Acumen Pharmaceuticals Reports Financial Results for Full Year Ended December 31, 2022 and Business Highlights

March 27, 2023

- INTERCEPT-AD, a Phase 1 clinical trial of ACU193 in patients with early Alzheimer's disease, completed enrollment in February 2023
    - Topline data expected in the third quarter of 2023
- Cash, cash equivalents and marketable securities of $193.4 million as of Dec. 31, 2022 expected to be sufficient to support clinical and operational goals through 2025
- Company to host conference call and webcast today at 8:00 a.m. ET

CHARLOTTESVILLE, Va. and CARMEL, Ind., March 27, 2023 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), a clinical-stage biopharmaceutical company focused on developing a novel therapeutic that targets toxic soluble amyloid beta oligomers (AβOs) and is designed for the treatment of Alzheimer's disease (AD), today reported financial results for the full year ended December 31, 2022 and provided a business update.

"2022 was a year of significant accomplishment as we advanced the clinical development of ACU193, our novel therapeutic targeting toxic amyloid beta oligomers for the treatment of Alzheimer's Disease. We recently completed enrollment in our Phase I INTERCEPT-AD trial and are encouraged by preliminary pharmacokinetic and safety data that support ACU193's differentiated product profile," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "We believe that our continued execution will drive Acumen's momentum during 2023. Our Phase 1 topline results expected in the third quarter and anticipated interaction with FDA in the fourth quarter of 2023 will help inform our next phase of clinical development. With cash runway expected through 2025, a strong scientific foundation, and an increasingly attractive market environment, we believe we are well positioned to achieve our near-term milestones and to advance our mission of delivering a novel treatment option for patients with Alzheimer's Disease."

Recent Business Highlights and Anticipated Milestones

ACU193 Clinical Development

- **In October 2022, Fast Track designation was granted by the U.S. Food and Drug Administration (FDA) for ACU193 for the treatment of early Alzheimer's disease.** Fast Track designation is granted to drugs being developed for the treatment of serious or life-threatening conditions where there is an unmet medical need. Fast Track designation does not change the standard for approval, but a drug candidate that receives Fast Track designation is eligible for more frequent communication with the FDA throughout the drug development process for the purpose of expediting the drug's development, review, and potential approval.
- **In January 2023, a protocol amendment was submitted to the FDA with respect to Cohort 7 of the Company's Phase 1 INTERCEPT-AD clinical trial to reduce the dose to 25 mg/kg every two weeks (updated from 60 mg/kg every two weeks).** The change was based in part on a blinded review of preliminary pharmacokinetic data in the trial, inclusive of levels of ACU193 in plasma and cerebrospinal fluid, which indicated a dose of 60 mg/kg every two weeks should not be needed to attain central target engagement, and preliminary safety data, including two asymptomatic cases of ARIA-E (one in Cohort 4 after a single 60 mg/kg dose and one in Cohort 5 after the third 10 mg/kg dose).
- **In February 2023, enrollment was completed in the Company's Phase 1 INTERCEPT-AD trial of ACU193 in patients with early Alzheimer's disease.**
    - Acumen anticipates reporting topline results from this trial, including safety and proof-of-mechanism data, in the third quarter of 2023.

Corporate

- **In 2022, we continued to expand our team with talent necessary to advance our mission to develop a novel treatment for AD.** These appointments included Liean Schenck, MS as our VP, Head of Chemistry, Manufacturing and Controls (CMC) and Derek Meisner, JD as our Chief Legal Officer.
- **In January 2023, Derrell Porter, M.D. joined Acumen's Board of Directors.** Dr. Porter is a physician-entrepreneur with

more than 20 years of experience in drug development. He is currently the Founder and CEO of Cellevolve, a development and commercialization company focused on cell therapy, and previously served in commercial and corporate development roles at Atara Biotherapeutics, Inc., Gilead, AbbVie and Amgen.

2022 Financial Results

- **Cash Balance.** As of December 31, 2022, cash, cash equivalents and marketable securities totaled $193.4 million, compared to cash, cash equivalents and marketable securities of $225.9 million as of December 31, 2021. The decrease in cash is related to funding ongoing operations.

- **Research and Development (R&D) Expenses.** R&D expenses for 2022 were $32.4 million compared to $12.3 million in 2021. The increase in R&D expenses in 2022 compared to 2021 was primarily due to increased costs related to our ongoing clinical trial, which was initiated in 2021 and started enrolling patients in the second half of 2021, as well as nonclinical research and development activity.

