UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-40551

Acumen Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**36-4108129**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
427 Park St., Charlottesville, Virginia	**22902**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (434) 297-1000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**ABOS**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 11, 2022, the registrant had 40,925,284 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q including statements regarding our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will” or “would” or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- the sufficiency of our existing cash and cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize ACU193, subject to necessary regulatory approvals;
- the ability of our clinical trials to demonstrate the safety and efficacy of ACU193, and other positive results;
- the therapeutic potential of ACU193, including its potential for improved safety and efficacy, as compared to other monoclonal antibodies approved and or in development, as well as the expectations concerning the INTERCEPT-AD trial;
- the success, cost and timing of our development activities, nonclinical studies and clinical trials;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing ACU193, subject to obtaining necessary regulatory approvals;
- our ability to attract and retain key scientific and clinical personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our reliance on third parties to manufacture and conduct clinical trials and nonclinical studies of ACU193;
- the success of competing therapies that are or may become available;
- our plans and ability to obtain or protect our intellectual property rights, including extensions of existing patent terms where available or the use of data market exclusivity to provide protection from generic or biosimilar versions of our product;
- the scope of protection that we are able to establish and maintain for intellectual property rights covering ACU193 and technology;
- potential claims relating to our intellectual property;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of ACU193, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our plans relating to the further development and manufacturing of ACU193, including additional therapeutic indications which we may pursue;
- our ability to develop and maintain our corporate infrastructure, including our ability to design and maintain an effective system of internal controls;

- our financial performance;
- the effects of the ongoing COVID-19 pandemic, geopolitical events such as the pending conflict with Russia and Ukraine; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

You should not rely on forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described under the header “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission, or the SEC, on March 28, 2022 (the Annual Report), and in our other filings with the SEC, as updated by the risk factors set forth in Part II, Item 1A “Risk Factors” of this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained herein. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made, and we undertake no obligation to update them to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law.

Unless the context otherwise indicates, references in this report to the terms “Acumen,” “the Company,” “we,” “our” and “us” refer to Acumen Pharmaceuticals, Inc.

We may announce material business and financial information to our investors using our investor relations website (www.investors.acumenpharm.com). We therefore encourage investors and others interested in Acumen to review the information that we make available on our website, in addition to following our filings with the SEC, webcasts, press releases and conference calls. Our website and information included in or linked to our website are not part of this Quarterly Report on Form 10-Q.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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 (Note 9)		
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

The accompanying notes are an integral part of these unaudited condensed financial statements.

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

The accompanying notes are an integral part of these unaudited condensed financial statements.

Acumen Pharmaceuticals, Inc.
Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands)
(unaudited)

For the Three Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2022	40,501,258	$ 4	$ 354,331	$ (146,851)	$ (965)	$ 206,519
Stock options exercised for cash	1,866	—	2	—	—	2
Stock-based compensation	—	—	840	—	—	840
Net loss	—	—	—	(10,710)	—	(10,710)
Balance as of September 30, 2022	40,503,124	$ 4	$ 355,173	$ (157,561)	$ (965)	$ 196,651

For the Three Months Ended September 30, 2021

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of June 30, 2021	477,297	$ 1,067	7,985,305	$ 22,963	19,770,070	$ 150,474	556,570	$ —	$ 9,241	$ (115,320)	$ —	$ (106,079)
Conversion of convertible preferred stock into common stock upon initial public offering	(477,297)	(1,067)	(7,985,305)	(22,963)	(19,770,070)	(150,474)	28,232,672	3	174,501	—	—	174,504
Issuance of stock for cash, net of issuance costs of $15,441	—	—	—	—	—	—	11,499,998	1	168,558	—	—	168,559
Cashless exercise of common stock warrants	—	—	—	—	—	—	178,847	—	—	—	—	—
Stock options exercised	—	—	—	—	—	—	2,236	—	2	—	—	2
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(28)	(28)
Stock-based compensation	—	—	—	—	—	—	—	—	304	—	—	304
Net loss	—	—	—	—	—	—	—	—	—	(3,902)	—	(3,902)
Balance as of September 30, 2021	—	$ —	—	$ —	—	$ —	40,470,323	$ 4	$ 352,606	$ (119,222)	$ (28)	$ 233,360

The accompanying notes are an integral part of these unaudited condensed financial statements.

Acumen Pharmaceuticals, Inc.
Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands)
(unaudited)

For the Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	40,473,270	$ 4	$ 352,981	$ (127,571)	$ (231)	$ 225,183
Unrealized loss on marketable securities	—	—	—	—	(734)	(734)
Stock options exercised for cash	25,108	—	19	—	—	19
Cashless stock options exercise	4,746	—	—	—	—	—
Stock-based compensation	—	—	2,173	—	—	2,173
Net loss	—	—	—	(29,990)	—	(29,990)
Balance as of September 30, 2022	40,503,124	$ 4	$ 355,173	$ (157,561)	$ (965)	$ 196,651

For the Nine Months Ended September 30, 2021

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	477,297	$ 1,067	7,537,879	$ 16,333	11,862,043	$ 39,253	419,124	$ —	$ 8,374	$ (26,965)	$ —	$ (18,591)
Issuance of milestone shares for cash, net of issuance costs of $16	—	—	—	—	7,908,027	30,031	—	—	—	—	—	—
Exercise of preferred stock warrant	—	—	447,426	1,250	—	—	—	—	—	—	—	—
Reclassification of preferred stock tranche rights liability upon issuance of milestone shares	—	—	—	—	—	81,190	—	—	—	—	—	—
Reclassification of warrant liability upon exercise of preferred stock warrant	—	—	—	5,380	—	—	—	—	—	—	—	—
Exercise of common stock warrants	—	—	—	—	—	—	137,446	—	614	—	—	614
Conversion of convertible preferred stock into common stock upon initial public offering	(477,297)	(1,067)	(7,985,305)	(22,963)	(19,770,070)	(150,474)	28,232,672	3	174,501	—	—	174,504
Issuance of common stock for cash, net of issuance costs of $15,441	—	—	—	—	—	—	11,499,998	1	168,558	—	—	168,559
Cashless exercise of common stock warrants	—	—	—	—	—		178,847	—	—	—	—	—
Stock options exercised	—	—	—	—	—	—	2,236	—	2	—	—	2
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(28)	(28)
Stock-based compensation	—	—	—	—	—	—	—	—	557	—	—	557
Net loss	—	—	—	—	—	—	—	—	—	(92,257)	—	(92,257)
Balance as of September 30, 2021	—	$ —	—	$ —	—	$ —	40,470,323	$ 4	$ 352,606	$ (119,222)	$ (28)	$ 233,360

The accompanying notes are an integral part of these unaudited condensed financial statements.

