UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-40971

AURA BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**32-0271970**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
85 Bolton Street **Cambridge, MA**	**02140**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 500-8864

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 $0.00001 per share	AURA	Nasdaq Global Market LLC

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 ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of November 19, 2021, the registrant had 29,210,549 shares of common stock, $0.00001 par value per share, outstanding.

Summary of the material risks associated with our business

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks are described more fully in Part II, "Item 1A—Risk Factors," and include, but are not limited to, the following:

- We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates.
- We are heavily dependent on the success of AU-011, our only product candidate to date.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for AU-011, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- We have not yet successfully initiated or completed any pivotal clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.
- If we fail to develop additional product candidates, or obtain additional indications of our first product candidate our commercial opportunity could be limited.
- We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.
- We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of AU-011 and may continue to rely on CMOs for the production of commercial supply of AU-011, if approved. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.
- If AU-011 or any future product candidates do not achieve broad market acceptance, the revenue that we generate from their sales may be limited, and we may never become profitable.
- If the market opportunity for AU-011 is smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.
- Our ability to compete may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantage.
- If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to pursue our business strategy will be impaired, could result in loss of markets or market share and could make us less competitive.
- Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.
- Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or the Quarterly Report, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, or the or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These statements are not guarantees of future results or performance and involve substantial risks and uncertainties. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to efficiently develop our existing product candidates and discover new product candidates;
- our ability to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- developments relating to our competitors and our industry;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Aura Biosciences, Inc.

Condensed Balance Sheets (Unaudited)
(in thousands, except share and per share amounts)

	As of	
	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 81,829	$ 17,393
Restricted cash and deposits	20	19
Prepaid expenses and other current assets	1,609	1,043
Total current assets	83,458	18,455
Restricted cash and deposits, net of current portion	125	75
Right of use assets - operating lease	1,096	-
Property and equipment, net	4,442	3,574
Deferred offering costs	1,583	-
Total Assets	$ 90,704	$ 22,104
Liabilities, Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities:		
Accounts payable	1,736	611
Current portion of operating lease liabilities	607	-
Accrued expenses and other current liabilities	3,488	2,050
Total current liabilities	5,831	2,661
Deferred rent	-	8
Operating lease liabilities, net of current portion	513	-
Warrant liability	71	72
Total Liabilities	6,415	2,741
Commitments and Contingencies (Note 12)		
Series A convertible preferred stock, $0.00001 par value, 1,701,141 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $3,403 at September 30, 2021 and December 31, 2020, respectively	3,368	3,368
Series A-1 convertible preferred stock, $0.00001 par value, 3,298,732 shares authorized, issued, and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $8,196 at September 30, 2021 and December 31, 2020, respectively	7,837	7,837
Series A-2 convertible preferred stock, $0.00001 par value, 4,325,021 shares authorized, and 4,324,998 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $5,373 at September 30, 2021 and December 31, 2020, respectively	5,373	5,373
Series B convertible preferred stock, $0.00001 par value, 22,705,646 shares authorized, and 22,531,819 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $38,894 and $37,429 at September 30, 2021 and December 31, 2020, respectively	20,806	20,806
Series C-1 convertible preferred stock, $0.00001 par value, 58,109,711 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $37,736 and $36,150 at September 30, 2021 and December 31, 2020, respectively	29,353	29,353
Series C-2 convertible preferred stock, $0.00001 par value, 33,218,192 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $15,332 and $14,697 at September 30, 2021 and December 31, 2020, respectively	11,746	11,746
Series D-1 convertible preferred stock, $0.00001 par value, 57,878,742 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $46,003 and $43,908 at September 30, 2021 and December 31, 2020, respectively	39,686	39,686
Series D-2 convertible preferred stock, $0.00001 par value, 24,598,481 shares authorized, and 24,598,481 and 14,469,710 issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of $17,982 and $10,176 at September 30, 2021 and December 31, 2020, respectively	16,889	9,907
Series E convertible preferred stock, $0.00001 par value, 102,671,041 shares authorized, issued and outstanding at September 30, 2021, and a liquidation preference of $83,525 at September 30, 2021; no shares authorized, issued or outstanding at December 31, 2020, respectively	80,246	-
Stockholders' Deficit:		
Common stock, $0.00001 par value, 470,183,383 and 232,697,999 authorized at September 30, 2021 and December 31, 2020, and 442,717 and 381,123 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	-	-
Additional paid-in capital	9,488	8,173
Accumulated deficit	(140,503)	(116,886)
Total Stockholders' Deficit	(131,015)	(108,713)
Total Liabilities, Convertible Preferred Stock, and Stockholders' Deficit	$ 90,704	$ 22,104

