Acumen Pharmaceuticals Reports Financial Results for the Year Ended December 31, 2023 and Business Highlights

March 26, 2024

- Initiation of a Phase 2 study, ALTITUDE-AD, to investigate sabirnetug (ACU193) for the treatment of early Alzheimer's disease expected in the first half of 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 $306.1 million as of Dec. 31, 2023, 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., March 26, 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 full year ended December 31, 2023 and provided a business update.

"2023 was a landmark year for Acumen. We delivered the first Phase 1 results from an oligomer-targeted antibody for the treatment of early Alzheimer's disease, which exceeded expectations. Beyond favorable safety results, our study confirmed near-maximal target engagement of abeta oligomers, significant plaque reduction and impressive improvements in fluid biomarkers for AD that together give us increased confidence that sabirnetug may offer a best-in-class therapeutic profile for patients," said Daniel O'Connell, Chief Executive Officer of Acumen. "We have entered 2024 from a position of strength. Our team is laser-focused on advancing the clinical development of sabirnetug and expects to initiate our Phase 2 study in the first half of this year. We also expect to initiate a subcutaneous bioavailability study in mid-2024, to extend the product profile and offer administration optionality for patients. We look forward to sharing our progress with you throughout the year."

Recent Highlights and Anticipated Milestones

Sabirnetug (ACU193) Clinical Development

- **In March 2024, the Company presented fluid biomarker and target engagement analyses from Phase 1 INTERCEPT-AD study in AD at the International Conference on Alzheimer's and Parkinson's diseases (AD/PD).**
  - Sabirnetug had an observed dose-dependent trend in the multiple ascending dose cohorts on CSF levels of p-tau181, total tau, neurogranin and the Aβ42/Aβ40 ratio, consistent with the downstream pharmacologic effects of the drug, after just three administrations. These findings are consistent with sabirnetug's proposed mechanism of action and intended target engagement of AβOs. Additionally, the apparent effect of sabirnetug on downstream biomarkers such as p-tau181 and neurogranin are consistent with the hypothesis that oligomers drive the downstream neurodegenerative process in AD.
  - Additionally, Acumen presented a poster detailing its method to develop the first assay to directly measure target engagement of AβOs by an immunotherapy (as measured by sabirnetug-AβO complex in CSF) in the INTERCEPT-AD trial. These data also informed the development of a pharmacokinetic-pharmacodynamic (PK/PD) model, which ultimately demonstrated that the highest doses used in INTERCEPT-AD (60 mg/kg Q4W and 25mg/kg Q2W) approached maximal target engagement (Emax), as was presented in October 2023.
- **The Company expects to initiate a Phase 2 study, ALTITUDE-AD, in the first half of 2024 to investigate the clinical efficacy, safety and tolerability of sabirnetug for the treatment of early Alzheimer's disease.**
- **The Company expects to initiate a Phase 1 bioavailability study to support a subcutaneous dosing option of sabirnetug in mid-2024.**

Corporate Updates

- **In February 2024, the Company announced the appointment of Dr. James Doherty as President and Chief Development Officer.**
  - Dr. Doherty's responsibilities include oversight of clinical and nonclinical development, chemistry, manufacturing & controls and regulatory functions, reporting to Daniel O'Connell, Chief Executive Officer.
  - Dr. Doherty brings decades of neuroscience-focused research and clinical development expertise to Acumen, from discovery through drug approval. Prior to joining Acumen, Dr. Doherty served as Chief Development Officer at Sage Therapeutics, where the team achieved U.S. Food and Drug Administration approvals of two treatments for

postpartum depression. Previously, he served as Director and Head of the Neuroscience Department for the Central Nervous System and Pain Innovative Medicines Unit of AstraZeneca Pharmaceuticals in Sodertalje, Sweden, where he led the company's research pipeline for Alzheimer's disease and neurodegeneration.

"Underpinning my decision to join Acumen at this transformative time in the Alzheimer's field is the intriguing science behind AβO toxicity paired with Acumen's impressive Phase 1 data. Not only does the data confirm sabirnetug's selectivity for AβOs in patients, it also highlights that the drug can actively improve downstream biomarkers associated with AD, moving the amyloid beta discussion beyond plaque to focus on amyloid species toxic to synaptic function," said Dr. Jim Doherty, President and Chief Development Officer of Acumen. "I am excited to help the team thoughtfully interrogate the multiple potential paths toward sabirnetug's next-generation differentiation – via greater efficacy, safety or both – that would be beneficial to patients as compared to existing AD therapeutics."