- **General and Administrative (G&A) Expenses.** G&A expenses for 2022 were $12.9 million, compared to $7.3 million in 2021. The increase in G&A expenses in 2022 compared to 2021 was primarily due to increased expenses as a public company and additions to its financial and administrative infrastructure, such as costs related to personnel, accounting, marketing, recruiting and travel and entertainment expenses.

- **Loss from Operations.** Losses from operations for 2022 were $45.2 million, compared with $19.6 million in 2021. 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, 2022 was $42.9 million, compared to a net loss of $100.6 million for the year ended December 31, 2021. Net loss in 2021 includes a $81.2 million non-cash expense that represents the changes in fair value of Acumen's Series B tranche liability and Series A-1 warrant liability.

Conference Call Details

Acumen will host a conference call and live audio webcast today, March 27, 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 recombinant humanized immunoglobin gamma 2 (IgG2) 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 what a growing body of evidence indicates is a primary underlying cause of the neurodegenerative process in AD. 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 multiple investigative sites located in the United States. 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 primary 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 and continued momentum, Acumen's ability to

achieve its strategic and financial goals, including its projected use of cash, cash equivalents and marketable securities and the sufficiency of its cash resources through 2025, and the therapeutic potential of Acumen's product candidate, ACU193, including the anticipated timeline for reporting topline safety and proof-of-mechanism data and results, ACU193'sits differentiated product profile, as supported by preliminary pharmacokinetic and safety data, as compared to other monoclonal antibodies in development, and the potential benefits and outcomes of receiving Fast Track designation from and anticipated upcoming interactions 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 the COVID-19 pandemic, 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.
Balance Sheets
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 130,101	$ 122,162
Marketable securities, short-term	47,504	72,075
Prepaid expenses and other current assets	2,724	4,424
Total current assets	180,329	198,661
Marketable securities, long-term	15,837	31,619
Property and equipment, net	165	36
Right-of-use asset	105	-
Other assets	151	14
Total assets	$ 196,587	$ 230,330
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,640	$ 1,088
Accrued clinical trial expenses	2,717	147
Accrued expenses and other current liabilities	3,350	3,912
Operating lease liability, current portion	105	-
Total current liabilities	7,812	5,147
Total liabilities	7,812	5,147
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, 2022 and 2021	-	-
Common stock, $0.0001 par value; 300,000,000 shares authorized and 41,025,062 and 40,473,270 shares issued and outstanding as of December 31, 2022 and 2021, respectively	4	4
Additional paid-in capital	359,949	352,981
Accumulated deficit	(170,427)	(127,571)
Accumulated other comprehensive loss	(751)	(231)
Total stockholders' equity	188,775	225,183
Total liabilities and stockholders' equity	$ 196,587	$ 230,330

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

	Year Ended December 31,	
	2022	2021

Operating expenses		
Research and development	$ 32,361	$ 12,305
General and administrative	12,876	7,279
Total operating expenses	45,237	19,584
Loss from operations	(45,237)	(19,584)
Other income (expense)		
Interest income, net	2,392	84
Other income (expense), net	(11)	51
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	-	(81,157)
Total other income (expense)	2,381	(81,022)
Net loss	(42,856)	(100,606)
Other comprehensive loss		
Unrealized loss on marketable securities	(520)	(231)
Comprehensive loss	$ (43,376)	$ (100,837)
Net loss per common share, basic and diluted	$ (1.06)	$ (5.02)
Weighted-average shares outstanding, basic and diluted	40,601,936	20,057,534

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (42,856)	$ (100,606)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	32	4
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	-	81,157
Stock-based compensation expense	3,061	922
Amortization of premiums and accretion of discounts on marketable securities, net	487	155
Amortization of right-of-use asset	137	-
Other non-cash expense	-	109
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,700	(3,881)
Other assets	(137)	(14)
Accounts payable	552	557
Accrued clinical trial expenses	2,570	147
Operating lease liability	(137)	-
Accrued expenses and other current liabilities	(562)	3,489
Net cash used in operating activities	(35,153)	(17,961)
Cash flows from investing activities		
Purchases of marketable securities	(41,514)	(104,080)
Proceeds from maturities and sales of marketable securities	80,860	-
Purchases of property and equipment	(161)	(40)
Net cash provided by (used in) investing activities	39,185	(104,120)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	3,792	168,556
Proceeds from exercise of stock options	115	15
Proceeds from issuance of Series B milestone shares, net of issuance costs	-	30,031
Proceeds from exercise of Series A-1 warrant	-	1,250
Proceeds from exercise of common stock warrants	-	614
Net cash provided by financing activities	3,907	200,466
Net change in cash and cash equivalents	7,939	78,385
Cash and cash equivalents at the beginning of the period	122,162	43,777
Cash and cash equivalents at the end of the period	$ 130,101	$ 122,162