Table of Contents

Table of Contents

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 June 30, 2021

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 August 13, 2021, the registrant had 40,468,087 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

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 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 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 conduct clinical trials of ACU193, and for the manufacture of ACU193 for nonclinical studies and clinical trials;
- 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;
- the scope of protection 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 financial performance;

- the effects of the ongoing COVID-19 pandemic; 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” and elsewhere in 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 Securities and Exchange Commission, webcasts, press releases and conference calls.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Acumen Pharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 68,812	$ 43,777
Grant receivable	109	109
Prepaid expenses and other current assets	1,651	543
Total current assets	70,572	44,429
Property and equipment, net	6	—
Deferred offering costs	2,352	—
Other assets	13	—
Total assets	$ 72,943	$ 44,429
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 2,907	$ 531
Accrued expenses and other current liabilities	1,611	423
Preferred stock tranche rights liability	—	5,033
Preferred stock warrant liability	—	380
Total liabilities	4,518	6,367
Series A convertible preferred stock, $0.0001 par value; 711,203 shares authorized as of June 30, 2021 and December 31, 2020; 477,297 shares issued and outstanding as of June 30, 2021 and December 31, 2020; liquidation preference of $1,067 as of June 30, 2021	1,067	1,067
Series A-1 convertible preferred stock, $0.0001 par value; 11,898,177 shares authorized as of June 30, 2021 and December 31, 2020; 7,985,305 and 7,537,879 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively; liquidation preference of $18,097 as of June 30, 2021	22,963	16,333
Series B convertible preferred stock, $0.0001 par value; 29,457,450 shares authorized as of June 30, 2021 and December 31, 2020; 19,770,070 and 11,862,043 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively; liquidation preference of $75,116 as of June 30, 2021	150,474	39,253
Stockholders' deficit		
Common stock, $0.0001 par value; 50,500,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 556,570 and 419,124 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	—	—
Additional paid-in capital	9,241	8,374
Accumulated deficit	(115,320)	(26,965)
Total stockholders' deficit	(106,079)	(18,591)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 72,943	$ 44,429

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Grant and other revenue	$ —	$ 151	$ —	$ 377
Operating expenses				
Research and development	2,254	1,927	4,832	3,977
General and administrative	1,187	259	2,402	481
Total operating expenses	3,441	2,186	7,234	4,458
Loss from operations	(3,441)	(2,035)	(7,234)	(4,081)
Other income (expense)				
Interest income	4	—	8	1
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	(57,940)	—	(81,157)	—
Other income	19	—	28	—
Total other income (expense)	(57,917)	—	(81,121)	1
Net loss attributable to common stockholders	$ (61,358)	$ (2,035)	$ (88,355)	$ (4,080)
Net loss per common share, basic and diluted	$ (141.93)	$ (4.86)	$ (207.52)	$ (9.73)
Weighted-average shares outstanding, basic and diluted	432,325	419,124	425,761	419,124

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' Deficit
(in thousands, except share data)
(Unaudited)

Three Months Ended June 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	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of March 31, 2021	477,297	$ 1,067	7,537,879	$ 16,333	11,862,043	$ 39,253	419,124	$ —	$ 8,500	$ (53,962)	$ (45,462)
Share-based compensation	—	—	—	—	—	—	—	—	127	—	127
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
Net loss	—	—	—	—	—	—	—	—	—	(61,358)	(61,358)
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)

Three Months Ended June 30, 2020

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of March 31, 2020	477,297	$ 1,067	7,537,879	$ 16,333	—	$ —	419,124	$ —	$ 8,259	$ (21,685)	$ (13,426)
Share-based compensation	—	—	—	—	—	—	—	—	38	—	38
Net loss	—	—	—	—	—	—	—	—	—	(2,035)	(2,035)
Balance as of June 30, 2020	477,297	$ 1,067	7,537,879	$ 16,333	—	$ —	419,124	$ —	$ 8,297	$ (23,720)	$ (15,423)

Six Months Ended June 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	Total Stockholders' 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)
Share-based compensation	—	—	—	—	—	—	—	—	253	—	253
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
Net loss	—	—	—	—	—	—	—	—	—	(88,355)	(88,355)
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)

Six Months Ended June 30, 2020

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2019	477,297	$ 1,067	7,537,879	$ 16,333	—	$ —	419,124	$ —	$ 8,220	$ (19,640)	$ (11,420)
Share-based compensation	—	—	—	—	—	—	—	—	77	—	77
Net loss	—	—	—	—	—	—	—	—	—	(4,080)	(4,080)
Balance as of June 30, 2020	477,297	$ 1,067	7,537,879	$ 16,333	—	$ —	419,124	$ —	$ 8,297	$ (23,720)	$ (15,423)

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

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

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (88,355)	$ (4,080)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	81,157	—
Stock-based compensation expense	253	77
Changes in operating assets and liabilities:		
Grant receivable	—	30
Prepaid expenses and other current assets	(1,108)	406
Other assets	(13)	(270)
Accounts payable	741	380
Accrued expenses and other current liabilities	691	147
Net cash used in operating activities	(6,634)	(3,310)
Cash flows from investing activities		
Purchase of fixed assets	(6)	—
Net cash used in investing activities	(6)	—
Cash flows from financing activities		
Proceeds from issuance of Series B milestone shares, net of issuance costs	30,031	—
Proceeds from exercise of Series A-1 warrant	1,250	—
Proceeds from exercise of common stock warrants	614	—
Payments for deferred offering costs	(220)	—
Net cash provided by financing activities	31,675	—
Net change in cash and cash equivalents	25,035	(3,310)
Cash and cash equivalents, at the beginning of the period	43,777	6,552
Cash and cash equivalents, at the end of the period	$ 68,812	$ 3,242
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ —	$ —
Supplemental disclosure of noncash financing activities		
Reclassification of preferred stock tranche rights liability upon share issuance	$ 81,190	$ —
Reclassification of warrant liability upon exercise of preferred stock warrant	$ 5,380	$ —
Deferred offering costs in accounts payable	$ 1,635	$ —
Deferred offering costs in accrued expenses and other current liabilities	$ 497	$ —

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 discovers and develops targeted therapies for the treatment of Alzheimer's disease. Acumen's lead drug candidate, ACU193, is a humanized monoclonal antibody which selectively targets amyloid-beta oligomers ("AßOs"). Acumen and Merck & Co. discovered and developed ACU193 through an eight-year research collaboration. Acumen currently holds exclusive rights to the program. The Company submitted an Investigation Drug Application ("IND") for ACU193 to the Food and Drug Administration ("FDA") in the fourth quarter of 2020. We initiated a Phase 1 clinical trial of ACU193 in patients with early Alzheimer's disease in April 2021.

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

November 2020 Reverse Stock Split

On November 20, 2020, the Company effected a 1-for-30 reverse stock split of its authorized, issued and outstanding shares of common stock and convertible preferred stock. Accordingly, all share and per share amounts for the periods presented in the accompanying financial statements and these notes have been adjusted retroactively, where applicable, to reflect this reverse stock split. On November 20, 2020, the Company also increased the number of shares of preferred stock and common stock authorized for issuance (see Note 5).

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 will receive 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 and 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 shares increased by 39,911,517 immediately following the closing of the IPO. See Note 9 for further information regarding subsequent events.

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

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 June 30, 2021 and December 31, 2020, the Company had an accumulated deficit of $115.3 million and $27.0 million, respectively, and working capital of $66.1 million and $38.1 million, respectively. The Company has historically relied on raising capital from venture capital firms and private investors and funding from a government grant to finance its operations.

On June 9, 2021, the Board and the holders of more than 67% of the then outstanding shares of Series B convertible preferred stock held by the Series B purchasers (the "Requisite Investors") elected to waive the achievement of the milestone subject to the terms and conditions of the Series B Preferred Stock Purchase Agreement (the "Series B Agreement") and consummate the subsequent closing (the "Milestone Closing") (see Note 4). On June 17, 2021, the Milestone Closing for the Series B convertible preferred stock occurred, resulting in the sale of 7,908,027 shares of Series B convertible preferred stock at $3.80 per share for gross proceeds of $30.0 million.

As a result of the Milestone Closing and the closing of the Company's IPO on July 6, 2021, management believes that its existing financial resources are sufficient to continue operating activities at least through 2024. 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.

The impact of the coronavirus ("COVID-19") outbreak on the Company's 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 of COVID-19 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, the Company's results of operations, financial position and cash flows may be materially adversely affected.

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

Basis of Presentation

The accompanying 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 and 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 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 condensed financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

Emerging Growth Company

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's condensed financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended, the Company meets the definition of an emerging growth company and has 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.

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

Use of Estimates

The preparation of condensed 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 condensed financial statements and the reported amounts of expenses during the reporting period. These estimates and assumptions are based on current facts and historical experience, as well as other pertinent industry and regulatory authority information, including the potential future effects of COVID-19, 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 materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company's cash equivalents consist of funds held in a money market account. The Company had $36.8 million in cash equivalents as of both June 30, 2021 and December 31, 2020.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality. The Company has not experienced any losses on these deposits.

Fair Value of Financial Instruments

The Company's financial assets and liabilities are accounted for in accordance with Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosure*s, which defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs when measuring fair value and classifies those inputs into three levels:

Level 1— Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the instrument's anticipated life.

Level 3—Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgement. Accordingly, the degree of judgement exercised by management in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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

The following tables present the Company's fair value hierarchy for its money market securities, preferred stock tranche rights liability and preferred stock warrant liability measured at fair value on a recurring basis (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 June 30, 2021
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 36,766	$ —	$ —	$ 36,766
Total fair value	$ 36,766	$ —	$ —	$ 36,766

	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, 2020
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 36,758	$ —	$ —	$ 36,758
Total fair value	$ 36,758	$ —	$ —	$ 36,758
Liabilities included in:				
Preferred stock tranche rights liability	$ —	$ —	$ 5,033	$ 5,033
Preferred stock warrant liability	—	—	380	380
Total fair value	$ —	$ —	$ 5,413	$ 5,413

The carrying values reported in the Company's condensed balance sheets for cash and cash equivalents, accounts payable, and accrued expenses are reasonable estimates of their fair values due to the short-term nature of these items.

Refer to Note 4 for further information about the Level 3 rollforward of activity and Level 3 inputs.

Grant Receivable

Grant receivable consists of research expenses reimbursable under a grant from the National Institute of Health ("NIH"). The Company carries its grant receivable at the unreimbursed amount. On a periodic basis, the Company evaluates its grant receivable to determine whether an allowance is required. The allowance is management's best estimate of probable losses. Management determined that no allowance was necessary as of June 30, 2021 and December 31, 2020.

Convertible Preferred Stock

The Company records shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The Company has applied the guidance in ASC 480-10-S99-3A, *SEC Staff Announcement: Classification and Measurement of Redeemable Securities* and has therefore classified the Series A, Series A-1 and Series B convertible preferred stock as mezzanine equity. The convertible preferred stock is recorded outside of stockholders' deficit because, in the event of certain deemed liquidation events considered not solely within the Company's control, such as a merger, acquisition and sale of all or substantially all of the Company's assets (a "Deemed Liquidation Event"), the convertible preferred stock will become redeemable at the option of the holders. In the event of a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the corresponding liquidation preferences. The Company did not adjust the carrying values of the convertible preferred stock to the deemed liquidation values of such shares since a liquidation event was not probable at any of the reporting dates. Subsequent adjustments to increase or decrease the carrying values to the ultimate liquidation values will be made only if and when it becomes probable that such a liquidation event will occur.

Preferred Stock Tranche Rights Liability

The Company determined that its obligation to issue, and the Company's investors' right to purchase, additional shares of Series B convertible preferred stock pursuant to the Milestone Closing (see Note 1 and Note 4) represented a freestanding financial instrument (the "tranche liability"). The tranche liability was initially recorded at fair value. The proceeds from the sale of the convertible preferred stock were first allocated to the fair value of the tranche liability with the remaining proceeds from the sale of the convertible preferred stock allocated to the Series B convertible preferred stock. The tranche liability was remeasured at each reporting period and upon the exercise of the obligation, with gains and losses arising from subsequent changes in its fair value recognized in other income and expense in the condensed statements of operations. As discussed above in Note 1, the Milestone Closing occurred on June 17, 2021 and, as a result, the remaining value of the tranche liability was reclassified to convertible preferred stock on the condensed balance sheet.

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

Preferred Stock Warrant Liability

The Company accounted for the warrant to purchase Series A-1 convertible preferred stock as a liability as this warrant was a freestanding financial instrument that required the Company to transfer assets upon exercise. The warrant liability was initially recorded at fair value. The warrant liability was remeasured at each reporting period and upon the exercise of the applicable warrant, with gains and losses arising from subsequent changes in its fair value recognized in other income and expense in the condensed statements of operations. The warrant was exercised on June 22, 2021 and the remaining value of the warrant liability was reclassified to convertible preferred stock on the condensed balance sheet.

Common Stock Warrants

The Company assesses whether warrants issued require accounting as derivatives. The Company determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with FASB ASC Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders' equity.

Grant and Other Revenue Recognition

The Company's NIH grant is not within the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), as the grant does not meet the definition of a contract with a customer. The Company has concluded that the grant meets the definition of a contribution and is a non-reciprocal transaction, and management has also concluded that Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as Acumen is a business entity and the grant is with a governmental agency.

In the absence of applicable guidance under U.S. GAAP, the Company's policy is to recognize grant revenue when the related costs are incurred and the right to payment is realized. Costs incurred are recorded in research and development and general and administrative expenses on the accompanying condensed statements of operations.

The Company believes the recognition of revenue as costs are incurred and amounts become realizable is analogous to the concept of transfer of control of a service over time under ASC 606.

Research and Development Expenses

Research and development expenses primarily consist of consultants and materials, biologic storage, salaries and other personnel-related expenses related to research and development activities and are expensed as incurred. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected on the condensed balance sheets as prepaid or accrued expenses. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs.

Stock-based Compensation

The Company expenses stock-based compensation to employees, non-employees and board members over the requisite service period based on the estimated grant-date fair value of the awards and actual forfeitures. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, which requires the use of a number of complex assumptions including the fair value of the common stock, expected volatility, risk-free interest rate, expected dividends, and the expected term of the option. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. All stock-based compensation costs are recorded in research and development expense or general and administrative expense in the condensed statements of operations based upon the respective employee's or non-employee's roles within the Company. Forfeitures are recorded as they occur. See also Note 6 below.

