Acumen Pharmaceuticals Reports Third Quarter 2023 Financial Results and Business Highlights

November 13, 2023

- Initiation of a Phase 2 study, ALTITUDE-AD, to investigate ACU193 for the treatment of early Alzheimer's disease expected in the first half of 2024, following positive FDA interaction in October 2023
- Announced global collaboration and license agreement with Halozyme for development of a subcutaneous formulation of ACU193
  - Initiation of a Phase 1 study to support a subcutaneous dosing option of ACU193 expected in mid-2024
- Announced a credit facility of up to $50 million from K2 HealthVentures, to provide capital to support subcutaneous clinical work and general corporate purposes
- CSF biomarker data observed in the Phase 1 INTERCEPT-AD trial support pharmacology of ACU193 and role of amyloid beta oligomers in Alzheimer's disease
- Cash, cash equivalents and marketable securities of $282.7 million as of Sept. 30, 2023, expected to support current clinical and operational activities into the second half of 2026
- Company to host conference call and webcast today at 8:00 a.m. ET

CHARLOTTESVILLE, Va., Nov. 13, 2023 (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 2023 and provided a business update.

"My excitement for Acumen's future is centered on the strength of our ACU193 development strategy for the treatment of early Alzheimer's disease, and the deep expertise of our team to execute on that strategy. We continue to make significant operational, regulatory and strategic progress. Following our positive Phase 1 data in the third quarter, we recently had a positive interaction with the FDA and plan to initiate a Phase 2 study in the first half of 2024. On a strategic front, I am excited about our recent collaboration and licensing agreement with Halozyme for the development of a subcutaneous formulation of ACU193, to broaden potential treatment optionality and increase convenience for patients. To help finance this important workstream, we are pleased to announce today that we have entered into an agreement with K2 HealthVentures for a debt facility of up to $50 million," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "We have also observed encouraging trends in CSF biomarker data from our Phase 1 study, further solidifying the pharmacology of ACU193. Our talented team is committed to pursuing the full potential of targeting amyloid beta oligomers for this patient population, and I am proud of our progress as we continue to execute at the highest level and work to generate strong and sustainable value, today and into the future."

Recent Highlights and Anticipated Milestones

ACU193 Clinical Development

- **In October 2023, the Company presented additional detail from first-in-human Phase 1 study of ACU193 for early AD at the Clinical Trials on Alzheimer's Disease (CTAD) conference.**
  - Announced dose selection of 50 mg/kg and 35 mg/kg every 4 weeks for ACU193 treatment arms in upcoming placebo-controlled Phase 2 trial based on significant target engagement of AβOs approaching maximal effect.
  - Presented data exploring target engagement modeling of ACU193 to inform dose selection, plus further analyses of dose-related amyloid plaque reduction and clinical characteristics of ARIA-E, confirming proof-of-mechanism for ACU193.
- **In October 2023, the Company met with the FDA to discuss the next clinical trial in the development program for ACU193.**
  - The agency indicated they are aligned in principle with the Phase 2/3 study design.
  - In the first half of 2024, the Company expects to initiate a Phase 2 study, ALTITUDE-AD, as the next phase of development for ACU193.
- **Today, the Company announced encouraging results from INTERCEPT-AD Phase 1 cerebrospinal fluid (CSF) biomarker data, further supporting the pharmacologic activity of ACU193.**
  - Observed dose dependent trend in the multiple ascending dose cohorts on CSF levels of p-tau181, total tau, neurogranin and Aβ 42/40 ratio.
  - P-tau181 (p=0.049) and neurogranin (p=0.037) showed statistically significant improvement at 60 mg/kg Q4W as compared to the placebo group after three administrations of ACU193.

- Nominally significant correlation between target engagement of AβOs and change in neurogranin observed across all doses.
- Trend between target engagement of AβOs and change in p-tau181 observed across all doses.
- Plasma biomarker analysis in progress.

“We have observed a dose-dependent trend toward drug effect of ACU193 on CSF levels of p-tau181, total tau, neurogranin and the Aβ 42/40 ratio after only three administrations. The fact that we are observing changes in CSF biomarkers is highly supportive of ACU193’s downstream pharmacology as determined in our Phase 1 study,” said Eric Siemers, Chief Medical Officer of Acumen. “Changes in neurogranin and p-tau181 were statistically significant at the highest dose level studied, and correlated with target engagement of AβOs, consistent with the mechanism of action of ACU193. These data increase our confidence that ACU193 has potential for the treatment of early Alzheimer’s disease, which we will investigate in our Phase 2 study that is expected to initiate in the first half of 2024.”