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
Proceeds from issuance of common stock upon initial public offering, net of offering costs	—	168,559
Payment of deferred offering costs	(296)	—
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

The accompanying notes are an integral part of these unaudited condensed financial statements.

Acumen Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(unaudited)

NOTE 1. DESCRIPTION OF ORGANIZATION AND BUSINESS OPERATIONS

Acumen Pharmaceuticals, Inc. ("Acumen" or the "Company") was incorporated in 1996 in the state of Delaware. Acumen is a clinical-stage biopharmaceutical company developing a novel disease-modifying approach to target what the Company believes to be a key underlying cause of Alzheimer's disease ("AD"). Acumen's sole drug candidate, ACU193, is a humanized monoclonal antibody which selectively targets amyloid-beta oligomers.

The Company is subject to the uncertainty of whether the Company's intellectual property will develop into successful commercial products.

June 2021 Reverse Stock Split

The Company's Board of Directors ("Board") approved a reverse split of shares of the Company's common stock and convertible preferred stock on a 1-for-1.49 basis (the "June 2021 Reverse Stock Split"), which was effected on June 23, 2021. The par value and the number of authorized shares of the convertible preferred stock and common stock were not adjusted in connection with the June 2021 Reverse Stock Split. All references to common stock, convertible preferred stock, warrants to purchase common stock, warrants to purchase convertible preferred stock, options to purchase common stock, share data, per share data and related information contained in the financial statements have been retrospectively adjusted to reflect the effect of the June 2021 Reverse Stock Split for all periods presented. No fractional shares of the Company's common stock were issued in connection with the June 2021 Reverse Stock Split. Any fractional share resulting from the June 2021 Reverse Stock Split was rounded down to the nearest whole share, and any stockholder entitled to a fractional share as a result of the June 2021 Reverse Stock Split received a cash payment in lieu of receiving fractional shares.

Initial Public Offering

On July 6, 2021, the Company issued 9,999,999 shares of common stock in an initial public offering ("IPO"), and on July 8, 2021, the Company issued an additional 1,499,999 shares of common stock that were purchased by the underwriters pursuant to the underwriters' option to purchase additional shares at the public offering price less underwriting discounts and commissions. The price to the public for each share was $16.00. The aggregate net proceeds from the Company's IPO, after underwriting discounts and commissions and other offering expenses of $15.4 million, were $168.6 million.

On July 6, 2021, in connection with the closing of the IPO, 477,297 shares of Series A, 7,985,305 shares of Series A-1, and 19,770,070 shares of Series B convertible preferred stock, respectively, automatically converted into an equal number of shares of common stock. Warrants to purchase shares of common stock were automatically net exercised for the purchase of an aggregate of 178,847 shares of common stock.

As a result of the IPO, the underwriters' exercise of their option, the conversions of the Series A, A-1 and B convertible preferred stock, and the exercise of the warrants, the Company's total number of outstanding common stock increased by 39,911,517 shares immediately following the closing of the IPO.

Liquidity and Capital Resources

The Company has incurred operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of September 30, 2022 and December 31, 2021, the Company had an accumulated deficit of $157.6 million and $127.6 million, respectively, and working capital of $195.9 million and $193.5 million, respectively. Management believes that the Company has sufficient cash to continue operating activities for beyond 12 months from issuance of these condensed financial statements.

Future capital requirements will depend upon many factors, including the timing and extent of spending on research and development and market acceptance of the Company's products. The Company may need to obtain additional financing to complete clinical trials and launch and commercialize any product candidates for which it receives regulatory approval. Until such time, if ever, the Company can generate revenue sufficient to achieve profitability, the Company expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of its stockholders will be diluted, and the terms of these securities may include liquidation of other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. The Company may be required to delay, limit, reduce or terminate its product discovery and development activities or future commercialization efforts.

Acumen Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(unaudited)

The Company initiated a Phase 1 clinical trial of ACU193 in 2021, which the Company named "INTERCEPT-AD." In October 2021, the Company announced the initial dosing of the first patient in the INTERCEPT-AD trial and the subsequent successful sentinel safety review of the first two patients. In October 2022, the U.S. Food and Drug Administration granted Fast Track designation for ACU193 for the treatment of early AD. Due to delays in clinical trial site activation and patient enrollment that the Company believes were principally related to effects of the coronavirus ("COVID-19") pandemic, the Company expanded the anticipated number of trial sites to support its enrollment objectives and anticipated timelines. As of November 11, 2022, 17 clinical trial sites have been activated and patient recruitment and enrollment is ongoing and progressing. The Company anticipates completing enrollment in INTERCEPT-AD in the first quarter of 2023. The Company's business, results of operations, financial position and cash flows will depend on future developments, including the duration and spread of the COVID-19 outbreak and related advisories and restrictions. The impact of the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine and related sanctions against Russia, inflation and rising interest rates on the financial markets and the overall economy are highly uncertain and cannot be predicted.

NOTE 2. BASIS OF PRESENTATION, SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND RECENT ACCOUNTING PRONOUNCEMENTS

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with Generally Accepted Accounting Principles in the United States of America ("U.S. GAAP") for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. In the opinion of management, the unaudited condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and note disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These unaudited condensed financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

A description of the Company's significant accounting policies is included in the Company's Annual Report. Other than as described below, there have been no material changes in the Company's significant accounting policies to those previously disclosed in the Company's Annual Report.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements, as well as the reported amounts of expenses during the reporting periods. These estimates and assumptions are based on the Company's historical experience, and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Reclassifications

Certain prior year amounts have been reclassified for consistency with the current period presentation. Interest income and interest expense are combined into one line item and presented net in the condensed statements of operations and comprehensive loss, whereas these line items were previously presented separately. Similarly, in the condensed statements of cash flows, amortization of premiums and accretion of discounts on marketable securities are now presented net, but previously had been presented on separate rows as amortization of premiums and non-cash interest income from marketable securities. These reclassifications had no effect on the reported results of operations.