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

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and net operating loss ("NOL") carryforwards and research and development tax credit ("R&D Credit") carryforwards. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset valuation allowance would increase income in the period such determination was made.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company has not recorded any accruals related to uncertain tax positions as of June 30, 2021 and December 31, 2020. The Company's policy is to record interest and penalties, if any, as part of income tax benefit. No interest or penalties were recorded during the six months ended June 30, 2021 and 2020.

Net Loss Per Share of Common Stock

Basic net loss per share of common stock is calculated using the two-class method under which earnings are allocated to both common shares and participating securities based on their participation rights. Net loss attributable to common stockholders is not allocated to the convertible preferred stock as the holders of the convertible preferred stock do not have a contractual obligation to share in any losses. Basic net loss per share is calculated by dividing the net loss attributable to common shares by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock is computed by dividing the net loss using the weighted-average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of stock options and warrants to purchase common stock (using the treasury stock method), and the conversion of convertible preferred stock and the preferred warrant (using the if-converted method). See Note 8 below.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, as amended, with guidance regarding the accounting for and disclosure of leases. This update requires lessees to recognize the liabilities related to all leases, including operating leases, with a term greater than 12 months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. This guidance will become effective for the Company for annual reporting periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. The adoption of Topic 842 is not expected to have a material impact on the financial statements.

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. This guidance is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022, with early adoption permitted. The Company is currently evaluating the impact of this standard on its financial statements.

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

NOTE 3. SUPPLEMENTAL FINANCIAL INFORMATION

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

	June 30, 2021	December 31, 2020
Research and development service agreements	$1,491	$ 432
Prepaid raw materials	65	91
Other	95	20
Total prepaid expenses and other current assets	$1,651	$ 543

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

	June 30, 2021	December 31, 2020
Research and development	$ 453	$ 133
Bonuses and other employee liabilities	600	—
Professional fees	506	200
Other	52	90
Total accrued expenses and other current liabilities	$1,611	$ 423

NOTE 4. CONVERTIBLE PREFERRED STOCK, TRANCHE LIABILITY AND WARRANT LIABILITY

Convertible Preferred Stock

On November 20, 2020, the Company entered into the Series B Agreement for a private placement of up to 19,770,070 shares of Series B convertible preferred stock, $0.0001 par value per share, at an original issuance price of $3.80 per share, subject to separate closings, including: (1) 11,862,043 shares at the Initial Closing on November 20, 2020, and (2) 7,908,027 shares at a subsequent closing that would be triggered by the achievement of a specific clinical milestone. The Series B Agreement obligated the Company to issue and sell and the Series B purchasers to purchase up to a total of 7,908,027 additional shares of Series B convertible preferred stock (the "Milestone Shares") at the same price per share upon the achievement of a certain defined clinical milestone. The determination as to whether the milestone event has been met was subject to certification by the Board and the Requisite Investors. Each Series B convertible preferred stock investor had the right, but not the obligation, to purchase all or any portion of the Milestone Shares at any time in its sole option and in its sole and absolute discretion, whether or not the Company achieved the applicable clinical milestone. See "*Series B Convertible Preferred Stock Tranche Rights Liability*" below).

As discussed above in Note 1, on June 9, 2021, the Board and the Requisite Investors elected to waive the achievement of the milestone subject to the terms and conditions of the Series B Agreement and consummate the Milestone Closing and, on June 17, 2021, the Milestone Closing occurred, resulting in the sale of 7,908,027 shares of Series B convertible preferred stock at $3.80 per share for gross proceeds of $30.0 million.

On June 22, 2021, a warrant to purchase 447,426 shares of Series A-1 convertible preferred stock at an exercise price of $2.794 per share was exercised (see *"Series A-1 Convertible Preferred Stock Warrant Liability"* below).

Convertible preferred stock consisted of the following (in thousands, except share and per share data):

	June 30, 2021				
	Shares Authorized	Shares Issued and Outstanding	Weighted Average Issuance Price per Share	Carrying Value	Liquidation Preference
Series A	711,203	477,297	$ 2.24	$ 1,067	$ 1,067
Series A-1	11,898,177	7,985,305	2.27	22,963	18,097
Series B	29,457,450	19,770,070	3.80	150,474	75,116
Total	42,066,830	28,232,672		$174,504	$ 94,280

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

	December 31, 2020				
	Shares Authorized	Shares Issued and Outstanding	Weighted Average Issuance Price per Share	Carrying Value	Liquidation Preference
Series A	711,203	477,297	$ 2.24	$ 1,067	$ 1,067
Series A-1	11,898,177	7,537,879	2.24	16,333	16,847
Series B	29,457,450	11,862,043	3.80	39,253	45,070
Total	42,066,830	19,877,219		$ 56,653	$ 62,984

Dividends

The holders of Series B, Series A-1 and Series A convertible preferred stock were entitled to receive dividends ahead of, or simultaneously with, common stockholders in an amount equal to the product of (A) the dividend payable on each share of the class or series of convertible preferred stock determined, if applicable, as if all shares of such class or series of convertible preferred stock had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of a share of preferred stock. No dividends have been declared since inception.

Liquidation preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of Series B convertible preferred stock were entitled to receive, prior and in preference to, holders of Series A-1 convertible preferred stock, Series A convertible preferred stock, and holders of common stock, in the amount of the original issue price plus any declared but unpaid dividends thereon. If upon occurrence of such an event, the assets and funds to be distributed among the holders of Series B convertible preferred stock were insufficient to permit full payment to such holders, the entire assets and funds of the Company legally available for distribution would have been distributed ratably among the holders of the Series B convertible preferred stock.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of Series A-1 convertible preferred stock were entitled to receive, prior and in preference to, holders of Series A convertible preferred stock and holders of common stock, in the amount of the original issue price plus any declared but unpaid dividends thereon. If upon occurrence of such an event, the assets and funds to be distributed among the holders of Series A-1 convertible preferred stock were insufficient to permit full payment to such holders, the entire assets and funds of the Company legally available for distribution would have been distributed ratably among the holders of the Series A-1 convertible preferred stock.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of Series A convertible preferred stock were entitled to receive, prior and in preference to, holders of common stock, in the amount of the original issue price plus any declared but unpaid dividends thereon. If upon occurrence of such an event, the assets and funds to be distributed among the holders of Series A convertible preferred stock were insufficient to permit full payment to such holders, the entire assets and funds of the Company legally available for distribution would have been distributed ratably among the holders of the Series A convertible preferred stock.

Conversion rights

Shares of all series of convertible preferred stock were convertible into such number of fully paid and non-assessable shares of common stock as determined by dividing the original issuance price for such series by the applicable conversion price for such series then in effect. The initial conversion price per share for each series of convertible preferred stock was the original issue price applicable to such series as shown in the table above, subject to adjustment in the event of certain dilutive issuances. The convertible preferred stock original issuance price and conversion price were each subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the convertible preferred stock.

Each share of convertible preferred stock was convertible at any time at the option of the holder at the conversion ratio then in effect. In addition, each share of convertible preferred stock was to be automatically converted into common stock at the conversion ratio then in effect upon either (a) the closing of an underwritten public offering resulting in gross proceeds to the Company of at least $75 million and at a price per share equal to at least two times the Series B original issuance price, or $7.60 (subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B convertible preferred stock), or (b) the date and time, or the occurrence of an event, specified in such vote or written consent of at least 67% of the holders of the then outstanding shares of Series B convertible preferred stock.

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

If any Series B purchaser failed to purchase its respective portion of the Milestone Shares upon occurrence of the Milestone Closing, each existing share of Series B convertible preferred stock held by such stockholder would have automatically converted into one share of common stock two days after the Milestone Closing.

On July 6, 2021, in connection with the closing of the IPO, each outstanding share of Series A, Series A-1 and Series B convertible preferred stock converted into one share of common stock.

Voting rights

Holders of convertible preferred stock were entitled to vote as a single class together with the holders of common stock and had one vote for each share of common stock into which the convertible preferred stock was convertible.

The holders of Series B convertible preferred stock were entitled to elect two directors to the Board, and the holders of Series A and Series A-1 convertible preferred stock, voting together as a single class, were also entitled to elect two directors to the Board. The holders of common stock, exclusively and as a separate class, are entitled to elect two directors to the Board. The final director to the Board was designated by the holders of a majority of the shares of the preferred stock and common stock, voting together as a single class.

A majority of the outstanding shares of convertible preferred stock was necessary for approving certain matters, including the ability to either increase or decrease the authorized number of directors constituting the Board, pursuant to protective provisions in the Company's amended and restated certificate of incorporation.

Series B Convertible Preferred Stock Tranche Rights Liability

The Company concluded that the tranche liability met the definition of a freestanding financial instrument, as it was legally detachable and separately exercisable from the initial closing of the Series B convertible preferred stock. The fair value for the tranche liability was estimated as a forward contract using a valuation model, calibrated at issuance. The valuation model at issuance estimated the implied value of the Series B stock as of the expected milestone date utilizing the probability of milestone achievement, expected timing of milestone achievement, and risk-free rate. The model was calibrated such that the value of the initial tranche and the forward contract were equal to the initial tranche proceeds at issuance. Subsequently, the fair value of the liability was discounted to the valuation date and adjusted for probability of the achievement of the milestone event. The calibrated valuation model was updated as of December 31, 2020, March 31, 2021 and in the Stay Private scenario utilized in the hybrid methodology as of June 17, 2021 (the date of the Milestone Closing). Significant estimates and assumptions impacting fair value include the discount rate, expected time to the Milestone Closing, and probability of the Milestone Closing. The discount rate was equal to the risk-free rate commensurate with the estimated timing of the Milestone Closing.

The following assumptions were used in the estimation of the fair value of the tranche liability as a forward contract as of each of the dates indicated:

	June 17, 2021	December 31, 2020
Risk-free interest rate	0.07%	0.12%
Expected time to Milestone Closing (in years)	0.8	1.3
Probability of achievement of Milestone Closing	100%	65%

For the other portion of the hybrid method used as of June 17, 2021, the fair value for the tranche liability was estimated based upon an allocation of the underlying equity value, which was determined using an IPO value as estimated through analysis of IPOs for comparable guideline companies, to arrive at a value per share in the IPO scenario. The estimated fair value of the tranche liability was $81,190,000 and $5,033,000 as of the Milestone Closing on June 17, 2021 and December 31, 2020, respectively. The significant increase in the June 17, 2021 valuation stems from both a shift in methodology from an option pricing method ("OPM") to a Hybrid Model where the concluded value of the forward tranche is derived by the sum of the probability weighted present value of the forward tranche in the Stay Private and IPO scenarios (with the former including all other potential exit scenarios other than an imminent IPO), as well as the increase in the probability of achievement of the Milestone Closing. The resulting difference in estimated fair value was recognized as a change in fair value within other income in the accompanying condensed statements of operations.

The tranche liability was revalued each reporting period with the change in fair value recorded in the accompanying condensed statements of operations through the issuance of the Milestone Shares on June 17, 2021. Following the Milestone Closing, the remaining tranche liability was reclassified to convertible preferred stock on the condensed balance sheet.

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

Series A-1 Convertible Preferred Stock Warrant Liability

On October 19, 2018, the Company issued a 10-year warrant (the "Series A-1 Warrant") to purchase up to an aggregate of 447,426 shares of Series A-1 convertible preferred stock at an exercise price of $2.794 on or before October 18, 2028.

The warrant liability met the definition of a freestanding financial instrument, as it was legally detachable and separately exercisable from the initial closing of the Series A-1 convertible preferred stock. As such, it was revalued each reporting period with the change in fair value recorded in the accompanying condensed statements of operations until the warrant was exercised on June 22, 2021.

The fair value of the warrant liability was estimated using the OPM backsolve method as of December 31, 2020 and using a hybrid method, which included an OPM backsolve in the Stay Private scenario as of June 22, 2021. The following assumptions were used in the estimation of the fair value of the warrant liability using the OPM backsolve method as of each of the dates indicated:

	June 22, 2021	December 31, 2020
Risk-free interest rate	0.25%	0.13%
Expected term (in years)	2.0	2.0
Expected volatility	90%	90%
Expected dividend yield	0%	0%

The hybrid method used to value the warrant liability at June 22, 2021 considered both the underlying equity value determined using the OPM backsolve method in a Stay Private scenario, as well as the underlying equity value that was determined using an expected IPO value as estimated through analysis of IPOs for comparable guideline companies, to arrive at a value per share in the IPO scenario. The underlying equity values from each approach were probability weighted based upon the expected likelihood of each scenario. The fair value of the warrant liability was estimated to be $12.02 and $0.85 as of June 22, 2021 and December 31, 2020, respectively.

The following table provides a reconciliation of the tranche liability and warrant liability measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Series A-1 Preferred Stock Warrant	Series B Tranche Rights	Total
Balance, December 31, 2020	$ 380	$ 5,033	$ 5,413
Change in fair value	5,000	76,157	81,157
Settlement of tranche liability due to issuance of Milestone Shares	—	(81,190)	(81,190)
Settlement of warrant liability upon exercise of warrant	(5,380)	—	(5,380)
Balance, June 30, 2021	$ —	$ —	$ —

NOTE 5. STOCKHOLDERS' DEFICIT

Authorized Shares

The Company amended its certificate of incorporation on November 20, 2020, such that the total number of shares of common stock authorized to be issued was increased to 50,500,000, and the total number of shares of preferred stock authorized to be issued was increased to 42,066,830, of which 711,203 were designated Series A convertible preferred stock, 11,898,177 were designated as Series A-1 convertible preferred stock and 29,457,450 were designated as Series B convertible preferred stock. The certificate of incorporation was also amended for the reverse stock splits that became effective on June 23, 2021 and November 20, 2020, but there were no changes to the authorized shares as a result of the reverse stock split that became effective on June 23, 2021 (see Note 1).

See additional information in Note 9 related to an amendment to the Company's certificate of incorporation effective upon the closing of the IPO on July 6, 2021.