Corporate Updates

- **In November 2023, announced a global collaboration and licensing agreement with Halozyme for the development of a subcutaneous formulation of ACU193, to potentially offer additional flexibility and convenience for patients and caregivers.**
  - Expect to initiate a Phase 1 trial investigating a subcutaneous dosing option of ACU193 in mid-2024.
- **Today, announced a credit facility for up to $50 million provided by K2 HealthVentures, for capital to support subcutaneous clinical work as well as general corporate purposes.**

Third Quarter 2023 Financial Results

- **Cash Balance.** As of September 30, 2023, cash, cash equivalents and marketable securities totaled $282.7 million, compared to cash, cash equivalents and marketable securities of $172.2 million as of June 30, 2023. This increase is due to the net proceeds from the Company’s public offering of approximately $122 million on July 21, 2023. Altogether, this runway is expected to be sufficient to support current clinical and operational activities into the second half of 2026.
- **Research and Development (R&D) Expenses.** R&D expenses were $11.2 million for the three-month period ended September 30, 2023, compared to $8.3 million for the three-month period ended September 30, 2022. The increase in R&D expenses was primarily due to increased costs related to materials, consulting, personnel and other costs.
- **General and Administrative (G&A) Expenses.** G&A expenses were $4.9 million for the three-month period ended September 30, 2023, compared to $3.1 million for the three-month period ended September 30, 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 were $16.0 million for the three-month period ended September 30, 2023, compared to $11.4 million for the three-month period ended September 30, 2022. This increase was due to the increased R&D and G&A expenses over the prior year period.
- **Net Loss.** Net loss was $13.0 million for the three-month period ended September 30, 2023, compared to $10.7 million for the three-month period ended September 30, 2022.

Conference Call Details

Acumen will host a conference call and live audio webcast today, Nov. 13, 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. 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 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 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 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 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 ACU193. More information can be found on www.clinicaltrials.gov, NCT identifier NCT04931459.

About Acumen Pharmaceuticals, Inc.

Acumen, headquartered in Charlottesville, VA, with 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, ACU193, a humanized monoclonal antibody that selectively targets toxic soluble AβOs, following positive topline 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 second half of 2026, the therapeutic potential of Acumen's product candidate, ACU193, including against other antibodies, the anticipated timeline for initiating a Phase 2 clinical trial of ACU193 and a Phase 1 trial to support a subcutaneous dosing option of ACU 193, 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)

	September 30, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 94,917	$ 130,101
Marketable securities, short-term	120,517	47,504
Prepaid expenses and other current assets	3,164	2,724
Total current assets	218,598	180,329
Marketable securities, long-term	67,270	15,837
Restricted cash	189	—
Property and equipment, net	123	165
Right-of-use asset	2	105
Other assets	189	151
Total assets	$ 286,371	$ 196,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,362	$ 1,640
Accrued clinical trial expenses	1,566	2,717
Accrued expenses and other current liabilities	3,168	3,350
Operating lease liability	2	105
Total current liabilities	6,098	7,812
Total liabilities	6,098	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 September 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 57,910,461 and 41,025,062 shares issued and outstanding as of September 30, 2023 and December 31, 2022	6	4
Additional paid-in capital	487,077	359,949
Accumulated deficit	(206,301)	(170,427)
Accumulated other comprehensive loss	(509)	(751)
Total stockholders' equity	280,273	188,775
Total liabilities and stockholders' equity	$ 286,371	$ 196,587

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,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 11,179	$ 8,309	$ 29,025	$ 21,615
General and administrative	4,860	3,062	13,627	9,374
Total operating expenses	16,039	11,371	42,652	30,989
Loss from operations	(16,039)	(11,371)	(42,652)	(30,989)
Other income (expense)				
Interest income, net	3,124	663	6,840	1,000
Other expense, net	(42)	(2)	(62)	(1)
Total other income	3,082	661	6,778	999
Net loss	(12,957)	(10,710)	(35,874)	(29,990)
Other comprehensive gain (loss)				
Unrealized gain (loss) on marketable securities	137	—	242	(734)
Comprehensive loss	$ (12,820)	$ (10,710)	$ (35,632)	$ (30,724)
Net loss per common share, basic and diluted	$ (0.24)	$ (0.26)	$ (0.79)	$ (0.74)
Weighted-average shares outstanding, basic and diluted	54,229,630	40,502,860	45,474,953	40,491,181

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (35,874)	$ (29,990)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	42	20
Stock-based compensation expense	4,511	2,173
Amortization of premiums and accretion of discounts on marketable securities, net	(1,344)	575
Amortization of right-of-use asset	103	100
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(436)	2,058
Other assets	(38)	(78)
Accounts payable	(278)	996
Accrued clinical trial expenses	(1,151)	1,358
Operating lease liability	(103)	(100)
Accrued expenses and other current liabilities	(182)	(1,062)
Net cash used in operating activities	(34,750)	(23,950)
Cash flows from investing activities		

Purchases of marketable securities	(178,857)	(12,129)
Proceeds from maturities and sales of marketable securities	55,997	71,860
Proceeds from sale of property and equipment	3	—
Purchases of property and equipment	(7)	(126)
Net cash provided by (used in) investing activities	(122,864)	59,605
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	122,294	—
Proceeds from exercise of stock options	325	19
Payments for deferred offering costs	—	(296)
Net cash provided by (used in) financing activities	122,619	(277)
Net change in cash and cash equivalents and restricted cash	(34,995)	35,378
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	$ 95,106	$ 157,540