Acumen Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(unaudited)

Leases

The Company accounts for its leases under Accounting Standards Codification ("ASC") 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the condensed consolidated balance sheet as both a right-of-use asset and a lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and right-of-use assets are amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset results in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred and not included in the measurement of right-of-use assets and lease liabilities.

ASC 842 provides practical expedients for an entity's ongoing accounting. In calculating right-of-use assets and lease liabilities, the Company has elected to combine lease and non-lease components. Additionally, the Company has elected to apply the practical expedient related to short-term leases (i.e., leases having initial terms of 12 months or less at commencement date) as an accounting policy election. For short-term leases, the Company will not recognize a right-of-use asset or lease liability, but instead will recognize lease payments as an expense on a straight-line basis over the lease term.

Recently Adopted Accounting Pronouncements

ASC 842 requires lessees to recognize the liabilities related to all leases, including operating leases, with a term greater than 12 months on the balance sheet and also requires lessees and lessors to disclose key information about their leasing transactions. The Company adopted this guidance on January 1, 2022, using the modified retrospective method and the Company elected the package of practical expedients upon transition, which retained the lease classification for leases that existed prior to the adoption of this guidance. The Company recorded both a right-of-use asset and a lease liability of approximately $0.2 million on its condensed balance sheet upon the adoption of ASC 842.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. The Company adopted this guidance on January 1, 2022 with no material impact to the Company's financial statements upon adoption.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which was codified with its subsequent amendments as ASC 326. ASC 326 seeks to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments, including trade receivables, and other commitments to extend credit held by a reporting entity at each reporting date. The amendments require an entity to replace the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects current expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The updated guidance is effective for the Company for annual reporting periods beginning after December 15, 2022, and early adoption is permitted. The Company's marketable securities portfolio consists entirely of available-for-sale debt securities and, as such, it does not expect this guidance to have a material impact on its financial statements and disclosures upon adoption.

Acumen Pharmaceuticals, Inc.
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NOTE 3. MARKETABLE SECURITIES

Marketable securities consisted of the following as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale securities, short-term				
Corporate debt securities	$ 16,531	$ —	$ (369)	$16,162
Asset-backed securities	3,008	—	(120)	2,888
U.S. treasury securities	24,080	—	(476)	23,604
Total available-for-sale securities, short-term	43,619	—	(965)	42,654
Total available-for-sale securities	$ 43,619	$ —	$ (965)	$42,654

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale securities, short-term				
Commercial paper	$ 47,939	$ —	$ —	$ 47,939
Corporate debt securities	7,992	—	(11)	7,981
Asset-backed securities	16,177	—	(22)	16,155
Total available-for-sale securities, short-term	72,108	—	(33)	72,075
Available-for-sale securities, long-term				
Corporate debt securities	16,816	—	(103)	16,713
Asset-backed securities	3,013	—	(25)	2,988
U.S. treasury securities	11,988	—	(70)	11,918
Total available-for-sale securities, long-term	31,817	—	(198)	31,619
Total available-for-sale securities	$103,925	$ —	$ (231)	$103,694

As of September 30, 2022, the Company's available-for-sale securities were all classified as short-term and mature in one year or less. Certain of the Company's available-for-sale marketable securities that were in an unrealized loss position as of September 30, 2022 have been in a loss position for approximately twelve months; however unrealized losses on available-for-sale securities as of September 30, 2022 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Accordingly, no other-than-temporary impairment was recorded for the three and nine months ended September 30, 2022. The Company does not intend to sell these securities and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

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NOTE 4. FAIR VALUE MEASUREMENTS

The Company's financial assets and liabilities subject to fair value measurement on a recurring basis and the level of inputs used for such measurements were as follows (in thousands):

	Fair value measurements at reporting date using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value at September 30, 2022
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 156,540	$ —	$ —	$ 156,540
Marketable securities				
Corporate debt securities	—	16,162	—	16,162
Asset-backed securities	—	2,888	—	2,888
U.S. treasury securities	—	23,604	—	23,604
Total fair value	$ 156,540	$ 42,654	$ —	$ 199,194

	Fair value measurements at reporting date using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value at December 31, 2021
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 121,162	$ —	$ —	$ 121,162
Marketable securities				
Commercial paper	—	47,939	—	47,939
Corporate debt securities	—	24,694	—	24,694
Asset-backed securities	—	19,143	—	19,143
U.S. treasury securities	—	11,918	—	11,918
Total fair value	$ 121,162	$ 103,694	$ —	$ 224,856

The carrying values reported in the Company's condensed balance sheets for cash (excluding cash equivalents which are recorded at fair value on a recurring basis), accounts payable and accrued expenses are reasonable estimates of their fair values due to the short-term nature of these items.

The fair value of the Company's money market funds is determined using quoted market prices in active markets for identical assets.

The fair value for the available-for-sale marketable securities is determined based on valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets or liabilities, yield curve, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, broker and dealer quotes, as well as other relevant economic measures.

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NOTE 5. SUPPLEMENTAL FINANCIAL INFORMATION

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Prepaid insurance	$ 1,666	$ 1,514
Prepaid raw materials	201	83
Research and development service agreements	172	2,591
Dues and subscriptions	121	96
Other	206	140
Total prepaid expenses and other current assets	$ 2,366	$ 4,424

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Research and development	$ 2,837	$ 2,623
Compensation and other employee liabilities	1,455	1,102
Legal	67	130
Other	37	204
Total accrued expenses and other current liabilities	$ 4,396	$ 4,059

NOTE 6. STOCKHOLDERS' EQUITY

Authorized Shares

The total number of shares of all classes of capital stock authorized to be issued is 310,000,000, with 10,000,000 shares designated as preferred stock with a par value of $0.0001, and 300,000,000 shares designated as common stock with a par value of $0.0001.

Common Stock

As of September 30, 2022, the Company's Amended and Restated Certificate of Incorporation authorized the issuance of 300,000,000 shares of common stock, $0.0001 par value per share. Each share of common stock is entitled to one voting right.