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

Common Stock

As of June 30, 2021, the Company's Amended and Restated Certificate of Incorporation authorized the issuance of 50,500,000 shares of common stock, $0.0001 par value per share. Each share of common stock was entitled to one voting right. The holders of common stock were entitled to elect two directors to the Board. Holders of common stock, voting together as a single class with the holders of preferred stock, could also designate an additional director to the Board. Common stock owners were entitled to dividends when funds are legally available and declared by the Board.

Common Stock Warrants

In June 2021, several holders of warrants to purchase the Company's common stock exercised their warrants and purchased a total of 137,446 shares of common stock at an exercise price of $4.47.

As of June 30, 2021 and December 31, 2020, the remaining outstanding warrants to purchase the Company's common stock were comprised of the following:

	Equity Upon Exercise	Exercise Price	Expiration Dates	June 30, 3021	December 31, 2020
Warrants issued in 2014	Common Stock	$ 4.47	3/21/2024 - 6/30/2025	72,178	83,726
Warrants issued in 2015	Common Stock	$ 4.47	6/30/2025	109,908	209,690
Warrants issued in 2016	Common Stock	$ 4.47	6/30/2025	34,396	34,396
Warrants issued in 2017	Common Stock	$ 4.47	6/30/2025	31,765	57,881
Total Warrants				248,247	385,693

NOTE 6. STOCK-BASED COMPENSATION

2013 Stock Performance Plan

On April 8, 2013, the Board and stockholders adopted the Company's Amended and Restated Stock Performance Plan (as amended from time to time, most recently on November 20, 2020, the "2013 Plan"). The 2013 Plan provided for the grant of incentive stock options, nonstatutory stock options, issuance of shares of restricted stock and other equity awards to the Company's employees, officers, directors, consultants and advisors. All outstanding awards issued under the 2013 Plan remain subject to the terms of the 2013 Plan. As of June 30, 2021, the aggregate number of shares authorized for issuance under the 2013 Plan totaled 4,179,202 and there were 483,681 shares available for future grants.

Stock Options

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

Risk-free interest rate	0.4% - 0.5%
Expected term in years	5.3 - 6.3
Expected volatility	90%
Expected dividend yield	0%

The fair value of the Company's common stock underlying the stock options has historically been 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 its common stock. The 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.

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

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. The fair value as of June 30, 2021 was 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. As of December 31, 2020, the Company derived the fair value of its common stock with the assistance of an independent third-party valuation firm utilizing the following assumptions:

Risk-free interest rate	0.13%
Expected time to liquidity event in years	2.0
Expected volatility	90%
Expected dividend yield	0%

The stock options granted after December 31, 2017 vest monthly over 24 or 36 months and 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 is a private company as of June 30, 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 weighted average grant date fair value of options granted during the six months ended June 30, 2021 was $1.34 per share. There were no options granted during the six months ended June 30, 2020.

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, 2020	1,001,517	$ 1.13		
Options granted	2,663,084	2.21		
Outstanding at June 30, 2021	3,664,601	$ 1.92	8.9	$ 51,625
Vested and exercisable at June 30, 2021	872,961	$ 1.19	7.3	$ 12,941

As of June 30, 2021, total unrecognized compensation costs related to unvested stock option awards granted was approximately $3.4 million, which the Company expects to recognize over a weighted-average period of approximately 3.3 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
General and administrative	$ 79	$ 26	$ 159	$ 52
Research and development	47	13	94	26
Total stock-based compensation	$ 127	$ 38	$ 253	$ 77

NOTE 7. 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.

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

Leases

The Company has been subleasing space in Indiana since March 1, 2020 under a lease that expired on December 31, 2020. The Company executed a new sublease for this space that was effective February 1, 2021. The term of the sublease is for 31 months, expiring on August 30, 2023. The Company will pay monthly rent of $12,719 and is also allowing others to sublease a portion of the space from the Company for less than a one-year period. As of June 30, 2021, the remaining aggregate minimum rent obligation over the remaining term was approximately $331,000.

At June 30, 2021, future minimum lease payments under lease agreements (including short-term leases) associated with our operations were as follows (in thousands):

Year ended December 31, 2021 (remaining 6 months)	$ 77
Year ended December 31, 2022	153
Year ended December 31, 2023	102
Total	$332

NOTE 8. NET LOSS PER SHARE

The Company computes loss per common share using the two-class method required for participating securities. Basic and diluted loss per share was the same for each period presented as the inclusion of all potential common stock outstanding would have been anti-dilutive.

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per common share because to do so would be anti-dilutive:

	Six Months Ended June 30,	
	2021	2020
Shares issuable upon conversion of Series A Preferred Stock	477,297	477,297
Shares issuable upon conversion of Series A-1 Preferred Stock	7,985,305	7,537,879
Shares issuable upon conversion of Series B Preferred Stock	19,770,070	—
Shares issuable upon exercise of stock options	3,664,601	1,004,898
Shares issuable upon exercise of common stock warrants	248,247	385,693
Shares issuable upon exercise of preferred stock warrant	—	447,426
Total	32,145,520	9,853,193

NOTE 9. SUBSEQUENT EVENTS

The Company has completed an evaluation of all subsequent events through August 16, 2021 to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements and events which occurred but were not recognized in the financial statements. Except as described below, the Company has concluded that no subsequent event has occurred that requires disclosure.

Initial Public Offering

On July 6, 2021, the Company issued 9,999,999 shares of common stock in an 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.

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

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 and 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 shares increased by 39,911,517 immediately following the closing of the IPO.

Authorized Shares

Effective upon the closing of the IPO on July 6, 2021, the Company amended its certificate of incorporation such that the total number of shares of all classes of capital stock authorized to be issued was increased to 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. Each share of common stock is entitled to one voting right.

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 July 6, 2021. Initially, 3,550,000 new shares, plus any shares that were still available for future grants under the 2013 Plan, as well as any shares that are returned due to expiration or other termination, forfeiture, withholding or reacquisition, may be issued under the 2021 Plan.

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 July 6, 2021. A total of 375,000 shares of our common stock will initially be reserved for issuance under the ESPP.

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 financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our final prospectus dated June 30, 2021 and filed with the Securities and Exchange Commission (the "SEC"), on July 2, 2021, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act"). 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 this Quarterly Report on Form 10-Q 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 (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 ("AßOs"), globular assemblies of the amyloid-beta ("Aß") peptide that are distinct from other forms of Aß and amyloid. We are currently focused on advancing a targeted immunotherapy drug candidate, ACU193, through clinical proof of mechanism in early AD patients. We initiated our Phase 1 clinical trial of ACU193 in the second quarter of 2021.

We were incorporated in 1996 and were party to an exclusive license and research collaboration with Merck in 2003. Although we acquired the exclusive rights to ACU193 from Merck in 2011 following Merck's strategic decision to focus its AD development efforts on a different product candidate, we did not recommence meaningful operations until we completed our first institutional fundraising in 2018. Since 2018, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, conducting discovery, research and development activities, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the sale of our convertible preferred stock and common stock, the issuance of notes, grant revenue and during our collaboration with Merck, certain payments received under our collaboration agreement.

From inception through June 30, 2021, we raised an aggregate of $99.4 million of gross proceeds through the issuance of convertible preferred stock, as well as sales of common stock and issuance of notes that were converted to preferred stock, with the vast majority of this capital being raised since our Series A-1 convertible preferred stock, or Series A-1, financing in 2018. In 2020, we conducted a Series B convertible preferred stock, or Series B, financing, with the funding to occur in two tranches. We closed the first tranche of the Series B financing in November 2020, selling 11,862,043 shares of Series B at $3.80 per share for gross proceeds of $45.1 million. On June 9, 2021, our board of directors and the holders of more than 67% of the outstanding shares of Series B preferred stock elected to waive the achievement of the milestone event. On June 17, 2021, we closed the second tranche of our Series B preferred stock financing, pursuant to which certain of our investors funded an additional $30.0 million.

We have incurred net losses and negative cash flows from operations since our inception. Our net loss was $88.4 million and $7.3 million for the six months ended June 30, 2021 and the year ended December 31, 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $115.3 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 into 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. 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 June 30, 2021, we had cash and cash equivalents of $68.8 million. In July 2021, we raised an additional $168.6 million in net proceeds from our IPO. Based on our current operating plan, we expect that the net proceeds from our IPO, together with our existing cash and cash equivalents as of June 30, 2021, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least through 2024. 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 Business 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. Although to date, our business has not been materially impacted by COVID-19, it is possible that our clinical development timelines could be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations.

Components of Results of Operations

Grants and Other Revenue

To date, we have not generated any revenues from the commercial sale of any products, and we do not expect to generate revenues from the commercial sale of any products for the foreseeable future, if ever. For the years ended December 31, 2019 and 2020, we derived revenue from a grant awarded by the National Institutes of Health in September 2017 and renewed annually in 2018 through 2020. The grant provides us with funding to support the completion of preclinical chemistry, manufacturing and control studies, toxicology and pharmacokinetic studies, submit an IND dossier to the FDA, and then conduct first in human clinical safety trials for ACU193. We recognize revenue from this grant when the related costs are incurred and the right to payment is realized. As of December 31, 2020, we had been awarded a total of $3.9 million under this grant, all of which has been recognized as revenue prior to or during the years ended December 31, 2019 and 2020.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) 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.

Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our nonclinical and clinical studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

As we currently only have one product candidate, ACU193, in development, we do not separately track expenses by program. Further, as we have historically relied exclusively on consultants for research and development activities, we did not have any material internal research and development costs for the year ended December 31, 2020 or for the six months ended June 30, 2021.

We expect that our research and development expenses will increase substantially in connection with our clinical development activities for our ACU193 program. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of, or obtain regulatory

approval for, any of our current or future product candidates. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- our ability to add and retain key research and development personnel;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such trials;
- the size and cost of any future clinical trials for existing or future product candidates in our pipeline;
- the costs associated with the development of any additional programs we identify in-house or acquire through collaborations and other arrangements and the success of such collaborations;
- the terms and timing of any additional collaborations, license or other arrangement, including the timing of any payments thereunder;
- our ability to establish and maintain agreements and operate with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- costs related to manufacturing of our product candidates or to account for any future changes in our manufacturing plans;
- our ability to obtain and maintain patents, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates, both in the United States and internationally;
- our ability to obtain and maintain third-party insurance coverage and adequate reimbursement for our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with other products if our product candidates are approved;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic or similar public health crisis; and
- our ability to maintain a continued acceptable safety profile for our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of management and business consultants and other related costs, including stock-based compensation. General and administrative expenses also include board of directors' expenses and professional fees for legal, patent, consulting, accounting, auditing, tax services and insurance costs.

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 changes in fair value of the Series A-1 warrant liability and the Series B tranche rights, other income and interest income, net.

The Series A-1 warrant was issued in October 2018 in connection with the Series A-1 preferred financing. The warrant liability met the definition of a freestanding financial instrument, as it was legally detachable and separately exercisable from the initial closing of the Series A-1 convertible preferred stock. The warrant liability was initially recorded at fair value as a liability on our balance sheet and was subsequently re-measured at fair value at the end of each reporting period and upon its exercise on June 22, 2021. The changes in the fair value were recognized as a component of other income (expense).

Included in the terms of the Series B stock purchase agreement in November 2020 were tranche rights granted to the holders of the Series B convertible preferred stock. The tranche rights provide the Series B holders with the right to purchase additional shares of Series B at $3.80 per share in an additional tranche after the achievement of a certain milestone event. On June 17, 2021 we closed the second tranche of our Series B preferred stock financing upon the election of a majority of the Series B investors, pursuant to which certain of our investors funded an additional $30.0 million. The tranche rights met the definition of a freestanding financial instrument as the tranche rights were legally detachable and separately exercisable from the Series B convertible preferred stock. The tranche rights were initially recorded at fair value as a liability on our balance sheet. The tranche rights were subsequently re-measured at fair value at the end of each reporting period and at settlement. Changes in the fair value were recognized as a component of other income (expense).

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,		
	2021	2020	Change
Grant and other revenue	$ —	$ 151	$ (151)
Costs and operating expenses			
Research and development	2,254	1,927	327
General and administrative	1,187	259	928
Total operating expenses	3,441	2,186	1,255
Loss from operations	(3,441)	(2,035)	(1,406)
Other income (expense)			
Interest income	4	—	4
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	(57,940)	—	(57,940)
Other income	19	—	19
Total other income (expense)	(57,917)	—	(57,917)
Net loss	$ (61,358)	$ (2,035)	$ (59,323)

Grant and Other Revenue

Revenue related to our NIH grant was nil and $0.2 million for the three months ended June 30, 2021 and 2020, respectively. Revenue under the NIH grant is recognized when the related costs were incurred and the right to payment was realized.

Research and Development Expenses

Research and development expenses were $2.3 million and $1.9 million for the three months ended June 30, 2021 and 2020, respectively. The $0.3 million increase was primarily due to increases in costs for contract research organizations and personnel of $0.9 million and $0.5 million, respectively, net of decreases in costs for consulting and drug safety testing of $0.6 million and $0.5 million, respectively.

General and Administrative Expenses

General and administrative expenses were $1.2 million and $0.3 million for the three months ended June 30, 2021 and 2020, respectively. The $0.9 million increase was primarily due to increased accounting expenses incurred of $0.4 million in anticipation of becoming a public company and increased personnel expenses of $0.4 million due to employees hired during the first three months of 2021. The remainder of the increase relates to increases for marketing and public relations costs and rent expense.

Other Income (Expense)

Increases in the fair value of the Series B tranche liability and the Series A-1 warrant liability of $54.6 million and $3.3 million, respectively, were primarily responsible for total other expense for the three months ended June 30, 2021. Other income (expense) was nil for the three months ended June 30, 2020.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020 (in thousands):

	Six Months Ended June 30,		
	2021	2020	Change
Grant and other revenue	$ —	$ 377	$ (377)
Costs and operating expenses			
Research and development	4,832	3,977	855
General and administrative	2,402	481	1,921
Total operating expenses	7,234	4,458	2,776
Loss from operations	(7,234)	(4,081)	(3,153)
Other income (expense)			
Interest income	8	1	7
Change in fair value of preferred stock tranche rights liability and preferred stock warrant liability	(81,157)	—	(81,157)
Other income	28	—	28
Total other income (expense)	(81,121)	1	(81,122)
Net loss	$ (88,355)	$ (4,080)	$ (84,275)

Grant and Other Revenue

Revenue related to our NIH grant was nil and $0.4 million for the three months ended June 30, 2021 and 2020, respectively. Revenue under the NIH grant is recognized when the related costs were incurred and the right to payment was realized.

