Acumen Pharmaceuticals Reports First Quarter 2023 Financial Results and Business Highlights

May 9, 2023

- Expect to report topline results from INTERCEPT-AD, a Phase 1 clinical trial of ACU193 in patients with early Alzheimer's disease, in the third quarter of 2023
- Cash, cash equivalents and marketable securities of $183.8 million as of March 31, 2023 expected to be sufficient to support clinical and operational activities through 2025
- Company to host conference call and webcast today at 8:00 a.m. ET

CHARLOTTESVILLE, Va. and Carmel, Ind., May 09, 2023 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), 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 first quarter of 2023 and provided a business update.

"In the first quarter, we remained focused on executing the Phase I INTERCEPT-AD trial of ACU193, our novel therapeutic for the treatment of early Alzheimer's disease. We are pleased to confirm our expectation that we will share the first clinical data in the field from a monoclonal antibody with high selectivity for toxic amyloid beta oligomers in the upcoming third quarter," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "Amid a dynamic and evolving Alzheimer's landscape, we look forward to reporting clinical evidence of the overall safety profile, pharmacokinetic data, including the potential for monthly dosing, as well as target engagement. We expect that these topline data will serve as the basis for an anticipated interaction with the FDA in the fourth quarter to inform our next phase of development for ACU193."

Recent Business Highlights and Anticipated Milestones

- **In February 2023, enrollment was completed in our Phase 1 INTERCEPT-AD trial, investigating the safety, tolerability, pharmacokinetics and target engagement of ACU193 in patients with early AD.**
  - Acumen continues to anticipate reporting topline results from this trial in the third quarter of 2023.
- **In March 2023, the Company presented research at the International Conference on Alzheimer's and Parkinson's Diseases (ADPD)**.
  - The research demonstrated the utility of a human in vitro model of induced pluripotent stem cell (iPSC)-derived excitatory neurons for a better understanding of which forms of amyloid beta oligomers contribute to the pathogenesis of AD in the human brain. Utilizing human iPSC-derived excitatory neurons as a model, a panel of Aβ detection antibodies, and a panel of globular soluble AβOs plus monomers, the current study found that soluble Aβ size may influence synaptic binding. Read more here.

First Quarter 2023 Financial Results

- **Cash Balance.** As of March 31, 2023, cash, cash equivalents and marketable securities totaled $183.8 million, compared to cash, cash equivalents and marketable securities of $193.4 million as of December 31, 2022. The decrease in cash is related to funding ongoing operations.
- **Research and Development (R&D) Expenses.** R&D expenses were $8.7 million for the three-month period ended March 31, 2023, compared to $6.0 million for the three-month period ended March 31, 2022. The increase in R&D expenses was primarily due to increased costs related to our ongoing clinical trial, as well as nonclinical research and development activity.
- **General and Administrative (G&A) Expenses.** G&A expenses were $4.4 million for the three-month period ended March 31, 2023, compared to $3.2 million for the three-month period ended March 31, 2022. The increase in G&A expenses was primarily due to increased costs related to personnel, consulting and travel expenses.
- **Loss from Operations.** Losses from operations were $13.1 million for the three-month period ended March 31, 2023, compared to $9.2 million for the three-month period ended March 31, 2022. This increase was due to the increased R&D and G&A expenses over the prior year period.
- **Net Loss.** Net loss was $11.3 million for the three-month period ended March 31, 2023, compared to $9.1 million for the three-month period ended March 31, 2022.

Conference Call Details

Acumen will host a conference call and live audio webcast today, May 9, 2023, 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.

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 ACU193

ACU193 is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble AβOs, which Acumen believes are the most 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, ACU193 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. ACU193 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 is 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 ACU193 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 ACU193. The INTERCEPT-AD study 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 has completed enrollment across all sites. 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 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, ACU193, a humanized monoclonal antibody that selectively targets toxic soluble AβOs 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, 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 through 2025, and the therapeutic potential of Acumen's product candidate, ACU193, including against other antibodies, and the anticipated timeline for reporting topline safety and proof of mechanism data and results and for further engagement with the FDA. 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, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 77,999	$ 130,101
Marketable securities, short-term	62,410	47,504
Prepaid expenses and other current assets	3,623	2,724

Total current assets	144,032	180,329
Marketable securities, long-term	43,419	15,837
Property and equipment, net	151	165
Right-of-use asset	67	105
Other assets	195	151
Total assets	$ 187,864	$ 196,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 762	$ 1,640
Accrued clinical trial expenses	5,203	2,717
Accrued expenses and other current liabilities	2,747	3,350
Operating lease liability	67	105
Total current liabilities	8,779	7,812
Total liabilities	8,779	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 March 31, 2023 and December 31, 2022	-	-
Common stock, $0.0001 par value; 300,000,000 shares authorized and 41,025,062 shares issued and outstanding as of March 31, 2023 and December 31, 2022	4	4
Additional paid-in capital	361,339	359,949
Accumulated deficit	(181,734)	(170,427)
Accumulated other comprehensive loss	(524)	(751)
Total stockholders' equity	179,085	188,775
Total liabilities and stockholders' equity	$ 187,864	$ 196,587

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

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 8,713	$ 5,985
General and administrative	4,422	3,221
Total operating expenses	13,135	9,206
Loss from operations	(13,135)	(9,206)
Other income (expense)		
Interest income, net	1,832	76
Other income (expense), net	(4)	1
Total other income	1,828	77
Net loss	(11,307)	(9,129)
Other comprehensive gain (loss)		
Unrealized gain (loss) on marketable securities	227	(583)
Comprehensive loss	$ (11,080)	$ (9,712)
Net loss per common share, basic and diluted	$ (0.28)	$ (0.23)
Weighted-average shares outstanding, basic and diluted	41,025,062	40,473,270

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

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (11,307)	$ (9,129)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	14	4
Stock-based compensation expense	1,390	618
Amortization of premiums and accretion of discounts on marketable securities, net	(334)	216
Amortization of right-of-use asset	38	33
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(899)	1,416
Other assets	(44)	(65)
Accounts payable	(878)	121
Accrued clinical trial expenses	2,486	281
Operating lease liability	(38)	(32)
Accrued expenses and other current liabilities	(603)	(1,762)
Net cash used in operating activities	(10,175)	(8,299)
Cash flows from investing activities		
Purchases of marketable securities	(52,131)	(9,090)
Proceeds from maturities and sales of marketable securities	10,204	4,000
Purchases of property and equipment	-	(9)
Net cash used in investing activities	(41,927)	(5,099)
Net change in cash and cash equivalents	(52,102)	(13,398)
Cash and cash equivalents at the beginning of the period	130,101	122,162
Cash and cash equivalents at the end of the period	$ 77,999	$ 108,764