Shelf Registration and At-The-Market Equity Offering

On July 1, 2022, the Company filed a shelf registration statement on Form S-3 (the "Registration Statement"). Pursuant to the Registration Statement, the Company may offer and sell securities having an aggregate public offering price of up to $200.0 million. In connection with the filing of the Registration Statement, the Company also entered into a sales agreement with BofA Securities, Inc. and Stifel, Nicolaus & Company, Incorporated (the "Sales Agents"), as sales agents, pursuant to which the Company may issue and sell shares of its common stock for an aggregate offering price of up to $50.0 million under an at-the-market offering program (the "ATM"), which is included in the $200.0 million of securities that may be offered pursuant to the Registration Statement. Pursuant to the ATM, the Company will pay the Sales Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. The Company is not obligated to make any sales of shares of its common stock under the ATM. The Company had not sold any shares of its common stock under the ATM as of September 30, 2022.

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NOTE 7. STOCK-BASED COMPENSATION

2021 Equity Incentive Plan

The 2021 Equity Incentive Plan (the "2021 Plan"), which provides for the grant of incentive stock options to employees, and the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors and consultants, became effective on June 30, 2021. The 2021 Plan is a successor to the Company's Amended and Restated Stock Performance Plan that was adopted by the Board and stockholders on April 8, 2013 (as amended from time to time, most recently on November 20, 2020, the "2013 Plan"). Following the effectiveness of the 2021 Plan, no further grants may be made under the 2013 Plan; however, any outstanding equity awards granted under the 2013 Plan continue to be governed by the terms of the 2013 Plan.

Initially, the maximum number of shares of the Company's common stock that may be issued under the 2021 Plan was 7,698,282 shares, which is the sum of (1) 3,550,000 new shares, plus (2) 667,104 shares that remained available for issuance under the Company's 2013 Plan at the time the 2021 Plan became effective, plus (3) any shares subject to outstanding stock options or other stock awards that were granted under the 2013 Plan that, on or after the 2021 Plan became effective, terminate or expire prior to exercise or settlement, are settled in cash, are forfeited or repurchased because of the failure to vest, or are reacquired or withheld to satisfy a tax withholding obligation or the purchase or exercise price in accordance with the terms of the 2013 Plan. In addition, the number of shares of the Company's common stock reserved for issuance under the 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to 5% of the total number of shares of the Company's common stock outstanding on December 31 of the fiscal year before the date of each automatic increase, or a lesser number of shares determined by the Board prior to the applicable January 1. On January 1, 2022, the Board increased the number of shares of common stock reserved for issuance under the 2021 Plan by 2,023,663 shares.

The maximum number of shares of the Company's common stock that may be issued upon the exercise of incentive stock options under the 2021 Plan is 12,000,000. As of September 30, 2022, 9,721,945 shares were authorized for issuance under the 2021 Plan and 4,030,960 shares remained available for issuance under the 2021 Plan.

Stock Options

The Black-Scholes option-pricing model was used to estimate the fair value of stock options granted during the nine months ended September 30, 2022 and 2021 with the following weighted average assumptions:

	Nine Months Ended September 30,	
	2022	2021
Risk-free interest rate	1.71% - 4.17%	0.4% - 1.1%
Expected term (in years)	5.8 - 6.1	5.3 - 6.1
Expected volatility	90%	90%
Expected dividend yield	0%	0%

The weighted average grant date fair value of options granted during the nine months ended September 30, 2022 and 2021, was $3.77 per share and $1.34 per share, respectively.

Prior to the Company's IPO, the fair value of the Company's common stock underlying the stock options was historically determined by the Board with assistance from management and, occasionally with input from an independent third-party valuation firm. For the year ended December 31, 2020, management engaged an independent third-party valuation firm to provide an estimate of the fair value of the Company's common stock, which was utilized as an input to the Company's Black-Scholes option pricing model for stock options awarded during the three months ended March 31, 2021. The December 31, 2020 fair value of common stock was determined considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry specific economic outlook. The fair value of the Company's common stock as of June 30, 2021 was estimated based upon the per share offering price of the Company's common stock to the public in its IPO which closed on July 6, 2021. The June 30, 2021 fair value for the Company's common stock was utilized as an input for options granted by the Company to its Board on June 30, 2021, which was immediately prior to the IPO. As of June 30, 2021 and December 31, 2020, management estimated the fair value of a share of common stock to be $16.00 and $0.83, respectively.

Stock options granted after December 31, 2017 vest monthly over a range of 12 to 36 months or vest monthly over a total of 48 months following a one-year cliff and all have a ten-year contractual term. Stock options granted prior to December 31, 2017 were either fully vested upon grant or generally vested monthly over a range of three to 24 months and have a ten-year term. The Company

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became publicly traded in July 2021 and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options has been determined using the "simplified" method for awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table reflects summarized stock option activity:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	3,835,618	$ 2.51		
Granted	1,932,050	$ 5.00		
Exercised	(31,848)	$ 0.86		
Forfeited	(79,872)	$ 6.35		
Outstanding at September 30, 2022	5,655,948	$ 3.31	8.3	$ 39,818
Vested and exercisable at September 30, 2022	2,084,736	$ 1.75	7.1	$ 17,772

As of September 30, 2022, total unrecognized compensation costs related to unvested stock option awards granted was approximately $9.4 million, which the Company expects to recognize over a weighted-average period of approximately 2.8 years.

The Company recorded stock-based compensation expense related to stock options in the following expense categories of its condensed statements of operations for the periods shown (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
General and administrative	$ 563	$ 254	$ 1,525	$ 412
Research and development	277	50	648	145
Total stock-based compensation	$ 840	$ 304	$ 2,173	$ 557

Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "ESPP"), which permits employees to purchase shares of the Company's common stock, became effective on June 30, 2021. A total of 375,000 shares of the Company's common stock were initially reserved for sale under the ESPP. The number of shares of the Company's common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 and through January 1, 2031, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on the last day of the fiscal year before the date of the automatic increase, and (2) 800,000 shares; provided that before the date of any such increase, the Board may determine that such increase will be less than the amount set forth in clauses (1) and (2). On January 1, 2022, the Board increased the number of shares of common stock reserved for issuance under the ESPP by 404,732 shares.