Research and Development Expenses

Research and development expenses were $4.8 million and $4.0 million for the six months ended June 30, 2021 and 2020, respectively. The $0.8 million increase was primarily due to increases in costs for contract research organizations and personnel of $1.7 million and $1.0 million, respectively, net of decreases in costs for drug safety testing and consulting of $1.1 million and $0.5 million, respectively, and a $0.2 million decrease for materials.

General and Administrative Expenses

General and administrative expenses were $2.4 million and $0.5 million for the six months ended June 30, 2021 and 2020, respectively. The $1.9 million increase was primarily due to increased accounting expenses incurred of $0.9 million in anticipation of becoming a public company, increased personnel expenses of $0.9 million due to employees hired during the first three months of 2021 and increased marketing and public relations expenses of $0.1 million.

Other Income (Expense)

Increases in the fair value of the Series B tranche liability and the Series A-1 warrant liability of $76.2 million and $5.0 million, respectively, were primarily responsible for total other expense for the six months ended June 30, 2021. Other income (expense) was de minimis for the six months ended June 30, 2020.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception up until the time of our IPO in July 2021, we have funded our operations primarily through the sale of our convertible preferred stock and common stock, the issuance of notes, grant revenue and, during our collaboration with Merck, certain payments received under our collaboration agreement. We do not have any products approved for sale and have not generated any revenue from product sales. From inception through June 30, 2021, we have raised an aggregate of $99.4 million of gross proceeds through the issuance of convertible preferred stock, as well as sales of common stock and issuance of notes that were converted to preferred stock, with the vast majority of this capital being raised since our Series A-1 financing in 2018. In 2020, we conducted a Series B financing, with the funding to occur in two tranches. We closed the first tranche of the Series B financing in November 2020 for gross proceeds of $45.1 million and the second tranche closed on June 17, 2021 for gross proceeds of $30.0 million following the election of our board of directors and a majority of the Series B investors to waive the requirement for a certain milestone event for ACU193 to be achieved prior to funding the second tranche on June 9, 2021. As of June 30, 2021, our cash and cash equivalents totaled $68.8 million.

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.

Cash Flows

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

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (6,634)	$ (3,310)
Net cash used in investing activities	(6)	—
Net cash provided by financing activities	31,675	—
Net change in cash and cash equivalents	$ 25,035	$ (3,310)

Operating Activities

Net cash used in operating activities was $6.6 million and $3.3 million for the six months ended June 30, 2021 and 2020, respectively. Net cash used in operating activities during the six months ended June 30, 2021 was primarily due to our net loss of $88.4 million, which includes $81.2 million of expense related to the change in the fair values of the Series B tranche liability and the Series A-1 warrant liability, plus $1.1 million of cash used for prepaid expenses associated with research and development activities; partially offset by cash provided of $0.7 million for both accounts payable and accrued expenses and other current liabilities. Net cash used in operating activities during the six months ended June 30, 2020 was primarily due to our net loss of $4.1 million, partially offset by $0.7 million of cash provided by changes in our operating assets and liabilities.

Investing Activities

Our cash used in investing activities for the six months ended June 30, 2021 was de minimis and was associated with computer hardware acquired.

Financing Activities

Net cash provided by financing activities was $31.7 million and nil for the six months ended June 30, 2021 and 2020, respectively. Net cash provided by financing activities during the six months ended June 30, 2021 was primarily due to the closing of the second tranche of our Series B convertible preferred stock for gross proceeds of $30.0 million, plus a total of $1.9 million received from the exercise of a Series A-1 preferred warrant, as well as exercises of common stock warrants, partially offset by $0.2 million of costs that were paid in connection with our IPO.

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 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 the net proceeds from our IPO, together with our existing cash and cash equivalents as of June 30, 2021, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least through 2024. 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 our 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 our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our 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 cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your 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.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Contractual Obligations

As of June 30, 2021, we have an operating lease obligation associated with a lease for our executive office space that totals less than $1,000 for the remainder of the lease term. This amount is due in equal monthly installments over the remaining lease term, which expires on August 31, 2021.

We have been subleasing space in Indiana since March 1, 2020 under a lease that expired on December 31, 2020. We executed a new sublease for this space that was effective February 1, 2021. The term of the sublease is for 31 months, expiring on August 30, 2023. We pay monthly rent of $12,719 and we are also allowing others to sublease a portion of the space from us for less than a one-year period. As of June 30, 2021, the remaining aggregate minimum rent obligation over the remaining term was approximately $331,000.

As of June 30, 2021, future minimum lease payments under lease agreements (including short-term leases) associated with our operations were as follows (in thousands):

Year ended December 31, 2021 (remaining 6 months)	$ 77
Year ended December 31, 2022	153
Year ended December 31, 2023	102
Total	$ 332

We enter into contracts in the normal course of business with contract research organizations (“CROs”) and contract manufacturing organizations (“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 cancelation consist only of payments for services provided and expenses incurred up to the date of cancelation.

Critical Accounting Estimates and Policies

This management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis, including those related to accrued expenses, the preferred stock tranche and warrant liabilities and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described 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.

There have been no significant changes to our critical accounting policies from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our final prospectus dated June 30, 2021, and filed with the SEC on July 2, 2021 pursuant to Rule 424(b)(4).

Recent Accounting Pronouncements

See 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 for a description of recent accounting pronouncements applicable to our financial statements.

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 $1.07 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.

We are exposed to market risk related to changes in interest rates. As of June 30, 2021, our cash and cash equivalents totaled $68.8 million. As of June 30, 2021, our cash equivalents consisted of interest-bearing checking accounts and money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature and the low risk profile of our interest-bearing accounts, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents or on our financial position or results of operations.

Inflation generally affects us by increasing our costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the six months ended June 30, 2021 and 2020.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has 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 the end of the period covered by this Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2021, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this 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 were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that 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.

RISK FACTORS

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in this “Risk Factors” section, including the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history.
- We have no product candidates approved for commercial sale, we have never generated any revenue from sales and we may never be profitable.
- We will require substantial additional funding to finance our operations, complete the development and commercialization of ACU193 for Alzheimer’s disease, or AD, and evaluate future product candidates. If we are unable to raise this funding when needed, we may be forced to delay, reduce or eliminate our drug development programs or other operations.
- We are substantially dependent on the success of ACU193, our sole product candidate, which will require significant clinical testing before we can seek regulatory approval and potentially launch commercial sales, and which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized, even if approved.
- We have concentrated our research and development efforts on the treatment of AD, a field that has to date seen very limited success in drug development.
- Our approach to the potential treatment of AD is based on a novel therapeutic approach, which exposes us to unforeseen risks.
- Nonclinical and clinical drug development involves a lengthy, expensive and uncertain process. The results of nonclinical studies and early clinical trials are not always predictive of future results. ACU193 or any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

- Clinical failure can occur at any stage of clinical development and we have never completed a clinical trial or submitted a biologics license application, or BLA, or marketing authorization application, or MAA.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We currently rely on CMOs, or contract manufacturing organizations, to supply components of and manufacture ACU193. The loss of any of these CMOs or the failure of any of them to meet their obligations to us could affect our ability to develop ACU193 in a timely manner.
- We intend to rely on CROs, or contract research organizations, and other third parties to conduct, supervise and monitor a significant portion of our research and nonclinical testing and clinical trials for our product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more effective than ours.
- If we are unable to enter into a commercial collaboration or, alternatively, establish internal sales, marketing and distribution capabilities, for ACU193 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidate, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidate, and other proprietary technologies if approved, may be adversely affected.
- We have identified a material weakness in our internal control over financial reporting which could, if not remediated, result in material misstatements in our financial statements.

Risks Related to our Financial Position and Capital Needs

We are a clinical-stage biopharmaceutical company with a limited operating history.

We are a clinical-stage biopharmaceutical company with a limited operating history focused on pioneering a novel disease-modifying therapeutic approach to treat AD. We were incorporated in 1996 and were party to an exclusive license and research collaboration with Merck & Co., Inc., or Merck, in 2003. Although we acquired the exclusive rights to ACU193 from Merck in 2011, following Merck's strategic decision to focus its AD development efforts on a different product candidate, we did not recommence meaningful operations until we completed our first institutional fundraising in 2018. As a result, we have a very limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We received clearance of our Investigational New Drug application, or IND, for our sole product candidate, ACU193, and initiated our Phase 1 clinical trial in the second quarter of 2021. To date, we have not completed a clinical trial, initiated a pivotal trial, obtained marketing approval for any product candidate, manufactured a commercial scale product candidate, arranged for a third party to do so on our behalf or conducted sales or marketing activities necessary for successful product candidate commercialization. Our short operating history makes any assessment of our future success and viability subject to significant uncertainty. We

will likely encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. If we do not address these risks and difficulties successfully, our business will suffer.

We have no product candidates approved for commercial sale, we have never generated any revenue from sales and we may never be profitable.

We have no product candidates approved for sale, have never generated any revenue from sales, have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception. For the six months ended June 30, 2021 and 2020, our net losses were $88.4 million and $4.1 million, respectively. As of June 30, 2021, we had an accumulated deficit of $115.3 million.

To date, we have devoted most of our financial resources to research and development of ACU193, including our nonclinical development activities of ACU193, and corporate overhead. We expect that it will be several years, if ever, before we have a product candidate approved and ready for commercialization. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, ACU193 and any other product candidate we may develop in the future, prepare for and begin the commercialization of any approved product candidates and add infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Further, these net losses may fluctuate significantly from quarter-to-quarter or year-to-year. To become and remain profitable, we must develop and eventually commercialize ACU193 or another drug with significant revenue.

We may never succeed in developing a commercial drug and, even if we succeed in commercializing one or more product candidates, we may never generate revenues that are large enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown challenges. Because of these numerous risks and uncertainties, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenues or achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis, and we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates.

We will require substantial additional funding to finance our operations, complete the development and commercialization of ACU193 for AD and evaluate future product candidates. If we are unable to raise this funding when needed, we may be forced to delay, reduce or eliminate our drug development programs or other operations.

To date, we have used substantial amounts of cash to fund our operations, and we expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development, conduct clinical trials of, and seek marketing approval for, ACU193. Developing ACU193 and conducting clinical trials for the treatment of AD and any other product candidates or indications that we may pursue in the future will require substantial amounts of capital. In addition, if we obtain marketing approval for ACU193 or any future product candidates, we expect to incur significant commercialization expenses related to the commercialization of the product, whether we are commercializing alone or with a collaborator. Furthermore, we expect to incur additional significant expenses associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. As of June 30, 2021, we had $68.8 million in cash and cash equivalents. In July 2021, we raised an additional $168.6 million in net proceeds from our IPO. Based on our current operating plan, we believe that our existing cash and cash equivalents, will be sufficient to enable us to fund our operations at least through 2024. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- the progress, costs, timing and results of our Phase 1 trial and other clinical trials of ACU193, including for potential additional indications that we may pursue beyond AD;
- the requirements of the U.S. Food and Drug Administration, or the FDA, and European Medicines Agency, or the EMA, for clinical trials and nonclinical studies and other work, for review and approval of ACU193 for AD;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to obtain sufficient quantities of our product candidates from our third-party manufacturers;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization capabilities if we were to elect to commercialize one or more products on our own;
- the economics and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter for the commercialization of our products;
- the costs and other terms, timing and success, of acquiring, in-licensing or investing in businesses, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;
- the effect of competing drugs and product candidates and other market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any funds we raise may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital on a timely basis, we could be forced to curtail our planned operations and the pursuit of our business strategy, which would have a material adverse effect on the value of our common stock.

Risks Related to the Development of our Product Candidates

We are substantially dependent on the success of ACU193, our sole product candidate, which will require significant clinical testing before we can seek regulatory approval and potentially launch commercial sales, and which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized, even if approved.

We are early in our development efforts. To date, we have invested substantially all of our efforts and financial resources in the research and development of ACU193, which is currently our only product candidate. Before seeking marketing approval from regulatory authorities for the sale of ACU193, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug in humans. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval. We cannot be certain that ACU193 will be successful in clinical trials. Further, ACU193 may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals for ACU193, we may not be able to continue our operations. Our prospects, including our ability to finance our operations and generate revenue, will depend entirely on the successful development, regulatory approval and commercialization of ACU193 by us or by one or more of our partners. The clinical and commercial success of ACU193 will depend on a number of factors, including the following:

- successful patient enrollment in our Phase 1 and other clinical trials of ACU193;
- sufficiency of our financial and other resources to complete the necessary clinical trials;
- the results from our Phase 1 clinical trial and future clinical trials of ACU193;
- the frequency and severity of adverse effects of ACU193;
- the ability of third-party manufacturers to manufacture supplies of ACU193 and to develop, validate and maintain a commercial-scale manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to demonstrate ACU193's safety and efficacy to the satisfaction of the FDA and foreign regulatory authorities in order to receive necessary marketing approvals for ACU193;
- whether we are required by the FDA to conduct additional clinical trials prior to the approval to market ACU193 and whether the FDA may disagree with the number, design, size, conduct, implementation or other aspects of our clinical trials;
- whether the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- our ability to successfully commercialize ACU193, if approved for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- our success in educating physicians and patients about the benefits, administration and use of ACU193;
- acceptance of ACU193 as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- achieving and maintaining compliance with all regulatory requirements applicable to ACU193, including any required post-marketing approval commitments;
- effectively competing with other AD therapies;

- the effectiveness of our own or any future collaborators' marketing, pricing, coverage and reimbursement, sales and distribution strategies and operations;
- our ability to maintain our existing patents and obtain newly issued patents that cover ACU193 and to enforce such patents and other intellectual property rights in and to ACU193;
- our ability to avoid third-party intellectual property claims;
- the availability of third-party coverage and adequate reimbursement for ACU193 and any other product candidates, once approved; and
- a continued acceptable safety, tolerability and efficacy profile of ACU193 following approval.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of ACU193. If we are not successful in commercializing ACU193, or are significantly delayed in doing so, our business will be materially harmed.

