Acumen Pharmaceuticals Reports Financial Results for Second Quarter 2022 and Business Highlights

August 15, 2022

- **Topline results expected in the first half of 2023 from INTERCEPT-AD, a multi-center, randomized, double-blind, placebo-controlled, single- and multiple-ascending dose Phase 1 clinical trial of ACU193 in patients with early Alzheimer's disease (AD)**
- **Key methods and assay model developed to potentially standardize the study of soluble amyloid-beta oligomers (AβOs) presented in a poster at the recent Alzheimer's Association International Conference (AAIC)**
- **$209.9 million in cash, cash equivalents and marketable securities as of June 30, 2022, which is expected to provide cash runway through 2025**
- **Company to host conference call and webcast today at 4:30 pm ET**

CHARLOTTESVILLE, Va. and CARMEL, Ind., Aug. 15, 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, today reported financial results for the quarter ended June 30, 2022 and provided a business update.

"We continue to make progress advancing INTERCEPT-AD, our Phase 1 clinical trial investigating the safety, tolerability, pharmacokinetics and target engagement of ACU193 in patients with early AD. We remain on track to report topline results in the first half of 2023," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "Importantly, based on our current plans, we expect our existing cash, cash equivalents and marketable securities to be sufficient to fund our operating expenses and capital expenditure requirements through 2025."

Recent Business Highlights and Anticipated Milestones

ACU193 Clinical Development

- **INTERCEPT-AD enrollment remains ongoing.** Patient screening and enrollment is continuing for INTERCEPT-AD. At present, we have 15 active clinical trial sites recruiting patients for INTERCEPT-AD. Acumen anticipates topline data from this trial in the first half of 2023.
- **Presentation of methodology for synthetic model assay to potentially standardize the study of soluble AβOs.** Methodology was recently presented in a poster, "Preparation and qualification of soluble amyloid beta oligomers for use in bioanalytic assays supporting Alzheimer's disease therapeutics" (P4-178), at the 2022 Alzheimer's Association International Conference. This presentation discussed utilizing Aβ-derived diffusible ligands (ADDLs) as a synthetic AβO model reagent to aid in standardization of AβO assays, including the use of ADDLs as a potential quantitative reference standard in potency and PK assays, and possibly to better understand the AβO specificity and selectivity of Aβ-targeting antibodies.
- **Phase 2/3 clinical trial preparation activities progressing.** Acumen anticipates initiating a Phase 2/3 trial for ACU193 following completion of INTERCEPT-AD, if successful, and subsequent consultation and feedback from the FDA. Chronic toxicology and chemistry manufacturing and controls (CMC) activities are ongoing to support readiness.

Corporate and Board

- **Acumen continues to expand its team with new appointments.** In Q2 2022, we hired Liean Schenck, MS as our VP, Head of Chemistry, Manufacturing and Controls (CMC). Ms. Schenck brings over 25 years of pharmaceutical industry experience in biologics process development, manufacturing, and CMC program management and has been responsible for CMC delivery of three commercial products since 2016 in her prior experience with other companies. Ms. Schenck started her career at Lonza Biologics in fermentation development before spending more than 20 years at Eli Lilly and Company in various CMC roles. In her most recent position, she served as Head of CMC program management at Novavax.
- Dr**.** Jeffrey Sevigny, the Chief Medical Officer of Prevail Therapeutics, Inc., a wholly owned subsidiary of Eli Lilly and Company, has departed from the Board effective August 12, 2022. Dr. Sevigny's departure was due to requirements of his current employment and not due to any disagreement with the Company. Dr. Sevigny joined Acumen's Board in 2019 and

has made valuable contributions to the company. “We thank Jeff for his service and support of Acumen over the last three years,” said Dan O’Connell, Chief Executive Officer of Acumen. “His extensive experience and detailed knowledge of clinical translation and neuroscience have been highly valued at Acumen as we have grown, and his early commitment and support of our program and team are greatly appreciated.”

Second Quarter 2022 Financial Results

- **Cash Balance.** As of June 30, 2022, cash, cash equivalents and marketable securities totaled $209.9 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 $7.3 million for the three-month period ended June 30, 2022, compared to $2.3 million for the three-month period ended June 30, 2021. The increase in research and development expenses was 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 June 30, 2022, compared to $1.2 million for the three-month period ended June 30, 2021. The increase in general and administrative expenses was primarily due to increased costs related to personnel, insurance, legal, marketing and recruiting expenses.

- **Loss from Operations.** Losses from operations were $10.4 million for the three-month period ended June 30, 2022, compared to $3.4 million for the three-month period ended June 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 $10.2 million for the three-month period ended June 30, 2022, compared to $61.4 million for the three-month period ended June 30, 2021. Net losses in the 2021 period includes a $57.9 million non-cash expense that represents the changes in fair value of Acumen’s Series B tranche liability and Series A-1 warrant liability. The remaining increase relates to increased operating expenses.