As of September 30, 2022, there are 779,732 shares authorized for issuance under the ESPP and there have been no purchases of shares under the ESPP.

NOTE 8. LEASES

The Company has been subleasing space in Indiana since March 1, 2020. The Company executed a new sublease for this space that was effective on February 1, 2021 and expires on August 30, 2023. The sublease does not provide the Company with any renewal options. The Company allows others to sublease a portion of the space from the Company for less than a one-year period.

On September 28, 2022, the Company entered into a lease for office space in Charlottesville, Virginia with a lease term of fifteen months beginning October 1, 2022. There is no automatic renewal, but any holdover tenancy shall be on a month-to-month basis thereafter.

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The following table summarizes quantitative information about the Company's operating leases for the period indicated (in thousands):

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Operating leases		
Operating lease cost	$ 38	$ 114
Less: sublease income	(12)	(44)
Operating lease expense	26	70
Short-term lease rent expense	1	11
Total rent expense	$ 27	$ 81

Supplemental information related to the Indiana lease was as follows (dollar amounts in thousands):

	Nine Months Ended September 30, 2022
Operating cash flows from operating leases	$ 114
Right-of-use assets obtained in exchange for operating lease liabilities	$ 233
Weighted-average remaining lease term – operating leases (in years)	0.9
Weighted-average discount rate – operating leases	10.0%

As of September 30, 2022, the present value of maturities of the Company's operating lease liabilities were as follows (in thousands):

Remaining period ended December 31, 2022	$ 39
Year ended December 31, 2023	102
Total	141
Less: present value discount	(8)
Operating lease liabilities	$133

The Company recognizes sublease income in other income (expense) on its condensed statements of operations and comprehensive loss. The Company expects to recognize approximately $3,000 in sublease income for the remainder of 2022.

Prior to the adoption of ASC 842, and for the three and nine months ended September 30, 2021, the Company recognized rent expense on a straight-line basis over the lease period and recorded deferred rent expense for rent expense incurred but not yet paid. During the three and nine months ended September 30, 2021, the Company recognized total rent expense of approximately $40,000 and $107,000, respectively, and recognized sublease income of approximately $19,000 and $47,000, respectively.

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Disclosures related to periods prior to adoption of ASC 842 included approximate future minimum rental payments due under the Company's leases as of December 31, 2021 as follows (in thousands):

Year ended December 31, 2022	$153
Year ended December 31, 2023	102
Total	$255

NOTE 9. COMMITMENTS AND CONTINGENCIES

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

NOTE 10. NET LOSS PER SHARE

The Company computes net loss per common share using the two-class method required for participating securities. Basic and diluted net loss per share was the same for each period presented as the inclusion of all potential common stock outstanding would have been anti-dilutive. Potentially dilutive securities not included in the calculation of diluted net loss per common share, because to do so would be anti-dilutive, include shares issuable upon the exercise of stock options of 5,655,948 and 3,662,365 for the nine months ended September 30, 2022 and 2021, respectively.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and in the audited financial statements and notes thereto as of and for the year ended December 31, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy, plans and objectives of management for future operations and the potential impact that the ongoing COVID-19 pandemic may have on our business, includes forward-looking statements that involve risks and uncertainties as described under the heading "Special Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q. You should review the disclosure under the heading "Risk Factors" in the Annual Report for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company developing a novel disease-modifying approach to target what we believe to be a key underlying cause of Alzheimer's Disease, or AD. Alzheimer's disease is a progressive neurodegenerative disease of the brain that leads to loss of memory and cognitive functions and ultimately results in death. Our scientific founders pioneered research on soluble amyloid-beta oligomers, or AßOs, which are globular assemblies of the Aß peptide that are distinct from Aß monomers and amyloid plaques. We are currently focused on advancing a targeted immunotherapy drug candidate, ACU193, through clinical proof of mechanism trials in early AD patients. We have confirmed that ACU193 is a consensus IgG2 subclass. We initiated a Phase 1 clinical trial of ACU193 in 2021, which we named "INTERCEPT-AD." This trial is enrolling patients with mild dementia or mild cognitive impairment due to AD, conditions referred to as "early AD." INTERCEPT-AD is a U.S.-based, multi-center, randomized, double-blind, placebo-controlled clinical trial with overlapping single ascending dose, or SAD, and multiple ascending dose, or MAD, cohorts involving a total of approximately 62 patients with early AD. The overall objective of the trial is to evaluate the safety and tolerability and establish clinical proof of mechanism of ACU193 administered intravenously. The primary trial endpoints are focused on safety and immunogenicity. An important safety measure will be the use of magnetic resonance imaging, or MRI, to assess the presence or absence of amyloid-related imaging abnormalities. Secondary endpoints include pharmacokinetics in plasma and cerebrospinal fluid, or CSF, and target engagement as evidenced by detection of ACU193 bound to AßOs in CSF. Clinical scales typically used in AD trials as well as computerized cognitive testing are included as exploratory measures. In October 2021, we announced the initial dosing of the first patient in the INTERCEPT-AD trial and the subsequent successful sentinel safety review of the first two patients. In October 2022, the U.S. Food and Drug Administration, or FDA, granted Fast Track designation for ACU193 for the treatment of early AD. Due to delays in clinical trial site activation and patient enrollment that we believe are principally related to the effects of the COVID-19 pandemic, we expanded the anticipated number of trial sites to support our enrollment objectives and anticipated timelines. As of November 11, 2022, 17 clinical trial sites have been activated, and patient recruitment and enrollment is ongoing and progressing. Based on current site activations and enrollment rates, we anticipate completing enrollment in INTERCEPT-AD in the first quarter of 2023 and reporting our topline data from the INTERCEPT-AD trial in the second half of 2023.