We have concentrated our research and development efforts on the treatment of AD, a field that has to date seen very limited success in drug development.

We have focused our research and development efforts solely on developing effective treatments for AD. Collectively, efforts by pharmaceutical companies in the field of AD have seen very limited successes in drug development. There are few approved products available for patients with AD.

Our future success is highly dependent on the successful development of ACU193 for treating AD. The development and, if approved, commercialization of ACU193 subjects us to a number of challenges, including ensuring that we select an effective dose of ACU193, executing appropriate clinical trials to test for safety and efficacy and obtaining regulatory approval from the FDA and other regulatory authorities. We cannot be sure that ACU193, or any other product candidate we develop, will ultimately prove to be safe and effective, scalable or profitable. Moreover, public perception of drug safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe novel treatments.

Our approach to the potential treatment of AD is based on a novel therapeutic approach, which exposes us to unforeseen risks.

There is no current scientific or general consensus on the causation of AD or method of action to treat AD. We have discovered and are developing ACU193, a humanized monoclonal antibody that selectively targets amyloid-beta oligomers, or AßOs, to treat AD. Our approach is based on research on AßOs, globular assemblies of the amyloid-beta, or Aß, peptide that are distinct from other forms of amyloid. AßOs have gained scientific acceptance as primary toxins involved in the initiation and propagation of AD pathology. Based on the results of our nonclinical studies to date, we believe ACU193 is different from current and prior clinical-stage anti-amyloid drugs and product candidates based on its selectivity for AßOs. We believe that this is a novel mechanism which has the potential to provide more clinically meaningful benefits, with a possible improved safety profile, as compared to approved therapies and product candidates in development and may potentially slow disease progression. However, we may ultimately discover that ACU193 does not possess properties required for therapeutic effectiveness. We have no evidence regarding the efficacy, safety or tolerability of ACU193 in humans. We may spend substantial funds attempting to develop ACU193 or other product candidates and never succeed in doing so.

The market for any products that we successfully develop, if any, will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it would cost to commercially manufacture ACU193, and the actual cost to manufacture ACU193 or any drug we develop in the future could materially and adversely affect the commercial viability of the drug. We may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. If we do not successfully develop ACU193 or any other drug we develop with drug product cannot be reliably and economically manufactured at scale, we will not become profitable, which would materially and adversely affect the value of our common stock.

Nonclinical and clinical drug development involves a lengthy, expensive and uncertain process. The results of nonclinical studies and early clinical trials are not always predictive of future results. ACU193 or any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of product candidates is extremely risky. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete nonclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of nonclinical studies and early clinical trials are not necessarily predictive of future results and ACU193, or any other product candidate that we may develop, may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the pharmaceutical industry have suffered setbacks in the advancement of their product candidates into later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding results in earlier nonclinical studies or clinical trials. We intend to enroll 62 patients with early AD in our Phase 1 clinical trial of ACU193. Even if the results of our Phase 1 clinical trial are positive, it may not be predictive of the results of outcomes in our later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in AD, where failure rates historically are higher than in most other disease areas.

In the event of negative or inconclusive results, we may decide, or regulatory authorities may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from clinical trials and nonclinical studies is susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

If we are unable to complete nonclinical studies or clinical trials of ACU193 or future product candidates, due to safety concerns or otherwise, or if the results of these trials are not sufficient to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization on a timely basis or at all. Even if we are able to obtain marketing approval for ACU193 or any future product candidates, those approvals may be for indications or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those product candidates. Moreover, if we are not able to differentiate our product candidate against other approved product candidates within the same class of drugs, or if any of the other circumstances described above occur, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Clinical failure can occur at any stage of clinical development and we have never completed a clinical trial or submitted a biologics license application, or BLA, or marketing authorization application, or MAA.

We are early in our development efforts for ACU193, and will need to successfully complete our ongoing and planned clinical trials, including pivotal clinical trials, in order to obtain FDA approval to market ACU193 or any

other product candidate we seek to develop. Carrying out clinical trials and the submission of a successful BLA is a complicated process. Although members of the Acumen team have significant experience in clinical development of drugs through regulatory approval, as an organization, Acumen has just begun conducting its first clinical trial, has no experience in conducting any clinical trials, has limited experience in preparing regulatory submissions and has not previously submitted a BLA for any product candidate.

In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of ACU193 will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of ACU193 or any other product candidate. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing ACU193 or any future product candidates we may develop, and failure to successfully complete any of these activities in a timely manner could have a material adverse impact on our business and financial performance.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulatory authorities, Institutional Review Boards, or IRBs, or Ethics Committees, or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or we may fail to reach a consensus with regulatory authorities on trial design; for example, our initial submission of the IND for ACU193 was placed on clinical hold by the FDA until we were able to address the FDA's initial concerns regarding potential off-target binding of ACU193 with an additional nonclinical tissue cross reactivity study, after which the FDA permitted us to initiate the Phase 1 clinical trial of ACU193 in April 2021;
- regulatory authorities in jurisdictions in which we seek to conduct clinical trials may differ from each other on our trial design, and it may be difficult or impossible to satisfy all such authorities with one approach;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different contract research organizations, or CROs, and trial sites;
- we may be unable to add or be delayed in adding a sufficient number of clinical trial sites and obtaining IRB or independent EC approval at each clinical trial site;
- clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- difficulties in having subjects complete a clinical trial or returning for post-treatment follow-up;
- changes to clinical trial protocols;

- our third-party contractors, including clinical investigators, contract manufacturers and vendors may fail to comply with applicable regulatory requirements, lose their licenses or permits, or otherwise fail, or lose the ability to, meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may lack adequate funding to continue one or more clinical trials;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- clinical trial sites may deviate from clinical trial protocol or drop out of a clinical trial; and
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies.

Adverse side effects, properties or other safety risks associated with ACU193 or any future product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is possible that there may be side effects and adverse events associated with the use of ACU193 or any future product candidates we may develop. Results of our Phase 1 trial of ACU193, or future clinical trials, could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics as the clinical trials progress to greater exposures and a larger number of patients. Undesirable side effects caused by, or unexpected or unacceptable characteristics associated with, ACU193 or any future product candidates we may develop, could result in the delay, suspension or termination of clinical trials by us, the FDA or other regulatory authorities, or IRBs for a number of reasons. We may also elect to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for such product candidate if approved. If we elect or are required to further delay, suspend or terminate any clinical trial of any product candidates we may develop, the commercial prospects of such product candidates will be harmed and our ability to generate drug revenues from any such product candidates will be delayed or eliminated.

It is possible that, as we test ACU193 in our Phase 1 trial or future trials, or as the use of ACU193 becomes more widespread if it receives regulatory approval, we may identify additional adverse events that were not identified or not considered significant in our earlier trials. If such side effects become later known in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly. If we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approval of ACU193 or any future product candidates;
- we may be required to recall a drug or change the way such drug is administered to patients;

- regulatory authorities may require additional warnings or statements in the labeling, such as a boxed warning or a contraindication or issue safety alerts, press releases or other communications containing warnings or other safety information about the product candidate, for example, field alerts to physicians and pharmacies;
- regulatory authorities may require us to implement a REMS to ensure that the benefits of the drug outweigh its risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be required to change the way a drug is distributed or administered, conduct additional clinical trials or be required to conduct additional post-marketing studies or surveillance;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the market;
- we could be sued and held liable for harm caused to patients;
- sales of the drug may decrease significantly or ACU193 or any future drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ACU193 or any future product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

We may experience delays or difficulties in the enrollment and retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates or approved products for the conditions for which we are developing our product candidates.

Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the severity and difficulty of diagnosing the disease under investigation;
- the eligibility and exclusion criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol;
- the perceived risks and benefits of the product candidate in the trial, including relating to cell therapy approaches;

- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Interim, "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more data become available and is subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are reported. Differences between preliminary, top-line or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Further, others, including regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

We cannot be certain that ACU193 or any of our future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We currently have no product candidates approved for sale and we cannot guarantee that we will ever have marketable product candidates. ACU193 is our sole product candidate designed for the treatment of AD. Our ability to generate revenue related to sales of ACU193, if ever, will depend on the successful development and regulatory approval of ACU193 for the treatment of AD and, potentially, other indications.

The development of a product candidate and its approval and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to extensive regulation by the FDA, the EMA and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States, Europe or other countries until we receive approval of a BLA from the FDA or MAA from the EMA, respectively. We have not submitted any marketing applications for ACU193.

BLAs and MAAs must include extensive nonclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. BLAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a BLA or a MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit a BLA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of product candidates.

Even if a drug is approved, the FDA or the EMA, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of product candidates with which we must comply prior with marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of drug development and the emergence of new information regarding ACU193 or other product candidates we may develop in the future. Also, regulatory approval for any of our product candidates may be withdrawn.

We initiated our Phase 1 trial in patients with AD in the second quarter of 2021. Before we submit a BLA to the FDA or a MAA to the EMA for ACU193 for the treatment of patients with AD, we will be required to successfully complete our Phase 1 clinical trial and at least one additional late-stage clinical trial. The FDA generally requires two pivotal clinical trials to support approval. In addition, we must scale up manufacturing and complete other standard nonclinical and clinical studies. We cannot predict whether our current or future trials will be successful or whether regulators will agree with our conclusions regarding the nonclinical studies and the clinical trials we conduct.

We may in the future conduct clinical trials for our product candidates outside the United States, and the FDA, EMA and other foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA or applicable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to current good clinical practice, or cGCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval

requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any other foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

We may not be successful in our efforts to build a pipeline of additional product candidates.

Our sole product candidate is ACU193. We may not be able to identify and successfully develop new product candidates in addition to ACU193. Even if we are successful in building our product pipeline, the potential product candidates that we identify may not be suitable for clinical development or, if deemed suitable for clinical development, successful in any clinical trials. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to obtain product revenue in future periods, which would result in significant harm to our financial position and adversely affect our stock price.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of nonclinical studies and clinical trials and the submission of regulatory filings, including BLA submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.

Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations may be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared a global pandemic by the World Health Organization in March 2020. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including public health directives and orders in the United States and the European Union that, among other things and for various periods of time, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and may disrupt our ongoing research and development activities and our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

Although we do not believe our operations have been materially impacted by the COVID-19 pandemic to date, we may experience related disruptions in the future that could severely impact our clinical trials, including:

- interruptions in our ability to obtain drug supply for our clinical trials;
- interruptions in our ability to obtain clinical test kits for our clinical trials;

- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations as part of a response to the COVID-19 outbreak that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruptions of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations, or CMOs, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether; and
- refusal of the FDA to accept data from clinical trials in these affected geographies.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the continued widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this prospectus, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

We may develop ACU193 and future product candidates for use in combination with other therapies, which could expose us to additional regulatory risks.

We may develop ACU193 and future product candidates for use in combination with one or more other approved therapies for AD. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA, EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved AD therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved AD therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. For example, we recently changed the storage conditions for future lots of ACU193 drug product, which required a change in contract manufacturer and submission of stability data to FDA in an IND amendment.

The change in contract manufacturer IND amendment was filed with the FDA on April 8, 2021. The FDA has confirmed there is no plan for a 30 day review or wait at the agency.

Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates.

Risks Related to the Commercialization of our Product Candidates

Even if ACU193 or any other product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If ACU193 or any other product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are licensed;
- the efficacy, safety and potential advantages compared to alternative treatments;

- our ability to demonstrate the advantages of our product candidates over other medicines;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA, EMA or other foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to commercialize the product either in collaboration with a third party or on our own;
- the timing of market introduction of our product candidates as well as competitive products;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for ACU193 and any other product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If we are unable to enter into a commercial collaboration or, alternatively, establish internal sales, marketing and distribution capabilities, for ACU193 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for ACU193 or any other product candidate for which we may obtain marketing approval, we will either need to establish a commercial collaboration with a pharmaceutical company that has a sales and marketing organization or we will be required to develop these capabilities internally. There are risks and limitations associated with entering into a commercial collaboration. For example, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. Even if we are able to enter into a collaboration, our revenue and profitability, if any, are likely to be significantly lower than if we were able to successfully commercialize a product ourselves. In addition, we likely would have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

At the same time, there are significant risks associated with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This would be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we do not establish sales, marketing and distribution capabilities successfully, either in collaboration with third parties or on our own, we will not be successful in commercializing our product candidates.

The affected populations for ACU193 or any other product candidate we may develop may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

Our projections of the number of people who have AD, as well as the subset of people with AD who have the potential to benefit from treatment with ACU193, are estimates based on our knowledge and understanding of the disease. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of the disease or narrow the universe of patients who would be understood to potentially benefit for treatment with ACU193, if approved. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for ACU193, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of ACU193.

The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative.

The estimated incidence and prevalence ranges included herein have been derived from data from multiple sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Accordingly, the incidence and prevalence estimates included in this prospectus should be viewed with caution. Further, the data and statistical information used in this prospectus, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

If ACU193 or any other product candidate we develop is approved by the FDA, we may only promote or market our product candidate for its specifically approved indications and consistent with its approved labeling. We or any third party collaborator responsible for commercialization of our products will train the marketing and sales forces responsible for our products against promoting them for uses outside of their approved indications for use, known as “off-label uses.” However, neither we, nor any future commercial partner of ours will be able to prevent a physician from using our products off-label, when in the physician’s independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be an increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice, or DOJ, the Office of Inspector General of the U.S. Department of Health and Human Services, or HHS, state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement or warning letters, mandates to issue corrective information to healthcare practitioners, inquiries, investigations, injunctions and civil and criminal sanctions by the FDA, DOJ or comparable foreign bodies. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and as enjoined several companies from engaging in an off-label promotion.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more effective than ours.