Conference Call Details

Acumen will host a conference call and live audio webcast today, August 15, 2022, at 4:30 pm 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 presentation with 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.

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,” “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, as well as the expectations concerning the INTERCEPT-AD trial and Acumen's planned Phase 2/3 clinical trial, including the anticipated number of trial sites, rate of site activation, rate of enrollment, enrollment objectives and the expected timing of reporting data, the potential utility of ADDLs as a synthetic AβO model reagent to aid in standardization of AβO assays, including the use of ADDLs as a potential quantitative reference standard in potency and PK assays and the potential to better understand the AβO specificity and selectivity of Aβ-targeting antibodies, and risks and uncertainties relating to the progression and duration of the COVID-19 pandemic and responsive measures , geopolitical events such as the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions such as rising inflation, supply disruptions, and uncertainty of credit and financial markets, and related effects on Acumen. 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. 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, Acumen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, and future filings and reports by Acumen, including Acumen's Quarterly Report on Form 10-Q for the quarter ended and June 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)

	June 30, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 111,067	$ 122,162
Marketable securities, short-term	78,844	72,075
Prepaid expenses and other current assets	1,142	4,424
Total current assets	191,053	198,661
Marketable securities, long-term	20,001	31,619
Property and equipment, net	113	36
Deferred offering costs	238	-
Right-of-use asset	167	-
Other assets	106	14
Total assets	$ 211,678	$ 230,330
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,710	$ 1,088
Accrued expenses and other current liabilities	3,282	4,059
Operating lease liability, current portion	142	-
Total current liabilities	5,134	5,147
Operating lease liability, net of current portion	25	-
Total liabilities	5,159	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 June 30, 2022 and December 31, 2021	-	-
Common stock, $0.0001 par value; 300,000,000 shares authorized and 40,501,258 shares and 40,473,270 issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	354,331	352,981
Accumulated deficit	(146,851)	(127,571)
Accumulated other comprehensive loss	(965)	(231)
Total stockholders' equity	206,519	225,183
Total liabilities and stockholders' equity	$ 211,678	$ 230,330

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 7,321	$ 2,254	$ 13,306	$ 4,832
General and administrative	3,090	1,187	6,312	2,402
Total operating expenses	10,411	3,441	19,618	7,234
Loss from operations	(10,411)	(3,441)	(19,618)	(7,234)
Other income (expense)				
Interest income, net	260	4	337	8
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	-	(57,940)	-	(81,157)
Other income, net	-	19	1	28
Total other income (expense)	260	(57,917)	338	(81,121)
Net loss	(10,151)	(61,358)	(19,280)	(88,355)
Other comprehensive loss				
Unrealized loss on marketable securities	(151)	-	(734)	-
Comprehensive loss	$ (10,302)	$ (61,358)	$ (20,014)	$ (88,355)
Net loss per common share, basic and diluted	$ (0.25)	$ (141.93)	$ (0.48)	$ (207.52)
Weighted-average shares outstanding, basic and diluted	40,497,087	432,325	40,485,244	425,761

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (19,280)	$ (88,355)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10	-
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	-	81,157
Stock-based compensation expense	1,333	253
Amortization of premiums and accretion of discounts on marketable securities, net	384	-
Amortization of right-of-use asset	66	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,282	(1,108)
Other assets	(92)	(13)
Accounts payable	580	741
Operating lease liability	(66)	-
Accrued expenses and other current liabilities	(984)	691
Net cash used in operating activities	(14,767)	(6,634)
Cash flows from investing activities		
Purchases of marketable securities	(12,129)	-
Proceeds from maturities and sales of marketable securities	15,860	-
Purchases of property and equipment	(45)	(6)
Net cash provided by (used in) investing activities	3,686	(6)
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	(31)	(220)
Proceeds from the exercise of stock options	17	-
Net cash provided by (used in) financing activities	(14)	31,675
Net change in cash and cash equivalents	(11,095)	25,035
Cash and cash equivalents at the beginning of the period	122,162	43,777
Cash and cash equivalents at the end of the period	$ 111,067	$ 68,812
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ -	$ -
Cash paid for interest	$ -	$ -
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	$ 207	$ 497
Purchases of property and equipment in accounts payable	$ 42	$ -
Reclassification of preferred stock tranche rights liability upon share issuance	$ -	$ 81,190
Reclassification of warrant liability upon exercise of preferred stock warrant	$ -	$ 5,380
Deferred offering costs in accounts payable	$ -	$ 1,635