We have incurred net losses and negative cash flows from operations since our inception. Our net losses were $30.0 million and $92.3 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $157.6 million and working capital of $195.9 million. Our net losses and cash flows from operations may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of nonclinical studies, clinical trials and our expenditures on other research and development activities. We expect our expenses and operating losses will increase substantially for the foreseeable future as we advance ACU193 in clinical trials, seek to expand our product candidate portfolio through developing additional product candidates, grow our clinical, regulatory and quality capabilities, and incur additional costs associated with operating as a public company. It is likely that we will seek third-party collaborators for the future commercialization of ACU193 or any other product candidate that is approved for marketing. However, we may seek to commercialize our products at our own expense, which would require us to incur significant additional expenses for marketing, sales, manufacturing and distribution.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. However, global economic conditions have been worsening, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide, rising inflation and supply disruptions resulting from the effects of COVID-19, the ongoing conflict between Russia and Ukraine and related sanctions, and otherwise. If these conditions persist and deepen, we could experience an inability to access additional capital, or our liquidity could otherwise be impacted. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs and/or future commercialization efforts. Our failure to raise capital or enter into such agreements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition.

As of September 30, 2022, we had cash and cash equivalents and marketable securities totaling $200.2 million. Based on our current operating plan, we expect that our existing cash and cash equivalents and marketable securities will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

COVID-19 and Macroeconomic Update

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely. We implemented a work-from-home policy allowing employees and consultants who can work from home to do so.

Business travel has been limited, and online video and teleconference technology is used to meet virtually rather than in person. We have taken measures to secure our research and development activities, while work in laboratories by our partners has been organized to reduce risk of COVID-19 transmission.

In October 2021, we announced the initial dosing of the first patient in the INTERCEPT-AD trial and the subsequent successful sentinel safety review of the first two patients. In October 2022, the FDA granted Fast Track designation for ACU193 for the treatment of early AD. Due to delays in clinical trial site activation and patient enrollment that we believe were principally related to effects of the COVID-19 pandemic, we expanded the anticipated number of trial sites to support our enrollment objectives and anticipated timelines. However, we cannot assure that we will not experience additional delays in site activation or enrollment. As of November 11, 2022, 17 clinical trial sites have been activated and patient recruitment and enrollment is ongoing and progressing. Based on current site activations and enrollment rates, we anticipate completing enrollment in INTERCEPT-AD in the first quarter of 2023 and reporting our topline data from this trial in the second half of 2023.

The ultimate impact of the COVID-19 pandemic, geopolitical events such as the ongoing conflict between Russia and Ukraine and related sanctions, and macroeconomic events, including higher inflation and supply chain disruptions, on our business, results of operations, financial position and cash flows will depend on future developments, including the duration and spread of the outbreak and related advisories and restrictions. These developments and the impact on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our business, results of operations, financial position and cash flows may be materially adversely affected.

Components of Results of Operations

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and Development Expenses

Research and development costs primarily consist of direct costs associated with consultants and materials, biologic storage, third party, contract research organization costs and contract development and manufacturing expenses, salaries and other personnel-related expenses. Research and development costs are expensed as incurred. More specifically, these costs include:

- costs of funding research performed by third parties that conduct research and development and nonclinical and clinical activities on our behalf;

- costs of manufacturing drug supply and drug product;
- costs of conducting nonclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs related to compliance with clinical regulatory requirements; and employee-related expenses, including salaries, benefits and stock-based compensation expense for our research and development personnel.

As we currently only have one product candidate, ACU193, in development, we do not separately track expenses by program. We expect that our research and development expenses will increase substantially in connection with our clinical development activities for our ACU193 program.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other personnel related expenses, including stock-based compensation, as well as costs for insurance, professional fees for legal, consulting, accounting, auditing, tax and recruiting services, investor and public relations, board of directors' expenses, franchise taxes, meetings, travel and rent, among others.

We expect that our general and administrative expenses will increase as our organization and headcount needed in the future grows to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, attorneys and accountants, among other expenses. Additionally, we expect to incur increased expenses associated with being a public company, including costs of additional personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other Income (Expense)

Other income (expense) primarily includes interest income, net and other income, net. Following our initial public offering, or IPO, we made investments in marketable securities and the interest income earned, as well as the amortization and accretion of premiums and discounts are recorded in interest income, net. Other income, net generally consists of sublease income offset by fees incurred on our investments in marketable securities.

Prior to our IPO on July 6, 2021, changes in the fair values of the Series A-1 warrant liability and the Series B tranche rights were recognized as a component of other income (expense). The Series A-1 warrant liability and the Series B tranche rights were initially recorded at fair value as liabilities on our balance sheet. Each was subsequently re-measured at fair value at the end of each reporting period and also upon the exercise of the warrant on June 22, 2021, and upon settlement of the tranche rights with the milestone closing for the Series B on June 17, 2021.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		
	2022	2021	Change
Operating expenses			
Research and development	$ 8,309	$ 1,800	$ 6,509
General and administrative	3,062	2,135	927
Total operating expenses	11,371	3,935	7,436
Loss from operations	(11,371)	(3,935)	(7,436)
Other income (expense)			
Interest income, net	663	14	649
Other income, net	(2)	19	(21)
Total other income	661	33	628
Net loss	(10,710)	(3,902)	(6,808)
Other comprehensive loss			
Unrealized loss on marketable securities	—	(28)	28
Comprehensive loss	$ (10,710)	$ (3,930)	$(6,780)

Research and Development Expenses

Research and development expenses were $8.3 million and $1.8 million for the three months ended September 30, 2022 and 2021, respectively. The $6.5 million increase was primarily due to increases of $2.1 million in contract research organization, or CRO, costs, $1.7 million for materials, $1.2 million in additional personnel expense, $1.0 million in consulting costs and $0.4 million in drug safety testing, as well as increases in miscellaneous expenses totaling $0.1 million; all related to our ongoing clinical trial which was initiated in 2021 and nonclinical research and development activity.

General and Administrative Expenses

General and administrative expenses were $3.1 million and $2.1 million for the three months ended September 30, 2022 and 2021, respectively. The $0.9 million increase was primarily due to increases of $0.7 million in personnel expenses, $0.2 million in accounting costs, $0.2 million in marketing costs and $0.1 million for each of the following: recruiting and travel expenses. These increases were partially offset by reductions of $0.2 million in both insurance and consulting expenses.