The development and commercialization of new drugs is highly competitive. Moreover, the AD field is characterized by strong competition and a strong emphasis on intellectual property. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

If approved, ACU193 will compete with therapies currently approved for the treatment of AD, which have primarily been developed to treat the symptoms of AD rather than the underlying cause of the disease, such as memantine and cholinesterase inhibitors. ACU193 may also compete with one or more potentially disease-modifying therapeutics that target Aß or amyloid plaques, the most advanced of which is Biogen Inc.'s aducanumab, which the FDA approved in June 2021 under the accelerated approval pathway, which allows for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. Regulatory approval of aducanumab is pending in Europe and Japan. Other companies known to be developing therapies with Aß/amyloid plaque-related targets include Alzheon, Inc., Alzinova AB, Chugai Pharmaceutical Co. Ltd., Cognition Therapeutics, Inc., Eisai Co., Ltd., Eli Lilly and Company, Grifols, S.A., KalGene Pharmaceuticals, Inc., Neurimmune AG, Novartis AG, ProMIS Neurosciences, Inc., Prothena Biosciences, Inc., Roche Holding AG (including Genentech, its wholly owned subsidiary) and Wren Therapeutics, Inc.. Additionally, ACU193, if approved, may also compete with other potential therapies intended to address underlying causes of AD that are being developed by several companies, including AbbVie Inc., AC Immune SA, Alector, Inc., Anavex Life Sciences Corp., Annovis Bio, Inc., Athira Pharma, Inc., Biohaven Pharmaceuticals, Inc., Cassava Sciences, Inc., Cortexyme, Inc., Denali Therapeutics, Inc., Johnson & Johnson (including Janssen, its wholly-owned subsidiary) and Takeda Pharmaceutical Co. Ltd.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved product candidates than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop. Furthermore, currently approved product candidates could be discovered to have application for treatment of AD,

which could give such product candidates significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours from the FDA, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, product candidates or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

If our competitors market product candidates that are more effective, safer or less expensive than our product candidates, if approved, or that reach the market sooner than our product candidates, we may not achieve commercial success. In addition, the pharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or product candidates developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

If we are successful in achieving regulatory approval to commercialize any biologic product candidate that we develop, it may face competition from biosimilar products. In the United States, ACU193 is, and we expect that any other product candidate we may seek to develop likely will be, regulated by the FDA as a biologic product subject to approval under the BLA pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four (4) years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed by the FDA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these therapies.

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement from third- party payors for ACU193 and any other product candidate we successfully develop, and the extent to which patients will be willing to pay out-of-pocket for such products, in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-

payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that ACU193 or any other product candidate, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g. Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

In Europe, the General Data Protection Regulation, or GDPR, took effect in May 2018. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area, or EEA, including clinical trial data. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, requires having lawful bases on which personal data can be processed, requires changes to informed consent practices, and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. In July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-U.S. Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or four percent (4%) of our consolidated annual worldwide gross revenue) and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and

obtain compensation for damages resulting from violations of the GDPR. Relatedly, following the United Kingdom's, or U.K., withdrawal from the EEA and the European Union, and the expiry of the transition period, which ended on January 1, 2021, companies have to comply with both the GDPR and the GDPR as incorporated into U.K. national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or four percent (4%) of global turnover. On January 1, 2021, the U.K. became a third country for the purposes of the GDPR.

The relationship between the U.K. and the European Union in relation to certain aspects of data protection law remains unclear. For example, it is unclear how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. Pursuant to the EU-U.K. Trade and Cooperation Agreement of

December 24, 2020, transfers of personal data from the European Union to the U.K. may continue to take place without a need for additional safeguards during a further transition period, to expire on (1) the date on which an adequacy decision with respect to the U.K. is adopted by the EU Commission; or (2) the expiry of four (4) months, which shall be extended by a further two (2) months unless either the European Union or the U.K. objects. It remains unclear whether the EU Commission will adopt an adequacy decision with respect to the U.K. In the absence of such decision after the expiry of the additional transition period, we may need to put in place additional safeguards for transfers of personal data from the European Union to the U.K., such as standard contractual clauses approved by the EU Commission.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020, and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Although the CCPA currently exempts certain health-related information, including clinical trial data, the CCPA and the CPRA may increase our compliance costs and potential liability. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from

these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could seriously harm our business.

Risks Related to Our Dependence on Third Parties

We currently rely on CMOs to supply components of and manufacture ACU193. The loss of any of these CMOs or the failure of any of them to meet their obligations to us could affect our ability to develop ACU193 in a timely manner.

We do not own or operate manufacturing facilities and rely on a limited number of CMOs to manufacture our product candidates. We have entered into agreements with third-party CMOs to manufacture ACU193 and supply the Phase 1 clinical trial material, in compliance with applicable regulatory and quality standards. We intend to continue to rely on third-party CMOs to manufacture our clinical supply for the foreseeable future. Any replacement of a third-party CMO could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate clinical supply that meets the necessary quality standards may delay our development or commercialization.

Our reliance on CMOs for manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. Under certain circumstances, these CMOs may be entitled to terminate their engagements with us. If a CMO terminates its engagement with us, or does not successfully carry out its contractual duties, meet expected deadlines or manufacture ACU193 or any other product candidate that we develop in accordance with regulatory requirements, or if there are disagreements between us and a CMO, we may not be able to complete, or may be delayed in completing, the nonclinical studies required to support clinical trials required for approval of ACU193 or any other product candidate. In such instance, we may need to enter into an appropriate replacement third-party relationship, which may not be readily available or available on acceptable terms, which would cause additional delay or increased expense prior to the approval of ACU193 or any future product candidate and would thereby have a negative impact on our business, financial condition, results of operations and prospects.

We may rely on additional third parties to manufacture ingredients of our product candidates in the future and to perform quality testing. Reliance on CMOs and other third-party service providers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of the applicable manufacturing and service agreements in a manner or at a time that is costly or damaging to us;
- the possible breach by our third-party manufacturers and service providers of our agreements with them;

- the failure of our third-party manufacturers and service providers to comply with applicable regulatory requirements;
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, impact our ability to successfully commercialize any of our product candidates or otherwise harm our business, financial condition, results of operations, stock price and prospects. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

We intend to rely on CROs and other third parties to conduct, supervise and monitor a significant portion of our research and nonclinical testing and clinical trials for our product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We intend to engage CROs and other third parties to conduct our planned nonclinical studies or clinical trials, including our Phase 1 trial and future clinical trials of ACU193, and to monitor and manage data. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, in the future. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of a CRO or clinical site or other vendor staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic.

In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our nonclinical studies and clinical trials and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs, which are standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform

additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, or may result in fines, adverse publicity and civil and criminal sanctions.

We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval for ACU193 or any other product candidate we develop.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

If any of our third-party manufacturers encounter difficulties in production of ACU193 or any future product candidate we develop, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or, if approved, for commercial sale could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing ACU193 and any other product candidate we may develop are highly-regulated and subject to multiple risks. As product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our third-party manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In order to conduct clinical trials of our product candidates, or supply commercial product candidates, if approved, we will need to manufacture them in both small and large quantities. We currently rely on third parties to manufacture ACU193 for clinical trial purposes, and our manufacturing partners will have to modify and scale-up the manufacturing process when we transition to commercialization of our product candidates. Our manufacturing partners may be unable to successfully modify or scale-up the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale-up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any product candidates that we may develop is subject to FDA, EMA and foreign regulatory requirements, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying cGMPs on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce product candidates in accordance with the requirements of the FDA, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such product candidates. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our third party contract manufacturers will be able to manufacture the approved product in accordance with the requirements of the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

We will likely seek collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates, including ACU193.

We will likely seek third-party collaborators for the commercialization of ACU193 and any of our future product candidates, in the United States and may enter into collaboration agreements for the development and commercialization of any of our product candidates outside the United States. In the United States, commercialization partners are likely to include large biotechnology or pharmaceutical companies. Our likely collaborators outside the United States would most likely include regional and national pharmaceutical companies and biotechnology companies. If we enter into such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

We may be exposed to a variety of international risks that could materially adversely affect our business.

We may enter into agreements with third parties for the development and commercialization of product candidates in international markets. International business relationships will subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for product approvals internationally;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- the potential for so-called “parallel importing,” which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- pricing pressure and differing reimbursement regimes:
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, pandemics, epidemics, floods, hurricanes and fires.

If we engage in acquisitions, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

Although we currently have no plans to do so, we may attempt to acquire businesses, technologies or drug candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology or drug candidates into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management’s attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits or synergies of any acquisition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidate, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidate, and other proprietary technologies if approved, may be adversely affected.

Our commercial success will depend in part on our ability to obtain and maintain a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidate, and other proprietary technologies we develop. If we are unable to obtain or maintain patent protection with respect to our product candidate, and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal, scientific, and factual questions and has been the subject of frequent litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued that protect our product candidate and other proprietary technologies we may develop or that effectively prevent others from commercializing competitive technologies and products. Further, no consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we may own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our product candidate and other proprietary technologies and their uses by obtaining, defending and enforcing patents. These risks and uncertainties include the following:

- the United States Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- issued patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or may otherwise not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our product candidate;
- other parties may have designed around our claims or developed technologies that may be related or competitive to ours, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications and/or patents, either by claiming the same composition of matter, methods or formulations or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any product candidate that we may develop;

- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidate and other proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of any application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidate in those countries.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidate and other proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to our product candidate but that are not covered by the claims of our patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable;
- our competitors might conduct research and development activities in countries where we do not have patent rights or where patent protection is weak and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that we will be able to successfully commercialize our product candidate on a substantial scale, if approved, before the relevant patents that we own or license expire; or
- the patents of others may have an adverse effect on our business.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

We cannot be certain that claims in an issued patent covering our product candidate will be considered patentable by the USPTO, courts in the United States, or by patent offices and courts in foreign countries. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property internationally.

The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. Patent applications that we file or in-license may fail to result in issued patents with claims that cover our product candidate in the United States or in foreign countries. Even if such patents do successfully issue, third parties may challenge the ownership, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidate. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our product candidate or prevent others from designing around our claims. If the breadth or strength of protection provided by our patents with respect to our product candidate is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product candidate.

For U.S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the “first to file” provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. It remains unclear what impact the America Invents Act will have on the operation of our business. As such, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patent terms may be inadequate to protect our competitive position on our product candidate for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. When the terms of all patents covering our product candidate expire, our business may become subject to competition from competitive products, including biosimilar version of our products.

Our product candidate is protected by patents covering the composition of matter and methods of using ACU193. The patents in this portfolio are predicted to expire in 2031 without taking into account any possible extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. We cannot be certain that we will file and, if filed, obtain patent protection for our product candidate beyond our rights in the current ACU193 patent portfolio. If we are unable to obtain additional patent protection on ACU193, our primary protection from biosimilar market entry will be limited to regulatory biologic exclusivity.

If we do not obtain patent term extension for our product candidate our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of our product candidate, one or more of patents issuing from U.S. patent applications that we file or license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term, or PTE, of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate, or SPC. If we encounter delays in our development efforts, including our future clinical trials, the period of time during which we could market our product candidate under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the license agreement;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidate, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and/or to secure the our rights to the licensed intellectual property, our business, results of operations, financial condition, and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

We were a party to a collaboration agreement with Merck to research, discover and develop certain technology related to amyloid beta-derived diffusible ligands, or ADDLs. This collaboration was initiated in 2003 and was later terminated by Merck in 2011. During the collaboration, ACU193, an ADDL-binding antibody, was developed and intellectual property was filed by Merck. Under the surviving provisions of the collaboration agreement, Merck exclusively licensed Merck's interest in patent rights claiming ADDL antibodies, ADDL antigens and/or products to Acumen. If a dispute were to arise in the future as to our rights to the intellectual property under the agreement, our ability to commercialize ACU193 may be jeopardized.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside counsel to pay these fees due to foreign patent agencies. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market with similar or identical products or technology earlier than should otherwise have been the case, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidate.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Our patent rights may be affected by developments or uncertainty in U.S. or foreign patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of foreign patent offices. Obtaining and enforcing patents in the biotechnology and pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States may, at any time, enact changes to U.S. patent law and regulations, including by legislation, by regulatory rule-making, or by judicial precedent, that adversely affect the scope of patent protection available and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and/or damages. For example, the scope of patentable subject matter under 35 U.S.C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. Other countries may likewise enact changes to their patent laws in ways that adversely diminish the scope of patent protection and weaken the rights of patent owners to obtain patents, enforce patent infringement, and obtain injunctions and/or damages.

Further, the United States and other governments may, at any time, enact changes to law and regulation that create new avenues for challenging the validity of issued patents. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. Filing, prosecuting, and defending patents on our product candidate, and other proprietary technologies we develop in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The requirements for patentability may differ in certain countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of claimed drug. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors.

In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees (including former employees of our licensors), collaborators or other third parties have an interest in our patents rights, trade secrets, or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. For example, we may have inventorship disputes arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidate or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through in-licenses.

Presently we have intellectual property rights to our product candidate, through a license from Merck. We also have an intellectual property license through a license with Northwestern University and, if this agreement remains in place, we could be required to pay low single digit royalties to Northwestern in the future. Because our program may require the use of additional proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidate may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license, on reasonable terms, proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for our product candidate. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Where we obtain licenses from or collaborate with third parties, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidate, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such application.

Moreover, we will likely have obligations under our current or future licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical or similar to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize our product candidate. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we have collaborated and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate an exclusive license to any of the institution's proprietary rights in technology resulting from the collaboration. Regardless of such option to negotiate a license, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so,

the institution may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program. In addition, disputes may arise under our existing or future license agreements with these institutions or with other counterparties which may, among other things, lead to the termination or renegotiation of these agreements, or otherwise require us to incur significant financial obligations.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights on commercially reasonable terms, our ability to commercialize our products, and our business, financial condition, and prospects for growth, could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including inter partes review, interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future and the outcome of such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidate may give rise to claims of infringement of the patent rights of others.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that any of our current or future product candidate will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidate.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, compositions, formulations, methods of manufacture or methods for treatment related to our product candidate, or the use or manufacture of our product candidate. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our product candidate, and other proprietary technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidate. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of management and other employee resources from our business.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation;

- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our product candidate until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be willfully infringing; and/or
- require us to enter into royalty or license agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do either. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity before federal courts requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidate to market and be precluded from developing, manufacturing or selling our product candidate.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidate in any jurisdiction, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidate or their uses;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims;
- patent applications in the United States are typically not published until 18 months after the priority date; and

- publications in the scientific literature often lag behind actual discoveries.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies or product candidate are not covered by a third party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidate.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidate or future products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidate. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidate. Any such patent application may have priority over one of our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If a third party prevails in a patent infringement lawsuit against us, we may have to stop making and selling the infringing product, pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidate. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidate, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidate, and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties including competitors may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States, or if we require, but do not receive, the consent or cooperation of our licensors to enforce such intellectual property.

