Acumen Pharmaceuticals Reports Third Quarter 2022 Financial Results and Business Highlights

November 14, 2022

- INTERCEPT-AD, a Phase 1 clinical trial of ACU193 in patients with early Alzheimer's disease continues to progress
    - Acumen anticipates completing enrollment in the first quarter of 2023 and reporting topline data from this trial in the second half of 2023
- ACU193 was granted Fast Track designation from the U.S. FDA for the treatment of early Alzheimer's disease
- Cash, cash equivalents and marketable securities of $200.2 million as of Sept. 30, 2022 expected to be sufficient to support clinical and operational goals through 2025
- Company to host conference call and webcast today at 4:30 p.m. ET

CHARLOTTESVILLE, Va. and CARMEL, Ind., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), a clinical-stage biopharmaceutical company focused on the development of novel targeted therapeutics for Alzheimer's disease (AD), today reported financial results for the third quarter of 2022 and provided a business update.

"During the third quarter, we remained focused on executing INTERCEPT-AD, our Phase 1 clinical trial of ACU193 in patients with early AD. We are pleased with the rate of progress in the study in the quarter, which is a testament to our team's efforts and the therapeutic promise of ACU193. We believe that our recent receipt of Fast Track designation from the FDA also reflects the clinical potential of ACU193 and underscores the high unmet need for additional disease-modifying treatments in the Alzheimer's patient community," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "We remain well capitalized through 2025 based on our current business plans and anticipate achieving the completion of study enrollment in INTERCEPT-AD in the first quarter of 2023 and topline results in the second half of 2023."

Dr. Eric Siemers, M.D., Chief Medical Officer of Acumen said, "ACU193 is the first clinical-stage monoclonal antibody designed to selectively target toxic soluble amyloid beta oligomers. Many studies have shown these soluble species disrupt neuronal function and initiate the process of neurodegeneration leading to AD. Underscoring our goal to expeditiously advance ACU193, the recent publication of our clinical development plan in the *Journal for Prevention of Alzheimer's Disease* details incorporation of several advancements in AD research methodology, including an adaptive Phase 2/3 trial design. Our recent Fast Track designation should also allow for close engagement with the FDA as we seek the most efficient path to develop ACU193 as a potential better and differentiated therapeutic option for patients living with AD."

Recent Business Highlights and Anticipated Milestones

ACU193 Clinical Development

- **INTERCEPT-AD enrollment remains ongoing.** Patient screening and enrollment is continuing for INTERCEPT-AD, with 17 active clinical trial sites currently recruiting patients.
    - The study has progressed as planned in the protocol and blinded safety data for ACU193 are consistent with our expectations.
    - Acumen anticipates completing enrollment in the first quarter of 2023 and reporting topline data from this trial in the second half of 2023.
- **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. 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 October 2022, the development rationale and clinical development plan for ACU193 was published in the *Journal for Prevention of Alzheimer's Disease* (JPAD).** It outlines the design of the ongoing Phase 1 INTERCEPT-AD trial for ACU193 and planned criteria for advancing to a Phase 2/3 clinical trial based on recent advancements in clinical research on Alzheimer's disease.

Corporate

- **In September 2022, Derek Meisner joined Acumen as Chief Legal Officer.** Mr. Meisner brings more than two decades of experience providing counsel to public and private companies across key legal and operational functions, including

regulatory compliance, debt and equity financings, mergers and acquisitions, strategic partnerships, and corporate governance. Mr. Meisner previously served in a similar capacity at two other publicly-traded biotechnology companies. He also served as the General Counsel of RA Capital Management and as a Branch Chief in the Division of Enforcement of the U.S. Securities and Exchange Commission.

Third Quarter 2022 Financial Results

- **Cash Balance.** As of September 30, 2022, cash, cash equivalents and marketable securities totaled $200.2 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 were $8.3 million for the three-month period ended September 30, 2022, compared to $1.8 million for the three-month period ended September 30, 2021. The increase in research and development expenses 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 were $3.1 million for the three-month period ended September 30, 2022, compared to $2.1 million for the three-month period ended September 30, 2021. The increase in general and administrative expenses was primarily due to increased costs related to personnel, accounting, marketing, recruiting and travel expenses.

- **Loss from Operations.** Losses from operations were $11.4 million for the three-month period ended September 30, 2022, compared to $3.9 million for the three-month period ended September 30, 2021. This increase was due to the increased R&D and G&A expenses over the prior year period.

- **Net Loss.** Net loss was $10.7 million for the three-month period ended September 30, 2022, compared to $3.9 million for the three-month period ended September 30, 2021. The increase was due to the increased R&D and G&A expenses over the prior year period.