Other Income (Expense)

Other income was $0.7 million for the three months ended September 30, 2022, which was primarily due to net interest income on the Company’s portfolio of marketable securities. Other income was de minimis for the three months ended September 30, 2021.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30, 2022	2021	Change
Operating expenses			
Research and development	$ 21,615	$ 6,632	$ 14,983
General and administrative	9,374	4,537	4,837
Total operating expenses	30,989	11,169	19,820
Loss from operations	(30,989)	(11,169)	(19,820)
Other income (expense)			
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	—	(81,157)	81,157
Interest income, net	1,000	22	978
Other income, net	(1)	47	(48)
Total other income (expense)	999	(81,088)	82,087
Net loss	(29,990)	(92,257)	62,267
Other comprehensive loss			
Unrealized loss on marketable securities	(734)	(28)	(706)
Comprehensive loss	$ (30,724)	$ (92,285)	$ 61,561

Research and Development Expenses

Research and development expenses were $21.6 million and $6.6 million for the nine months ended September 30, 2022 and 2021, respectively. The $15.0 million increase was primarily due to our ongoing clinical trial which was initiated in 2021 and nonclinical research and development activity, and includes increases of $4.2 million of CRO costs, $3.4 million in consulting costs, $3.0 million for materials, $2.7 million in personnel costs, and $1.5 million for drug safety testing, as well as $0.2 million for other miscellaneous expenses.

General and Administrative Expenses

General and administrative expenses were $9.4 million and $4.5 million for the nine months ended September 30, 2022 and 2021, respectively. The $4.8 million increase was primarily due to increases of $2.1 million in personnel costs, $1.3 million in insurance costs, $0.5 million in legal costs, $0.4 million in marketing costs, $0.2 million for each of the following: travel expenses and recruiting costs, and $0.1 million for other miscellaneous expense.

Other Income (Expense)

Other income was $1.0 million for the nine months ended September 30, 2022, which was due to net interest income on the Company's portfolio of marketable securities. Other expense was $81.1 million for the nine months ended September 30, 2021, primarily due to increases in the fair values of the Series B tranche liability and Series A-1 warrant liability of $76.2 million and $5.0 million, respectively.

Liquidity and Capital Resources

On July 6, 2021, we issued 9,999,999 shares of common stock in our IPO, and on July 8, 2021, we issued an additional 1,499,999 shares of common stock that were purchased by the underwriters pursuant to the underwriters' option to purchase additional shares at the public offering price less underwriting discounts and commissions. The price to the public for each share was $16.00. The aggregate net proceeds from our IPO, after underwriting discounts and commissions and other offering expenses of $15.4 million, were $168.6 million.

As of September 30, 2022, our cash and cash equivalents and marketable securities totaled $200.2 million. Our available-for-sale marketable securities mature over the next 12 months. Based on our current operating plan, we expect that our existing cash and cash equivalents and marketable securities will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through 2025.

We enter into contracts in the normal course of business with CROs and contract manufacturing organizations, or CMOs, for clinical trials, nonclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments and are generally cancelable by us upon prior notice of 30 days. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

Future minimum lease payments under our Indiana lease agreement total approximately $0.1 million.

Shelf Registration and At-The-Market Equity Offering

On July 1, 2022, we filed a shelf registration statement on Form S-3, or the Registration Statement. Pursuant to the Registration Statement, we may offer and sell securities having an aggregate public offering price of up to $200.0 million. In connection with the filing of the Registration Statement, we also entered into a sales agreement with BofA Securities, Inc. and Stifel, Nicolaus & Company, Incorporated, or the Sales Agents, pursuant to which we may issue and sell shares of our common stock for an aggregate offering price of up to $50.0 million under an at-the-market offering program, or ATM, which is included in the $200.0 million of securities that may be offered pursuant to the Registration Statement. Pursuant to the ATM, we will pay the Sales Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of our common stock. We are not obligated to make any sales of shares of our common stock under the ATM. We had not sold any shares of our common stock under the ATM as of September 30, 2022.

Cash Flows

The following table summarizes our sources and uses of cash (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$ (23,950)	$ (14,322)
Net cash provided by (used in) investing activities	59,605	(94,109)
Net cash provided by (used in) financing activities	(277)	200,456
Net change in cash and cash equivalents	$ 35,378	$ 92,025

Operating Activities

Net cash used in operating activities was $24.0 million and $14.3 million for the nine months ended September 30, 2022 and 2021, respectively. Net cash used in operating activities during the nine months ended September 30, 2022 primarily consisted of our net loss of $30.0 million, which was reduced by non-cash adjustments of $2.2 million for stock-based compensation, $0.6 million for net accretion and amortization on marketable securities, and $0.1 million of amortization on our right-of-use asset, plus cash provided of $2.1 million by prepaid expenses mainly associated with research and development and insurance and cash provided by accounts payable of $1.0 million and $0.3 million from accrued expenses and other current liabilities mainly due to research and development liabilities, partially offset by cash used of $0.1 million each for other assets and our operating lease.

Net cash used in operating activities during the nine months ended September 30, 2021 primarily consisted of our net loss of $92.3 million, which was reduced by non-cash adjustments of $81.2 million related to the change in the fair values of the Series B tranche liability and the Series A-1 warrant liability, and $0.6 million for stock-based compensation, plus cash provided of $0.7 million from accrued expenses and other current liabilities, offset by cash used of $4.3 million for prepaid expenses associated with ongoing research and development activities as we commenced our clinical trial, as well as costs associated with the transition from a private to a public company and insurance costs.

Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2022 was $59.6 million and was primarily related to maturities and sales of marketable securities of $71.9 million, partially offset by purchases of marketable securities and property and equipment of $12.1 million and $0.1 million, respectively.

Cash used in investing activities for the nine months ended September 30, 2021 was $94.1 million and was predominantly related to the purchase of marketable securities, but also included nominal purchases of computer hardware.

Financing Activities

Net cash used in financing activities was $0.3 million for the nine months ended September 30, 2022 and was primarily due to payment of deferred offering costs related to the Registration Statement, which were partially offset by proceeds from stock option exercises.

