



Acumen Pharmaceuticals Reports Financial Results for Full Year Ended December 31, 2021 and Business Highlights

March 28, 2022

- **Acumen is progressing ACU193, the first monoclonal antibody designed to selectively target toxic amyloid-beta oligomers (A β Os) to enter clinical testing**
- **Currently enrolling 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**
- **INTERCEPT-AD clinical trial design was presented at 2021 Clinical Trials on Alzheimer's Disease (CTAD) Conference in November 2021**
- **Topline results from INTERCEPT-AD now expected in the first half of 2023**
- **Acumen team expanded and Kim Drapkin appointed to the Board of Directors to enhance depth and breadth of expertise at the company**
- **\$225.9 million in cash, cash equivalents and marketable securities at December 31, 2021, 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., March 28, 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 full year ended December 31, 2021, and provided recent business highlights.

"After a transformational year in 2021, highlighted by multiple accomplishments, including our IPO, Acumen is completely focused on executing our business strategy with a primary emphasis on INTERCEPT-AD, our Phase 1 clinical trial investigating the safety, tolerability, pharmacokinetics and target engagement of ACU193 in early Alzheimer's patients. Based on current progress in the trial and our current plan to report a dataset inclusive of Cohort 7 Day 168 follow up, we now expect to report topline results in the first half of 2023. We have experienced slower than anticipated enrollment due to the COVID-19 pandemic, however our strong cash position has provided us the ability to expand the study footprint to support recruitment and to include a longer follow-up period prior to read out," said Daniel O'Connell, President and Chief Executive Officer at Acumen. "With the proceeds from our successful IPO last year, we estimate our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital requirements through 2025 based on our current plans."

Recent Business Highlights and Anticipated Milestones

ACU193 Clinical Development

- **INTERCEPT-AD enrollment continues to progress.** Patient screening and enrollment is ongoing for INTERCEPT-AD at eight active sites, with six additional sites selected for potential activation. Acumen anticipates topline results from this trial in the first half of 2023, subject to the rate of site activation and patient recruitment.
- **Clinical trial design for INTERCEPT-AD presented at 2021 Clinical Trials on Alzheimer's Disease (CTAD) Conference.** The presentation included the scientific rationale for targeting toxic A β Os, the clinical trial design of the Phase 1 INTERCEPT-AD study of ACU193, and how the study is designed to establish Proof of Mechanism for ACU193 and serve as the basis for moving to a Phase 2/3 trial.
- **Phase 2/3 clinical trial preparation activities progressing.** Given the continued advancement of necessary actions for the planned Phase 2/3 trial, including chronic toxicology and chemistry manufacturing and controls (CMC) activities, Acumen plans to be ready to initiate a Phase 2/3 trial on the success of INTERCEPT-AD results.

Corporate

In the fourth quarter of 2021, Acumen expanded its team with several new appointments. The new team members include **Julie Bockenstette**, Head of Human Relations; **Siew Tin Gan**, Head of Clinical Operations; and **Stephen Reynolds**, Corporate Controller and Treasurer.

"We welcome Julie, Siew Tin and Stephen, who are joining Acumen at a critical time in our company's growth as we continue to pioneer a new approach to treating Alzheimer's disease," said Daniel O'Connell. "We believe their individual experience and collective passion for improving the lives of patients with Alzheimer's disease will help us move closer to our ambitious goals."

- Ms. Bockenstette has more than 20 years of experience in human resources and sales at high-growth companies. Prior to this role, Bockenstette was Vice President of HR and Head of HR at the Diabetes Care Europe and North America division of Roche Diabetes Care. She has also held several key human resources and leadership roles at Elanco Animal Health and Eli Lilly and Co., both in Indiana.
- Ms. Gan has more than 20 years of experience in clinical research with a history of working in the pharmaceuticals and nutrition industries. Prior to this role, Gan was Senior Clinical Operations Program Leader in Neuroscience at Takeda, in addition to senior research and leadership positions at Danone Nutricia Research (Singapore), Lundbeck (Singapore), and Novo Nordisk (New Jersey).
- Mr. Reynolds has more than 25 years of finance experience in the healthcare industry. Prior to this role, Reynolds was Global Controller and Treasurer at Envigo RMS in Indianapolis, in addition to several other financial management positions at Roche Diagnostics, LDI and FinishMaster, Eli Lilly and Co., Memry Corporation, Roche Health Solutions, and Assembly Biosciences.

