# Acumen Pharmaceuticals Reports Financial Results for First Quarter 2022 and Business Highlights

May 16, 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**
- ***Frontiers in Neuroscience* recently published a summary of preclinical evidence supporting the development of ACU193, a monoclonal antibody designed to selectively target toxic soluble amyloid-beta oligomers (AβOs), for the potential treatment of early Alzheimer's disease**
- **$216.7 million in cash, cash equivalents and marketable securities as of March 31, 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., May 16, 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 quarter ended March 31, 2022 and provided a business update.

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

The Acumen team is pleased with the recent publication of the Frontiers in Neuroscience article in which preclinical evidence characterizing ACU193's selectivity and differentiated profile is reviewed with the rationale for targeting soluble amyloid-beta oligomers in early AD. "The Frontiers article is timely, as we and others in the field look at upcoming clinical and regulatory events and as we continue to position ACU193 as potentially having a best-in-class treatment profile based on its potential safety, including anticipated limited to no ARIA-E, and clinical benefits on cognitive measures," said Eric Siemers, Acumen's Chief Medical Officer. "Each other monoclonal antibody which is approved or is in development has a different profile targeting various forms of A□ or amyloid. We believe the differences in these profiles are likely to lead to meaningful differences in the benefit-to-risk ratios of other products and product candidates and ACU193. The potential clinical significance of ACU193's ability to selectively target toxic soluble A□ Os is something we are excited to address in the clinic."

**Recent Business Highlights and Anticipated Milestones**

***ACU193 Clinical Development***

- **INTERCEPT-AD enrollment remains ongoing.** Patient screening and enrollment is ongoing for INTERCEPT-AD. Acumen anticipates topline data from this trial in the first half of 2023, subject to the rate of site activation and patient recruitment.
- **Frontiers in Neuroscience recently published a comprehensive summary of preclinical evidence supporting ACU193 for the potential treatment of early Alzheimer's disease.** The article is titled "ACU193: An immunotherapeutic poised to test the amyloid β oligomer hypothesis of Alzheimer's disease" and can be accessed here.
- **Phase 2/3 clinical trial preparation activities progressing.** Acumen plans to be ready to initiate a Phase 2/3 trial if INTERCEPT-AD results are positive. Chronic toxicology and chemistry manufacturing and controls (CMC) activities are ongoing to support readiness.

***First Quarter 2022 Financial Results***

- **Cash Balance.** As of March 31, 2022, cash, cash equivalents and marketable securities totaled $216.7 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 $6.0 million for the three-month period ended March 31, 2022, compared to $2.6 million for the three-month period ended March 31, 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.

- **General and Administrative (G&A) Expenses.** G&A expenses were $3.2 million for the three-month period ended March 31, 2022, compared to $1.2 million for the three-month period ended March 31, 2021. The increase in general and administrative expenses was primarily due to increased costs related to being a public company.
- **Loss from Operations.** Losses from operations were $9.2 million for the three-month period ended March 31, 2022, compared to $3.8 million for the three-month period ended March 31, 2021.
- **Net Loss.** Net loss was $9.1 million for the three-month period ended March 31, 2022, compared to $27.0 million for the three-month period ended March 31, 2021. Net losses in the 2021 period includes a $23.2 million non-cash expense that represents the changes in fair value of Acumen's Series B tranche liability and Series A-1 warrant liability. The remaining increase relates to increased operating expenses.

**Conference Call Details**

Acumen will host a conference call and live audio webcast today, May 16, 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 2586595.

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 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 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 A□ 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 anticipated number of trial sites, enrollment objectives and the expected timing of 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and future filings and reports by Acumen, including Acumen's Quarterly Report on Form 10-Q for the quarter ended March 31, 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)**

| | March 31, 2022 | December 31, |
|---|---|---|

| | | 2021 |
|---|---|---|
| | (unaudited) | |
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 108,764 | $ 122,162 |
| Marketable securities, short-term | 80,326 | 72,075 |
| Prepaid expenses and other current assets | 3,008 | 4,424 |
| Total current assets | 192,098 | 198,661 |
| Marketable securities, long-term | 27,658 | 31,619 |
| Property and equipment, net | 51 | 36 |
| Right-of-use asset | 201 | - |
| Other assets | 79 | 14 |
| Total assets | $ 220,087 | $ 230,330 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 1,219 | $ 1,088 |
| Accrued expenses and other current liabilities | 2,578 | 4,059 |
| Operating lease liability, current portion | 139 | - |
| Total current liabilities | 3,936 | 5,147 |
| Operating lease liability, net of current portion | 62 | - |
| Total liabilities | 3,998 | 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 March 31, 2022 and December 31, 2021 | - | - |
| Common stock, $0.0001 par value; 300,000,000 shares authorized and 40,473,270 shares issued and outstanding as of March 31, 2022 and December 31, 2021 | 4 | 4 |
| Additional paid-in capital | 353,599 | 352,981 |
| Accumulated deficit | (136,700) | (127,571) |
| Accumulated other comprehensive loss | (814) | (231) |
| Total stockholders' equity | 216,089 | 225,183 |
| Total liabilities and stockholders' equity | $ 220,087 | $ 230,330 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Operating expenses | | |
| Research and development | $ 5,985 | $ 2,578 |
| General and administrative | 3,221 | 1,215 |
| Total operating expenses | 9,206 | 3,793 |
| Loss from operations | (9,206) | (3,793) |
| Other income (expense) | | |
| Interest income, net | 76 | 4 |
| Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability | — | (23,217) |
| Other income, net | 1 | 9 |
| Total other income (expense) | 77 | (23,204) |
| Net loss | (9,129) | (26,997) |
| Other comprehensive loss | | |
| Unrealized loss on marketable securities | (583) | — |
| Comprehensive loss | $ (9,712) | $ (26,997) |
| Net loss per common share, basic and diluted | $ (0.23) | $ (64.41) |
| Weighted-average shares outstanding, basic and diluted | 40,473,270 | 419,124 |

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

**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| **Cash flows from operating activities** | | |
| Net loss | $ (9,129) | $ (26,997) |
| 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 | — | 23,217 |
| Stock-based compensation expense | 618 | 126 |
| Amortization of premiums and accretion of discounts on marketable securities, net | 216 | — |
| Amortization of right-of-use asset | 33 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 1,416 | (44) |
| Other assets | (65) | (13) |
| Accounts payable | 121 | 387 |
| Operating lease liability | (32) | — |
| Accrued expenses and other current liabilities | (1,481) | 954 |
| Net cash used in operating activities | (8,299) | (2,370) |
| **Cash flows from investing activities** | | |
| Purchases of marketable securities | (9,090) | — |
| Proceeds from maturities and sales of marketable securities | 4,000 | — |
| Purchases of property and equipment | (9) | — |
| Net cash used in investing activities | (5,099) | — |
| Net change in cash and cash equivalents | (13,398) | (2,370) |
| Cash and cash equivalents at the beginning of the period | 122,162 | 43,777 |
| Cash and cash equivalents at the end of the period | $ 108,764 | $ 41,407 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for income taxes | $ — | $ — |
| Cash paid for interest | $ — | $ — |
| **Supplemental disclosure of noncash investing and financing activities** | | |
| Purchases of property and equipment in accounts payable | $ 10 | $ — |
| Deferred offering costs in accrued expenses and other current liabilities | $ — | $ 257 |