Net cash provided by financing activities was $200.5 million for the nine months ended September 30, 2021 and was primarily due to our IPO for net proceeds of $168.6 million, the closing of the second tranche of our Series B convertible preferred stock for gross proceeds of $30.0 million, plus a total of $1.3 million received from the exercise of the Series A-1 preferred warrant, as well as proceeds from exercises of common stock warrants of $0.6 million.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development, conduct clinical trials, and seek marketing approval for our current and any of our future product candidates. Furthermore, we have and expect to incur additional costs associated with operating as a public company following our July 2021 IPO. It is likely that we will seek third-party collaborators for the future commercialization of ACU193 or any other product candidate that is approved for marketing. However, we may seek to commercialize our products at our own expense, which would require us to incur significant additional expenses for marketing, sales, manufacturing and distribution, which costs we may seek to offset through entry into collaboration agreements with third parties. As a result, we expect that we will need to obtain substantial additional funding in connection with our future operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Based on our current operating plan, we expect that our existing cash and cash equivalents and marketable securities will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through 2025. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of discovery, nonclinical development, laboratory testing and clinical trials for other potential product candidates we may develop, if any;
- the costs, timing and outcome of regulatory review of ACU193 or any future product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of ACU193 or any future product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of ACU193 or any future product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our longer-term cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect rights as a common stockholder. Any debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies, Significant Judgments and Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements and the reported amounts of expenses during the reporting period. A description of our significant accounting policies is included in our Annual Report. Please read the unaudited condensed financial statements in conjunction with our audited financial statements and accompanying notes in our Annual Report.

Our critical accounting policies that require significant judgments and estimates are more fully described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies, Significant Judgments and Use of Estimates” in our Annual Report and in Note 2 to our audited financial statements contained in our Annual Report. There have been no significant changes to our critical accounting policies that require significant judgments and estimates from those disclosed in our Annual Report.

Recent Accounting Pronouncements

Information regarding recent accounting pronouncements applicable to us, adopted and not yet adopted as of the date of this report, is included in Note 2 to our unaudited condensed financial statements located in “Part I – Financial Information, Item 1. Financial Statements” in this Quarterly Report on Form 10-Q.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We elected the extended transition period for complying with new or revised accounting standards, which delays the adoption of these accounting standards until they would apply to private companies.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on financial statements.

We may take advantage of these provisions until we no longer qualify as an emerging growth company. We will cease to qualify as an emerging growth company on the date that is the earliest of: (i) December 31, 2025, (ii) the last day of the fiscal year in which we have more than $1.235 billion in total annual gross revenues, (iii) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, or (iv) the date on which we have issued more than $1.0 billion of non-convertible debt over the prior three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. We have taken advantage of certain reduced reporting requirements in this Quarterly Report on Form 10-Q and our other filings with the SEC. Accordingly, the information contained herein may be different than you might obtain from other public companies in which you hold equity interests.

We are also a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either: (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide the information required by this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2022. Based on the evaluation of our disclosure controls and procedures, our management concluded that, as of September 30, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was: (a) reported within the time periods specified by SEC rules and regulations, and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, that occurred during the fiscal quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and trading price of our securities. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors described in Part I, Item 1A. “Risk Factors” of our Annual Report.

The FDA granted Fast Track designation for ACU193 for the treatment of early Alzheimer’s disease, and we may seek Fast Track designation for other product candidates. Even if received, Fast Track designation may not actually lead to a faster review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

The FDA granted Fast Track designation for ACU193 for the treatment of early Alzheimer’s disease, and we may seek Fast Track designation for our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. There is no assurance that the FDA will grant this status to any of our other product candidates. If granted, Fast Track designation makes a product eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of product candidates with Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation at any time if it believes that the designation is no longer supported by data from our clinical development program.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (i) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (ii) expanded the entities eligible for discounts under the 340B drug pricing program; (iii) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP; (iv) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new eligibility categories for individuals with income at or below 133% (as calculated, it constitutes 138%) of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability; (v) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated

for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (vi) introduced a new Medicare Part D coverage gap discount program in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (increased from 50%, effective January 1, 2019, pursuant to the Bipartisan Budget Act of 2018); (vii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (viii) established the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (the Tax Act) included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is also unclear how any additional healthcare reform measures of the Biden administration will impact the ACA or our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018 and the Infrastructure Investment and Jobs Act, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. It is unclear whether these or similar policy initiatives will be implemented in the future.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for ACU193 or any other product candidate we may develop. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products, and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of ACU193 or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds

On June 30, 2021, our Registration Statement on Form S-1, as amended (File No. 333-256945), was declared effective in connection with our initial public offering, pursuant to which we sold an aggregate of 11,499,998 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share. BofA Securities, Inc, Credit Suisse Securities (USA) LLC, and Stifel, Nicolaus & Company, Incorporated acted as joint lead book-running managers and UBS Securities LLC also acted as a book-running manager for the offering.

The initial public offering closed on July 6, 2021 with respect to 9,999,999 shares of common stock. On July 8, 2021, the offering closed with respect to an additional 1,499,999 shares purchased by the underwriters pursuant to the underwriters' option to purchase additional shares. The aggregate net proceeds from our initial public offering, after underwriting discounts and commissions, and other offering expenses of $15.4 million, were $168.6 million. In connection with our initial public offering, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 2, 2021.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40551), filed with the Securities and Exchange Commission on July 7, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-40551), filed with the Securities and Exchange Commission on July 7, 2021).
10.1	Sales Agreement, dated as of July 1, 2022, by and among the Company, BofA Securities, Inc. and Stifel, Nicolaus & Company, Incorporated (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 (File No. 333-266004), filed with the Securities and Exchange Commission on July 1, 2022.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Incline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

\# These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ACUMEN PHARMACEUTICALS, INC.

Date: November 14, 2022

By: /s/ Daniel O'Connell

Daniel O'Connell
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2022

By: /s/ Matthew Zuga

Matthew Zuga
Chief Financial Officer and Chief Business Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel O'Connell, certify that:

1. I have reviewed this Form 10-Q of Acumen Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: /s/ Daniel O'Connell

Daniel O'Connell
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Zuga, certify that:

1. I have reviewed this Form 10-Q of Acumen Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: /s/ Matthew Zuga

Matthew Zuga
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Daniel O'Connell, Chief Executive Officer of Acumen Pharmaceuticals, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

By: /s/ Daniel O'Connell

Daniel O'Connell
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Matthew Zuga, Chief Financial Officer of Acumen Pharmaceuticals, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, to which this Certification is attached as Exhibit 32.2 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

By: /s/ Matthew Zuga

Matthew Zuga
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)