Conference Call Details

Acumen will host a conference call and live audio webcast today, Nov. 14, 2022, at 4:30 p.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 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

Approximately 62 individuals with early AD (mild cognitive impairment or mild dementia due to AD) are expected to be randomized into this double-blind, placebo-controlled, first-in-human study of ACU193. INTERCEPT-AD is designed to establish safety and proof of mechanism. It 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 is enrolling at 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 disease-modifying approach to treat Alzheimer's disease. 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, 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, and the therapeutic potential of Acumen's product candidate, ACU193, including its potential for improved safety and efficacy as compared to other monoclonal antibodies in development and expectations with respect to blinded safety data and the potential of soluble amyloid beta (Ab) species to be more effective or safer disease-modifying therapeutic targets, as well as the expectations concerning the INTERCEPT-AD trial and criteria for Acumen's planned Phase 2/3 clinical trial, and the potential benefits of receiving Fast Track designation from 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and future filings with the SEC, including Acumen's Quarterly Report on Form 10-Q for the quarter ended and September 30, 2022. 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, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 157,540	$ 122,162
Marketable securities, short-term	42,654	72,075
Prepaid expenses and other current assets	2,366	4,424
Total current assets	202,560	198,661
Marketable securities, long-term	-	31,619
Property and equipment, net	142	36
Deferred offering costs	337	-
Right-of-use asset	133	-
Other assets	92	14
Total assets	$ 203,264	$ 230,330
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,084	$ 1,088
Accrued expenses and other current liabilities	4,396	4,059
Operating lease liability, current portion	133	-
Total current liabilities	6,613	5,147
Total liabilities	6,613	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 September 30, 2022 and December 31, 2021	-	-
Common stock, $0.0001 par value; 300,000,000 shares authorized and 40,503,124 and 40,473,270 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	355,173	352,981
Accumulated deficit	(157,561)	(127,571)
Accumulated other comprehensive loss	(965)	(231)
Total stockholders' equity	196,651	225,183
Total liabilities and stockholders' equity	$ 203,264	$ 230,330

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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 8,309	$ 1,800	$ 21,615	$ 6,632
General and administrative	3,062	2,135	9,374	4,537
Total operating expenses	11,371	3,935	30,989	11,169
Loss from operations	(11,371)	(3,935)	(30,989)	(11,169)
Other income (expense)				
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	-	-	-	(81,157)
Interest income, net	663	14	1,000	22
Other income, net	(2)	19	(1)	47
Total other income (expense)	661	33	999	(81,088)
Net loss	(10,710)	(3,902)	(29,990)	(92,257)
Other comprehensive loss				
Unrealized loss on marketable securities	-	(28)	(734)	(28)
Comprehensive loss	$ (10,710)	$ (3,930)	$ (30,724)	$ (92,285)
Net loss per common share, basic and diluted	$ (0.26)	$ (0.10)	$ (0.74)	$ (7.00)
Weighted-average shares outstanding, basic and diluted	40,502,860	38,266,593	40,491,181	13,177,983

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (29,990)	$ (92,257)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	20	1
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	-	81,157
Stock-based compensation expense	2,173	557
Amortization of premiums and accretion of discounts on marketable securities, net	575	(6)
Amortization of right-of-use asset	100	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,058	(4,297)
Other assets	(78)	(13)
Accounts payable	996	(149)
Operating lease liability	(100)	-
Accrued expenses and other current liabilities	296	685
Net cash used in operating activities	(23,950)	(14,322)
Cash flows from investing activities		
Purchases of marketable securities	(12,129)	(94,095)
Proceeds from maturities and sales of marketable securities	71,860	-
Purchases of property and equipment	(126)	(14)
Net cash provided by (used in) investing activities	59,605	(94,109)
Cash flows from financing activities		
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

Payments for deferred offering costs	(296)	168,559
Proceeds from the exercise of stock options	19	2
Net cash provided by (used in) financing activities	(277)	200,456
Net change in cash and cash equivalents	35,378	92,025
Cash and cash equivalents at the beginning of the period	122,162	43,777
Cash and cash equivalents at the end of the period	$ 157,540	$ 135,802
Supplemental disclosure of noncash investing and financing activities		
Right-of-use asset obtained in exchange for operating lease liabilities	$ 233	$ -
Deferred offering costs in accrued expenses and other current liabilities	$ 41	$ -
Conversion of convertible preferred stock into common stock upon initial public offering	$ -	$ 174,504
Reclassification of preferred stock tranche rights liability upon share issuance	$ -	$ 81,190
Reclassification of warrant liability upon exercise of preferred stock warrant	$ -	$ 5,380