2023 Financial Results

- **Cash Balance.** As of December 31, 2023, cash, cash equivalents and marketable securities totaled $306.1 million, compared to cash, cash equivalents and marketable securities of $193.4 million as of December 31, 2022. This increase is due to the net proceeds from the Company's public offering of approximately $122 million on July 21, 2023, as well as approximately $30 million from K2 HealthVentures as part of a debt financing of up to $50 million announced in November 2023. Altogether, this runway is now expected to be sufficient to support current clinical and operational activities into the first half of 2027.
- **Research and Development (R&D) Expenses.** R&D expenses in 2023 were $42.3 million, compared to $32.4 million in 2022. The increase in R&D expenses was primarily due to increased costs related to consulting, personnel and other costs.
- **General and Administrative (G&A) Expenses.** G&A expenses in 2023 were $18.8 million, compared to $12.9 million in 2022. The increase in G&A expenses was primarily due to increased costs related to personnel, consulting and legal/patent services.
- **Loss from Operations.** Losses from operations in 2023 were $61.1 million, compared to $45.2 million in 2022. This increase was due to the increased R&D and G&A expenses over the prior year period.
- **Net Loss.** Net loss for the year ended December 31, 2023 was $52.4 million, compared to a net loss of $42.9 million for the year ended December 31, 2022.

Conference Call Details

Acumen will host a conference call and live audio webcast today, March 26, 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 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 directly address a growing body of evidence indicating that soluble AβOs are a primary underlying cause of the neurodegenerative process in Alzheimer's disease. Sabirnetug has been granted Fast Track designation for the treatment of early Alzheimer's disease by the U.S. Food and Drug Administration.

About INTERCEPT-AD

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 (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, 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 2 clinical trial of sabirnetug and 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.

CONTACTS:

Investors:
Alex Braun
abraun@acumenpharm.com

Media: AcumenPR@westwicke.com

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

	December 31,	
	2023	**2022**
ASSETS		
Current assets		
Cash and cash equivalents	$ 66,886	$ 130,101
Marketable securities, short-term	176,636	47,504
Prepaid expenses and other current assets	3,093	2,724
Total current assets	246,615	180,329
Marketable securities, long-term	62,553	15,837
Restricted cash	233	-
Property and equipment, net	122	165
Right-of-use asset	381	105
Other assets	221	151
Total assets	$ 310,125	$ 196,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,379	$ 1,640
Accrued clinical trial expenses	4,387	2,717
Accrued expenses and other current liabilities	6,339	3,350
Finance lease liability, short-term	756	-
Operating lease liability, short-term	110	105
Total current liabilities	12,971	7,812
Operating lease liability, long-term	284	-
Debt, long-term	29,897	-
Total liabilities	43,152	7,812
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding as of December 31, 2023 and 2022	-	-

Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2023 and 2022; 57,910,461 and 41,025,062 shares issued and outstanding as of December 31, 2023 and 2022, respectively	6	4
Additional paid-in capital	489,453	359,949
Accumulated deficit	(222,798)	(170,427)
Accumulated other comprehensive income (loss)	312	(751)
Total stockholders' equity	266,973	188,775
Total liabilities and stockholders' equity	$ 310,125	$ 196,587

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

	Year Ended December 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 42,318	$ 32,361
General and administrative	18,820	12,876
Total operating expenses	61,138	45,237
Loss from operations	(61,138)	(45,237)
Other income (expense)		
Interest income	10,791	2,392
Change in fair value of embedded derivatives	(1,360)	-
Interest expense	(581)	-
Other expense, net	(83)	(11)
Total other income	8,767	2,381
Net loss	(52,371)	(42,856)
Other comprehensive gain (loss)		
Unrealized gain (loss) on marketable securities	1,063	(520)
Comprehensive loss	$ (51,308)	$ (43,376)
Net loss per common share, basic and diluted	$ (1.08)	$ (1.06)
Weighted-average shares outstanding, basic and diluted	48,609,383	40,601,936

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (52,371)	$ (42,856)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	61	32
Stock-based compensation expense	6,145	3,061
Amortization of premiums and accretion of discounts on marketable securities, net	(3,121)	487
Change in fair value of embedded derivatives	1,360	-
Amortization of right-of-use asset	123	137
Non-cash research and development expense	739	-
Realized gain on marketable securities	(11)	-
Non-cash interest expense	145	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(369)	1,700
Other assets	(70)	(137)
Accounts payable	(261)	552

Accrued clinical trial expenses	1,670	2,570
Accrued expenses and other current liabilities	2,989	(562)
Finance lease liability	17	-
Operating lease liability	(110)	(137)
Net cash used in operating activities	(43,064)	(35,153)
Cash flows from investing activities		
Purchases of marketable securities	(250,634)	(41,514)
Proceeds from maturities and sales of marketable securities	78,981	80,860
Proceeds from sale of property and equipment	3	-
Purchases of property and equipment	(21)	(161)
Net cash provided by (used in) investing activities	(171,671)	39,185
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	121,904	3,792
Proceeds from term loan	30,000	-
Payments for financing costs	(476)	-
Proceeds from exercise of stock options	325	115
Net cash provided by financing activities	151,753	3,907
Net change in cash and cash equivalents and restricted cash	(62,982)	7,939
Cash and cash equivalents and restricted cash at the beginning of the period	130,101	122,162
Cash and cash equivalents and restricted cash at the end of the period	$ 67,119	$ 130,101