In addition to these appointments, **Kim Drapkin**, CPA, has been appointed to the Board of Directors effective April 1, 2022. Ms. Drapkin is currently the Chief Financial Officer of Jounce Therapeutics. Ms. Drapkin brings more than 25 years of experience working with private and publicly traded biotechnology and pharmaceutical companies, including building and leading finance functions, raising capital, and leading strategic financial planning. Ms. Drapkin will also serve as the chair of the company's audit committee.

"I'm incredibly excited to join the Board of Directors of Acumen at this exciting time. We face a massive unmet need in Alzheimer's disease, and I believe that Acumen's approach of targeting toxic amyloid-beta oligomers has the potential to transform the treatment of the disease. I look forward to working with the team and the rest of the Board to support the company's growth and, in particular, the development of ACU193," said Ms. Drapkin.

2021 Financial Results

- **Cash Balance.** As of December 31, 2021, our cash, cash equivalents and marketable securities totaled \$225.9 million, compared to cash and cash equivalents of \$43.8 million and no marketable securities as of December 31, 2020.
- **Research and Development (R&D) Expenses.** R&D expenses were \$12.3 million for the twelve-month period ended December 31, 2021, compared to \$8.0 million for the twelve-month period ended December 31, 2020. The net increase in research and development expenses in 2021 from 2020 was primarily due to increased costs related to initiating our clinical trial in 2021.
- **General and Administrative (G&A) Expenses.** G&A expenses were \$7.3 million for the twelve-month period ended December 31, 2021, compared to \$1.4 million for the twelve-month period ended December 31, 2020. Following the initial public offering, we added a number of new personnel and a large portion of the other increase is a direct result of our transition from a private to a public company.
- **Loss from Operations.** Losses from operations were \$19.6 million for the twelve-month period ended December 31, 2021, compared to \$7.9 million for the twelve-month period ended December 31, 2020.
- **Net Loss.** Net losses were \$100.6 million for the twelve-month period ended December 31, 2021, compared to \$7.3 million for the twelve-month period ended December 31, 2020. Net losses in 2021 include a non-cash expense of \$81.2 million that represents the changes in fair value of Acumen's Series B tranche liability and Series A-1 warrant liability. The tranche liability and warrant liability were initially recorded at fair value as liabilities on Acumen's balance sheet and were subsequently re-measured at fair value at the end of each reporting period. The increases in the fair value of these instruments were recognized as a component of other expense. The second tranche of the Series B Preferred Stock financing round closed in June 2021 and, as a result, the remaining value of the tranche liability was reclassified to convertible preferred stock on Acumen's condensed balance sheet. Additionally, the Series A-1 warrant was exercised in June 2021, and the remaining value of the warrant liability was reclassified to convertible preferred stock on Acumen's condensed balance sheet. Upon the closing of the initial public offering, all outstanding shares of convertible preferred stock converted into equivalent shares of common stock.

Conference Call Details

Acumen will host a conference call and live audio webcast today, March 28th, at 4:30 pm ET. The live webcast may be accessed from the Investors section of the Company's website at www.acumenpharm.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 877 311-0573 in the U.S., or +1 470 495-9505 outside the U.S., and entering passcode 3629669.

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 monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble A β Os, which Acumen believes are the most toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques. Soluble A β Os have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble A β Os, 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 Pharmaceuticals, 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 toxic soluble A β Os, 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 A β Os, in 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" 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 expected timing of initiation, enrollment and reporting data, and risks and uncertainties relating to the progression and duration of the COVID-19 pandemic and responsive measures thereto 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. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, and future filings and reports by Acumen, including Acumen's Annual Report on Form 10-K for the year ended December 31, 2021. 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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Balance Sheets (in thousands, except share and per share data)

	December 31,	
	2021	2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 122,162	\$ 43,777
Marketable securities, short-term	72,075	-
Grant receivable	-	109
Prepaid expenses and other current assets	4,424	543
Total current assets	198,661	44,429
Marketable securities, long-term	31,619	-
Property and equipment, net	36	-
Other assets	14	-
Total assets	\$ 230,330	\$ 44,429
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	\$ 1,088	\$ 531
Accrued expenses and other current liabilities	4,059	423
Preferred stock tranche rights liability	-	5,033
Preferred stock warrant liability	-	380
Total liabilities	5,147	6,367