If we choose to go to court to stop another party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of written description, indefiniteness, or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution, i.e., committed inequitable conduct. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation, or amendment of any foreign patents we or our licensors hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our future clinical trials, continue our research programs, license necessary technology from third parties, or enter into development or manufacturing partnerships that would help us bring our product candidate to market.

We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Our ability to enforce our patent rights depends on our ability to establish standing in a court of competent jurisdiction. Whether a patent holder or licensee of a patent has standing can be uncertain and the considerations complex. However, if a licensor is required to be joined, and they are unwilling to do so, we may be unable to proceed with an infringement action.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent or patents that may issue from patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and/or other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer, or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the

art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and/or consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names, once registered, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any names we may propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Similar requirements exist in Europe. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our future products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate;
- a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Intellectual property discovered through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Some of our patents may have been generated through the use of U.S. government funding, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). If the U.S. government exercised its march-in rights in our existing or future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or

sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;

- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services ("CMS"), information related to: (i) payments or other "transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives; and
- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain regulatory approval for ACU193 or any future product candidates, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Even if we obtain any regulatory approval for ACU193 or any future product candidates, such product candidates will be subject to ongoing regulatory requirements applicable to research, development, testing, manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals that we receive for ACU193 or any future product candidates may also be subject to REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval or requirements that we conduct potentially costly post-marketing testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of ACU193 or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- issue a safety alert, Dear Healthcare Provider letter, press release or other communication containing warnings or safety information about the product;
- mandate corrections to promotional materials and labeling or issuance of corrective information;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;

- refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of products or product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize ACU193 or any future product candidates and harm our business, financial condition, results of operations and prospects.

Even if we obtain FDA or EMA approval any of our product candidates in the United States or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional nonclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

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 Affordable Care Act (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 December 14, 2018, a Texas United States District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. Although the United States Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate 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 instructs 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. It is also unclear how the Supreme Court ruling, other such litigation and the 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, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Legislation is currently pending in Congress that would further extend the suspension through December 31, 2021. 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, 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. The likelihood of implementation of any of the other Trump administration reform initiatives is uncertain, particularly in light of the new Biden administration.

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. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

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. For example, the results of the 2020 U.S. Presidential election may impact our business and industry. The Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these requirements will be interpreted and implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. 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.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act of 1977, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA, U.S. domestic bribery statutes, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we may operate, including the U.K. Bribery Act of 2010. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. There is no certainty that all of our employees, agents, contractors or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product candidates in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of ACU193 or any other product candidate. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Risks Related to Employee Matters and Managing our Growth

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we advance ACU193 through clinical development, and potentially expand the number of our drug development programs, we will need to increase our drug development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing and sales infrastructure; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the research and development, clinical, regulatory and business development expertise of Daniel O'Connell, President and Chief Executive Officer, Matthew Zuga, our Chief Financial Officer and Chief Business Officer, Eric Siemers, M.D., our Chief Medical Officer and Russell Barton, our Chief Operating Officer. If we lose the services of any of these individuals, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

We have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Non-compete agreements are not permissible or are limited by law in certain jurisdictions and, even where they are permitted, these individuals typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing product candidates or technologies that may compete with ours.

We have identified a material weakness in our internal control over financial reporting which could, if not remediated, result in material misstatements in our financial statements.

In connection with the preparation and audit of our consolidated financial statements as of December 31, 2020 and 2019 and for the years then ended, a material weakness was identified in our internal control over financial reporting. In addition, we have in the past identified other material weaknesses in our internal controls over financial accounting, which have since been remediated. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Our existing material weakness is related to segregation of duties related to roles and responsibilities in our accounting department which is lacking in various circumstances, including with respect to account reconciliation and receipt/disbursement duties, independent review of journal entries and access to the accounting systems. Our existing material weakness did not result in a misstatement to our financial statements, however, it could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. We plan to remediate this material weakness by hiring additional accounting staff and upgrading our accounting systems, though there is no guarantee that these remediation efforts will be successful.

In order to maintain and improve the effectiveness of our internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight. Our independent registered public accounting firm is not required to formally attest to the effectiveness of its internal control over financial reporting until after it is no longer an "emerging growth company" as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which its internal control over financial reporting is documented, designed, or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could adversely affect our business and operating results and could cause a decline in the price of our common stock.

If we fail to build our finance infrastructure and improve our accounting systems and controls, we may be unable to comply with the financial reporting and internal controls requirements for publicly traded companies.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq Global Select Market, or Nasdaq. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending December 31, 2022, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to our initial public offering, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. We expect that we will need to implement a new internal system to combine and streamline the management of our financial, accounting, human resources and other functions. However, such a system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the Commission or other regulatory authorities.

Risks Related to Ownership of our Common Stock and our Status as a Public Company

An active trading market for our common stock may not continue to be developed or sustained.

Prior to our initial public offering, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares of our common stock at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of our clinical trials, including the Phase 1 clinical trial of ACU193 and any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for ACU193 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- delays in, or termination of, clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of ACU193 or any other product candidate we develop;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- announcements by our competitors of new product candidates or technologies, or the results of clinical trials or regulatory decisions;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;

- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market in general, Nasdaq and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of August 13, 2021, we had 40,468,087 shares of common stock outstanding. All of the shares of common stock sold during the initial public offering are currently freely tradable, except for any shares held by our affiliates as defined in Rule 144 under the Securities Act of 1933. Substantially all of the remaining shares of common stock outstanding after the initial public offering are restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers until at least December 27, 2021, which is 180 days after the date of the prospectus for our initial public offering. The underwriters may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements with the underwriters prior to expiration of the lock-up period.

Additionally, the holders of approximately 28.2 million shares of common stock, or their transferees, have rights, subject to some conditions, with respect to registration of such shares under the Securities Act pursuant to an investor rights agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital, we may be required to offer these holders the right to participate in the offering and, if we are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired.

We have filed a registration statement on Form S-8 under the Securities Act registering approximately 7,406,178 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance, subject to the vesting of the equity awards, other restrictions provided under the terms of the applicable plan or equity award, the lock-up agreements described above, and the restrictions of Rule 144 in the case of our affiliates.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and

- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our directors, executive officers and beneficial owners of greater than 5% of our outstanding stock and their respective affiliates beneficially own, in the aggregate, a majority of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the public offering price and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of the last day of the fiscal year (i) following the fifth anniversary of the closing of our initial public offering, or July 6, 2026, (ii) in which we have total annual gross revenue of at least $1.07 billion, or (iii) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Our management team may use our cash and cash equivalents, including the net proceeds from our initial public offering, in ways in which you may not agree or in ways which may not yield a return.

Our management has broad discretion over the use of our cash and cash equivalents, including the net proceeds from our recent public offering. You will not have the opportunity to influence our decisions on how to use our cash and cash equivalents and will need to rely on our judgment with respect to the use of our cash and cash equivalents. The failure by our management to apply our cash and cash equivalents effectively could adversely affect our ability to continue maintaining and expanding our business.

We have never paid dividends on our capital stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy Nasdaq's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement. Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action asserting a breach of fiduciary duty;
- any claim or cause of action against us arising under DGCL;
- any claim or cause of action arising under or seeking to interpret our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any claim or cause of action against us that is governed by the internal affairs doctrine.

The provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

General Risk Factors

We incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant additional legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the Commission and Nasdaq, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies.

We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred NOLs during our history, we expect to continue to incur significant NOLs for the foreseeable future, and we may not achieve profitability prior to the time that certain of our NOLs expire. As of December 31, 2020, we had federal and state NOL carryforwards of $22.3 million and $31.0 million, respectively, that will begin expiring in the year 2028 for both federal and state NOLs if not utilized. We also have $15.9 million of federal net operating loss carryforwards as of December 31, 2020, that do not expire as a result of recent tax law changes. Our NOL carryforwards are subject to review and possible adjustment by U.S. and state tax

authorities. Our NOL carryforwards could expire unused or be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Federal NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") signed into law on March 27, federal NOLs arising in tax years beginning after December 31, 2017, and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss, and federal NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning after December 31, 2020. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards to offset taxable income in taxable years beginning after 2019 and before 2023. It is generally uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes (such as research and development tax credits) to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. The completion of our recent initial public offering, together with private placements and other transactions that have occurred since our inception, my trigger such an ownership change pursuant to Section 382. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have an adverse effect on our cash flows and results of operations.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Furthermore, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. Among the changes made by the Tax Act was a reduction of the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs." We continue to examine the impact this tax reform legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of the Tax Act and potential changes in U.S. tax laws on an investment in our common stock.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity or a natural disaster.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails,

persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed.

Disruptions at the FDA, the Commission and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Commission and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

FDA and regulatory authorities outside the United States may adopt policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. In response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products while local, national and international conditions warrant. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which the FDA continues to update. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. As of July 2020, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future. Should FDA determine that an inspection is necessary for approval, and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic or political disruption could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

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

(a) Recent Sales of Unregistered Equity Securities

Issuances of Common Stock

In June 2021, six holders of warrants to purchase common stock exercised warrants to purchase a total of 137,446 shares of common stock at an exercise price of $4.47 per share, for aggregate consideration of approximately $0.6 million.

The issuance of such shares of common stock was exempt from registration under Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder).

Issuances of Preferred Stock

In June 2021, we issued 7,908,027 shares of our Series B convertible preferred stock to 31 individual and institutional accredited investors for $3.80 per share, for aggregate consideration of $30.0 million. Also in June 2021, an accredited institutional investor exercised a warrant to purchase 447,426 shares of our Series A-1 preferred stock at a per-share exercise price of $2.794 per share, for aggregate consideration of approximately $1.3 million. The issuance of such shares of Series A-1 and Series B convertible preferred stock was exempt from registration under Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder).

Issuances Pursuant to our Equity Plan

On June 30, 2021, we issued options to purchase an aggregate of 183,423 shares of common stock at an exercise price equal to the initial public offering price of $16.00 per share. The recipients of these securities were employees, directors or bona fide consultants of the Company and received the securities under the 2021 Equity Incentive Plan. The issuance of such options was exempt from registration under Rule 701 promulgated under Section 3(b) of the Securities Act.

(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.

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

Exhibit Number	Description
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	2021 Equity Incentive Plan and Forms of Option Grant Notice and Agreement, Exercise Notice, Early Exercise Notice and Restricted Stock Award Notice (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.2	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.3	Form of Indemnification Agreement with Executive Officers and Directors (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.4	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.5	Executive Employment Agreement, by and between the Registrant and Daniel O'Connell (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.6	Employment Agreement by and between the Registrant and Eric Siemers, M.D. (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.7	Employment Agreement by and between the Registrant and Russell Barton (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.8*	Employment Agreement by and between the Registrant and Matthew Zuga.
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
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.

Company Name

Date: August 16, 2021

By: /s/ Daniel O'Connell

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

Date: August 16, 2021

By: /s/ Matthew Zuga

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

EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT** (the "***Agreement***") is entered into effective **May 15, 2021** (the "***Effective Date***"), by and between **Wm. Matthew Zuga** (the "***Executive***") and **Acumen Pharmaceuticals, Inc.** (the "***Company***") and supersedes and replaces any prior consulting agreement or employment letter between the Parties and any of their affiliates, including that certain Consulting Agreement between the Company and Executive dated August 16, 2019, that certain Employment Agreement between Executive dated January 1, 2021, that certain Letter Agreement between the Company and Executive dated March 11, 2021 .

WHEREAS, the Company desires to employ Executive and, in connection therewith, to compensate Executive for Executive's personal services to the Company; and

WHEREAS, Executive wishes to be employed by the Company and provide personal services and certain covenants to the Company in return for certain compensation and benefits.

Accordingly, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position. Subject to the terms set forth herein, the Company agrees to employ Executive, in the position of **Chief Financial Officer and Chief Business Officer**, and Executive hereby accepts such employment. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of his business time and attention to the business of the Company.

1.2 Duties. Executive will initially report to the Chief Executive Officer (the "***CEO***") of the Company. Executive shall perform his duties under this Agreement initially principally out of his personal residence and the Company's corporate offices in Charlottesville, VA and offices in Carmel, IN or such other location as assigned by the Company. In addition, Executive shall make business trips to such places as may be necessary or advisable for the efficient operations of the Company.

1.3 Company Policies and Benefits. The employment relationship between the parties shall also be subject to the Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. Executive will be eligible to participate on the same basis as similarly situated employees in the Company's benefit plans in effect from time to time during Executive's employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of the such plan. The Executive shall be entitled to paid vacation in accordance with the plans, policies, programs and practices of the Company applicable to its senior executives in effect from time to time, but in no event shall the Executive be entitled to less than four (4) weeks of vacation per calendar year (pro-rated for any partial year of service). The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. COMPENSATION.

2.1 Salary. Executive shall receive for services to be rendered hereunder an initial base salary of $ 380,000.00 on annualized basis, subject to review and adjustment from time to time by the Company, and payable subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices ("***Base Salary***").

2.2 Annual Discretionary Bonus. Executive shall be eligible for a discretionary annual calendar year performance bonus (the "***Annual Bonus***") with an annual target of forty percent (40%) of Executive's then-current Base Salary (the "***Target Amount***"). Whether or not Executive is eligible for any Annual Bonus will be dependent upon the actual achievement by Executive and the Company of the applicable individual and corporate performance goals, as determined by the Board. No amount of any Annual Bonus is guaranteed at any time and may be greater or lesser than the Target Amount and may be zero. Any Annual Bonus, if awarded, will be paid in a single installment paid at the same time annual bonuses are generally paid to other similarly-situated employees of the Company and in any event no later than March 1st of the calendar year following the calendar year to which the Annual Bonus is applicable, and will be subject to deductions and withholdings. Executive's eligibility for an Annual Bonus and the Target Amount, if any, is subject to change in the discretion of the Board (or any authorized committee thereof).

