(1,344)
Change in fair value of embedded derivatives	(1,040)	-
Amortization of right-of-use asset	85	103
Realized gain on marketable securities	(97)	-
Non-cash interest expense	823	-
Other non-cash expense	230	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,196)	(436)
Other assets	51	(38)
Accounts payable	963	(278)
Accrued clinical trial expenses	8,130	(1,151)
Accrued expenses and other current liabilities	(1,413)	(182)
Finance lease liability	(23)	-
Operating lease liability	(80)	(103)
Net cash used in operating activities	(59,000)	(34,750)
Cash flows from investing activities		
Purchases of marketable securities	(155,631)	(178,857)
Proceeds from maturities and sales of marketable securities	174,011	55,997
Proceeds from sale of property and equipment	-	3
Purchases of property and equipment	(16)	(7)
Net cash provided by (used in) investing activities	18,364	(122,864)
Cash flows from financing activities		

Proceeds from issuance of common stock, net of issuance costs	7,938	122,294
Payment for financing lease	(739)	-
Payments for deferred offering costs	(230)	-
Repurchase of common shares to pay employee withholding taxes	(32)	-
Proceeds from exercise of stock options	-	325
Net cash provided by financing activities	6,937	122,619
Net change in cash and cash equivalents and restricted cash	(33,699)	(34,995)
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	$ 33,420	$ 95,106