Series A convertible preferred stock, \$0.0001 par value; no shares authorized, issued and outstanding as of December 31, 2021; 711,203 shares authorized and 477,297 shares issued and outstanding as of December 31, 2020; liquidation preference of \$1,067 as of December 31, 2020

- 1,067

Series A-1 convertible preferred stock, \$0.0001 par value; no shares authorized, issued and outstanding as of December 31, 2021; 11,898,177 shares authorized and 7,537,879 shares issued and outstanding as of December 31, 2020; liquidation preference of \$16,847 as of December 31, 2020

- 16,333

Series B convertible preferred stock, \$0.0001 par value; no shares authorized, issued and outstanding as of December 31, 2021; 29,457,450 shares authorized and 11,862,043 shares issued and outstanding as of December 31, 2020; liquidation preference of \$45,070 as of December 31, 2020

- 39,253

Stockholders' equity (deficit)

Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding as of December 31, 2021; no shares authorized, issued and outstanding as of December 31, 2020

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Common stock, \$0.0001 par value; 300,000,000 shares authorized and 40,473,270 shares issued and outstanding as of December 31, 2021; 50,500,000 shares authorized and 419,124 shares issued and outstanding as of December 31, 2020

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Additional paid-in capital

352,981 8,374

Accumulated deficit

(127,571) (26,965)

Accumulated other comprehensive loss

(231) -

Total stockholders' equity (deficit)

225,183 (18,591)

Total liabilities, convertible preferred stock and stockholders' equity (deficit)

\$ 230,330 \$ 44,429

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

	Year Ended December 31,	
	2021	2020
Grant and other revenue	\$ -	\$ 1,436
Operating expenses		
Research and development	12,305	7,997
General and administrative	7,279	1,351
Total operating expenses	19,584	9,348
Loss from operations	(19,584)	(7,912)
Other income (expense)		
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	(81,157)	586
Interest income, net	84	1
Other income, net	51	-
Total other income (expense)	(81,022)	587
Net loss	(100,606)	(7,325)
Other comprehensive loss		
Unrealized loss on marketable securities	(231)	-
Comprehensive loss	\$ (100,837)	\$ (7,325)
Net loss per common share, basic and diluted	\$ (5.02)	\$ (17.48)
Weighted-average shares outstanding, basic and diluted	20,057,534	419,124

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities		

Net loss	\$	(100,606)	\$	(7,325)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		4		-
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability		81,157		(586)
Stock-based compensation expense		922		154
Amortization of premiums and accretion of discounts on marketable securities, net		155		-
Other non-cash expense		109		-
Changes in operating assets and liabilities:				
Grant receivable		-		(79)
Prepaid expenses and other current assets		(3,881)		53
Other assets		(14)		144
Accounts payable		557		308
Accrued expenses and other current liabilities		3,636		(119)
Net cash used in operating activities		<u>(17,961)</u>		<u>(7,450)</u>
Cash flows from investing activities				
Purchases of available-for-sale marketable securities		(104,080)		-
Purchases of property and equipment		(40)		-
Net cash used in investing activities		<u>(104,120)</u>		<u>-</u>
Cash flows from financing activities				
Proceeds from issuance of Series B milestone shares, net of issuance costs		30,031		-
Proceeds from issuance of convertible preferred stock, net of issuance costs		-		44,675
Proceeds from exercise of Series A-1 warrant		1,250		-
Proceeds from exercise of common stock warrants		614		-
Proceeds from issuance of common stock upon initial public offering, net of issuance costs		168,556		-
Proceeds from stock option exercises		15		-
Net cash provided by financing activities		<u>200,466</u>		<u>44,675</u>
Net change in cash and cash equivalents		78,385		37,225
Cash and cash equivalents at the beginning of the period		43,777		6,552
Cash and cash equivalents at the end of the period	\$	<u>122,162</u>	\$	<u>43,777</u>
Supplemental disclosure of cash flow information				
Cash paid for income taxes	\$	-	\$	-
Cash paid for interest	\$	-	\$	-
Supplemental disclosure of noncash financing activities				
Reclassification of preferred stock tranche rights liability upon share issuance	\$	81,190	\$	-
Reclassification of warrant liability upon exercise of preferred stock warrant	\$	5,380	\$	-
Conversion of convertible preferred stock into common stock upon IPO	\$	174,504	\$	-