2.3 Expense Reimbursement. The Company will reimburse Executive for reasonable business expenses in accordance with the Company's standard expense reimbursement policy, as the same may be modified by the Board from time to time. The Company shall reimburse Executive for all customary and appropriate business-related expenses actually incurred and documented in accordance with Company policy, as in effect from time to time . For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"): (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

2.4 Stock Option. On January 4, 2021, the Company granted to Executive an option to purchase 672,541 shares of the Company's common stock at $0.80 per share (the "***Option***"). The Option is governed by the terms and conditions of the Company's Equity Incentive Plan (the "***Plan***") and the option grant agreement, and will vest 25% on the one-year anniversary of the date of grant, and thereafter over the ensuing 3 years in a series of thirty-six (36) successive equal monthly installments, subject to your Continuous Service (as defined in the Plan) as of each such date. The Company confirms that as your Continuous Service has remained uninterrupted from the date of the grant through the date of this Agreement, notwithstanding any change to your status as an employee or consultant.

3. CONFIDENTIAL INFORMATION, INVENTIONS, NON-COMPETITION AND NON-SOLICITATION OBLIGATIONS. As a condition of employment, Executive agrees to execute and abide by the Employee Confidential Information, Inventions, Non-Solicitation and Non- Competition Agreement, attached as Exhibit A which may be amended by the parties from time to time without regard to this Agreement (the "***Confidential Information Agreement***"). The Confidential Information Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

4. OUTSIDE ACTIVITIES DURING EMPLOYMENT. Except with the prior written consent of the Company, Executive will not, while employed by the Company, undertake or engage in any other employment, occupation or business enterprise that would interfere with Executive's responsibilities and the performance of Executive's duties hereunder except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non- profit and/or other charitable organization as Executive may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties; and (iii) such other activities as may be specifically approved in writing by the Company.

5. NO CONFLICT WITH EXISTING OBLIGATIONS. Executive represents that Executive's performance of all the terms of this Agreement and as an Executive of the Company do not and will not breach any agreement or obligation of any kind made prior to Executive's employment by the Company, including agreements or obligations Executive may have with prior employers or entities for which Executive has provided services. Executive has not entered into, and Executive agrees that Executive will not enter into, any agreement or obligation, either written or oral, in conflict herewith.

6. TERMINATION OF EMPLOYMENT. The parties acknowledge that Executive's employment relationship with the Company is at-will. Either Executive or the Company may terminate the employment relationship for any reason whatsoever at any time, with or without Cause or advance notice. The provisions in this Section govern the amount of compensation, if any, to be provided to Executive upon termination of employment and do not alter this at-will status.

6.1 Termination by the Company without Cause or Resignation by Executive for Good Reason.

(a) The Company shall have the right to terminate Executive's employment with the Company pursuant to this Section 6.1 at any time without Cause (as defined in Section 6.2(b) below) by giving notice as described in Section 7.1 of this Agreement. A termination pursuant to Section 6.4 or 6.5 below is not a termination without Cause for purposes of receiving the benefits described in this Section 6.1.

(b) In the event the Company terminates Executive's employment without Cause or Executive Resigns for Good Reason (as defined in Section 6.1(g) below), and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), then Executive shall be entitled to receive the Accrued Obligations (as defined below) and, subject to Executive's compliance with the obligations in Section 6.1(c) below, Executive shall be eligible to receive the following severance benefits (the "***Severance Benefits***"):

(i) The Company will pay Executive an amount equal to Executive's then current Base Salary for nine (9) months, less all applicable withholdings and deductions, and paid in equal installments beginning on the Company's second regularly scheduled payroll date following the Release Effective Date (as defined in Section 6.1(c) below), with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter.

(ii) If Executive timely elects continued coverage under COBRA for Executive and Executive's dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Executive's and his covered dependents' health insurance coverage in effect for Executive (and Executive's covered dependents) on the termination date until the earliest of: (i) twelve (12) months following the termination date (the "***COBRA Severance Period***"); (ii) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (i)-(iii), (the "***COBRA Payment Period***"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Executive's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding, for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Executive of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company.

(c) Executive will be paid all of the Accrued Obligations (as defined in Section 6.1(d) below) on the Company's first payroll date after Executive's date of termination from employment or earlier if required by law. If eligible to receive the Severance Benefits pursuant to Section 6.1(b) of this Agreement, Executive will only receive such Severance Benefits if: (i) within the time period provided in the separation agreement (which shall be no longer than 60 days following the date of Executive's Separation from Service), Executive has signed and delivered to the Company a separation agreement that includes, among other terms, an effective general release of claims in favor of the Company and its affiliates and representatives, in the form presented by the Company (the "***Release***"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "***Release Effective Date***"); and (ii) if Executive holds any other positions with the Company, he resigns such position(s) to be effective no later than the date of Executive's termination date (or such other date as requested by the Board); (iii) Executive returns all Company property; (iv) Executive complies with his post- termination obligations under this Agreement and the Confidential Information Agreement; and (v) Executive complies with the terms of the Release, including, without limitation, any non- disparagement, confidentiality and cooperation provisions contained in Release.

(d) For purposes of this Agreement, "***Accrued Obligations***" are (i) Executive's accrued but unpaid salary through the date of termination, (ii) any unreimbursed business expenses incurred by Executive payable in accordance with the Company's standard expense reimbursement policies, and (iii) benefits owed to Executive under any qualified retirement plan or health and welfare benefit plan in which Executive was a participant in accordance with applicable law and the provisions of such plan.

(e) The Severance Benefits provided to Executive pursuant to this Section 6.1 are in lieu of, and not in addition to, any benefits to which Executive may otherwise be entitled under any Company severance plan, policy or program.

(f) Any damages caused by the termination of Executive's employment without Cause would be difficult to ascertain; therefore, the Severance Benefits for which Executive is eligible pursuant to Section 6.1(b) above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

(g) "***Good Reason***" for purposes of this Agreement shall mean the occurrence of any of the following conditions without Executive's consent, after Executive's provision of written notice to the Company of the existence of such condition (which notice must be provided as described in Section 7.1 within thirty (30) days of the initial existence of the condition and must specify the particular condition in reasonable detail), provided that the Company has not first provided notice to Executive of its intent to terminate Executive's employment: (i) a material reduction in Executive's duties, responsibilities or authorities, provided, however, that neither the conversation of the Company to a subsidiary, division or unit of an acquiring entity, or Executive's reporting relationships following a Change in Control, nor a change in title, will be deemed a "material reduction" in and of itself or material adverse alteration in, Executive's position, title, duties, or responsibilities; (ii) a material (greater than 10%) reduction by the Company of Executive's Base Salary (except in the case of either an across the board reduction in salaries or a temporary reduction due to financial exigency); or (iii) the relocation of Executive's principal place of employment by fifty (50) or more miles from Executive's then- current principal place of employment. Notwithstanding the foregoing, Good Reason shall only exist if the Company is provided a thirty (30) day period to cure the event or condition giving rise to Good Reason, and it fails to do so within that cure period (and, additionally, Executive must resign for such Good Reason condition by giving notice as described in Section 7.1 within thirty (30) days after the period for curing the violation or condition has ended).

6.2 <u>Termination by the Company for Cause</u>.

(a) The Company shall have the right to terminate Executive's employment with the Company at any time for Cause by giving notice as described in Section 7.1 of this Agreement.

(b) "***Cause***" for purposes of this Agreement shall mean that the Company has determined in its sole discretion that Executive has engaged in any of the following: (i) a material breach of any covenant or condition under this Agreement or any other agreement between the Company and Executive; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law;

(iv) violation of any Company policy or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive of Company; (vi) negligence or incompetence in the performance of Executive's duties or failure to perform such duties in a manner satisfactory to the Company after the expiration of ten (10) days without cure after written notice of such failure; (vii) failure to pass to the satisfaction of the Company, a preliminary background check or failure to submit proof of legal eligibility to work in the United States; or (viii) breach of fiduciary duty.

(c) In the event Executive's employment is terminated at any time for Cause, Executive will not receive Severance Benefits, or any other compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

6.3 Resignation by Executive (other than for Good Reason).

(a) Executive may resign from Executive's employment with the Company at any time by giving notice as described in Section 7.1.

(b) In the event Executive resigns from Executive's employment with the Company (other than for Good Reason), Executive will not receive Severance Benefits, or any other compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

6.4 Termination by Virtue of Death or Disability of Executive.

(a) In the event of Executive's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, and the Company shall, pursuant to the Company's standard payroll policies, provide to Executive's legal representatives Executive's accrued but unpaid salary through the date of death together with all compensation and benefits payable to Executive based on his participation in any compensation or benefit plan, program or arrangement through the date of termination.

(b) Subject to applicable state and federal law, the Company shall at all times have the right, upon written notice to Executive, to terminate this Agreement based on Executive's Disability (as defined below). Termination by the Company of Executive's employment based on "***Disability***" shall mean termination because Executive is unable due to a physical or mental condition to perform the essential functions of Executive's position with or without reasonable accommodation for one hundred twenty (120) consecutive calendar days or six (6) months in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In the event Executive's employment is terminated based on Executive's Disability, Executive will not receive the Severance Benefits, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Executive the accrued but unpaid salary of Executive through the date of termination, together with all compensation and benefits payable to Executive based on his participation in any compensation or benefit plan, program or arrangement through the date of termination.

6.5 [RESERVED]

6.6 Notice; Effective Date of Termination.

(a) Termination of Executive's employment pursuant to this Agreement shall be effective on the earliest of:

(i) immediately after the Company gives notice to Executive of Executive's termination, with or without Cause, unless pursuant to Section 6.2(b)(vi) in which case ten (10) days after notice if not cured or unless the Company specifies a later date, in which case, termination shall be effective as of such later date;

(ii) immediately upon Executive's death;

(iii) ten (10) days after the Company gives notice to Executive of Executive's termination on account of Executive's Disability, unless the Company specifies a later date, in which case, termination shall be effective as of such later date, provided that Executive has not returned to the full time performance of Executive's duties prior to such date;

(iv) ten (10) days after Executive gives written notice to the Company of Executive's resignation, provided that the Company may set a termination date at any time between the date of notice and the date of resignation, in which case Executive's resignation shall be effective as of such other date. Executive will receive compensation through any required notice period; or

(v) for a termination for Good Reason, immediately upon Executive's full satisfaction of the requirements of Section 6.1(g).

(b) In the event notice of a termination under subsections (a)(i) and (iii) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five (5) business days of the request in compliance with the requirement of Section 7.1 below. In the event of a termination for Cause, written confirmation shall specify the subsection(s) of the definition of Cause relied on to support the decision to terminate.

6.7 Cooperation With Company After Termination of Employment. Following termination of Executive's employment for any reason, Executive shall fully cooperate with the Company in all matters relating to the winding up of Executive's pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company. The Company will reimburse Executive for reasonable out-of-pocket expenses Executive incurs in connection with any such cooperation (excluding forgone wages, salary, or other compensation) and will make reasonable efforts to accommodate Executive's scheduling needs.

6.8 Application of Section 409A. It is intended that all of the benefits and payments under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code provided under Treasury Regulations 1.409A-1(b)(4),

1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions. If not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A of the Code, and incorporates by reference all required definitions and payment terms. For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) will be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder will at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of his Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then if delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, the timing of the payments upon a Separation from Service will be delayed as follows: on the earlier to occur of (i) the date that is six months and one day after the effective date of Executive's Separation from Service, and (ii) the date of Executive's death (such earlier date, the "***Delayed Initial Payment Date***"), the Company will (A) pay to Executive a lump sum amount equal to the sum of the payments upon Separation from Service that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payments had not been delayed pursuant to this paragraph, and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth above. No interest will be due on any amounts so deferred.

7. GENERAL PROVISIONS.

7.1 Notices. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Executive at Executive's address as listed on the Company payroll or to Executive's Company-issued email address or Executive's email address as listed in Company records, or at such other address as the Company or Executive may designate by ten (10) days advance written notice to the other.

7.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

7.3 Survival. Provisions of this Agreement which by their terms must survive the termination of this Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the term, termination of Executive's employment, or otherwise, for such period as may be appropriate under the circumstances.

7.4 Waiver. If either party should waive any breach of any provisions of this Agreement, it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

7.5 Complete Agreement. This Agreement constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof. This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by Executive and an authorized officer of the Company. The parties have entered into a separate Confidential Information Agreement and have or may enter into separate agreements related to equity. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of Executive's employment under this Agreement, may be amended or superseded by the parties without regard to this Agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

7.6 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

7.7 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

7.8 Successors and Assigns. The Company shall assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any Company or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said Company or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. Executive may not assign or transfer this Agreement or any rights or obligations hereunder, other than to Executive's estate upon Executive's death.

7.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the law of the Commonwealth of Virginia.

7.10 Resolution of Disputes. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of Executive's employment with the Company or out of this Agreement, or Executive's termination of employment or termination of this Agreement, may not be in the best interests of either Executive or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The

parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or Executive's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Executive Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the Employment Arbitration Rules and Mediation Procedures of the American Arbitration Association; provided however, that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the Charlottesville, Virginia area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the Company; provided however, that at Executive's option, Executive may voluntarily pay up to one-half the costs and fees. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Executive and the Company. The parties each further agree that the arbitration provisions of this Agreement shall provide each party with its **exclusive remedy**, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.**

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the parties have executed this Employment Agreement on the day and year written below effective as of the Effective Date (as defined herein).

Acumen Pharmaceuticals, Inc.

By: /s/ Daniel J. O'Connell
Daniel J. O'Connell,
President and Chief Executive Officer

Executive:

/s/ William Matthew Zuga
Wm. Matthew Zuga

5/15/2021
Date

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 Quarterly Report on 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: August 16, 2021

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 Quarterly Report on 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: August 16, 2021

By: /s/ Matthew Zuga

Matthew Zuga
Chief Financial 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

In connection with the Quarterly Report of Acumen Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 16, 2021

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

In connection with the Quarterly Report of Acumen Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 16, 2021

By: /s/ Matthew Zuga

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