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

Condensed Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands except for share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating Expenses:				
Research and development	$ 6,365	$ 2,850	$ 17,182	$ 14,499
General and administrative	2,530	781	6,441	2,798
Total operating expenses	8,895	3,631	23,623	17,297
Total operating loss	8,895	3,631	23,623	17,297
Other income (expense):				
Change in fair value of warrant liability	-	-	1	-
Change in fair value of derivative liability	52	-	-	-
Interest income (expense), including amortization of discount	5	-	8	(2)
Loss from disposal of assets	-	-	(3)	-
Total other income (expense)	57	-	6	(2)
Net loss and comprehensive loss	$ (8,838)	$ (3,631)	$ (23,617)	$ (17,299)
Net loss attributable to common stockholders—basic and diluted	$ (12,506)	$ (5,579)	$ (33,244)	$ (23,101)
Net loss per share attributable to common stockholders—basic and diluted	(28.33)	(14.81)	(77.93)	(63.69)
Weighted average common stock outstanding—basic and diluted	441,448	376,738	426,604	362,735

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

Aura Biosciences, Inc.

Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit (Unaudited)
(in thousands, except share data)

	Convertible Preferred Stock														Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Series A		Series A-1		Series A-2		Series B		Series C-1 and C-2		Series D-1 and D-2		Series E						
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2019	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	57,878,742	$ 39,686	—	—	340,591	—	$ 7,274	$ (94,680)	$ (87,406)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	177	—	177
Stock option exercises	—	—	—	—	—	—	—	—	—	—	—	—	—	—	7,880	—	33	—	33
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(7,512)	(7,512)
Balance, March 31, 2020	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	57,878,742	$ 39,686	—	$ —	348,471	$ —	$ 7,484	$ (102,192)	$ (94,708)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	189	—	189
Stock option exercises	—	—	—	—	—	—	—	—	—	—	—	—	—	—	24,648	—	97	—	97
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(6,156)	(6,156)
Balance, June 30, 2020	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	57,878,742	$ 39,686	—	$ —	373,119	$ —	$ 7,770	$ (108,348)	$ (100,578)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	191	—	191
Stock option exercises	—	—	—	—	—	—	—	—	—	—	—	—	—	—	6,783	—	18	—	18
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(3,631)	(3,631)
Balance, September 30, 2020	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	57,878,742	$ 39,686	—	$ —	379,902	$ —	$ 7,979	$ (111,979)	$ (104,000)
Balance, December 31, 2020	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	72,348,452	$ 49,593	—	$ —	381,123	$ —	$ 8,173	$ (116,886)	$ (108,713)
Issuance of Series D Tranche 2, convertible preferred stock, net of issuance costs of $18	—	—	—	—	—	—	—	—	—	—	10,128,771	6,982	—	—	—	—	—	—	—
Issuance of Series E convertible preferred stock, net of issuance costs of $237	—	—	—	—	—	—	—	—	—	—	—	—	102,671,041	80,246	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	185	—	185
Stock option exercises	—	—	—	—	—	—	—	—	—	—	—	—	—	—	54,296	—	265	—	265
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(5,927)	(5,927)
Balance, March 31, 2021	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	82,477,223	$ 56,575	102,671,041	$ 80,246	435,419	$ —	$ 8,623	$ (122,813)	$ (114,190)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	271	—	271
Stock option exercises	—	—	—	—	—	—	—	—	—	—	—	—	—	—	3,649	—	20	—	20
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,852)	(8,852)
Balance, June 30, 2021	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	82,477,223	$ 56,575	102,671,041	$ 80,246	439,068	$ —	$ 8,914	$ (131,665)	$ (122,751)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	554	—	554
Stock option exercises	—	—	—	—	—	—	—	—	—	—	—	—	—	—	3,649	—	20	—	20
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,838)	(8,838)
Balance, September 30, 2021	1,701,141	$ 3,368	3,298,732	$ 7,837	4,324,998	$ 5,373	22,531,819	$ 20,806	91,327,903	$ 41,099	82,477,223	$ 56,575	102,671,041	$ 80,246	442,717	$ —	$ 9,488	$ (140,503)	$ (131,015)

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

Aura Biosciences, Inc.

Condensed Statements of Cash Flows (Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (23,617)	$ (17,299)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	601	605
Change in fair value of warrant liability	(1)	-
Stock-based compensation expense	1,010	557
Loss on disposal of property and equipment	(3)	-
Operating lease expense	4	-
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(566)	(52)
Accounts payable	891	(1,837)
Accrued expenses and other liabilities	1,357	(2,538)
Net cash used in operating activities	(20,324)	(20,564)
Cash flows from investing activities:		
Purchases of property and equipment	(1,306)	(639)
Net cash used in investing activities	(1,306)	(639)
Cash flows from financing activities:		
Proceeds from exercise of stock options	305	148
Advanced proceeds from issuance of Series D convertible preferred stock, net of issuance costs	-	4,849
Proceeds from issuance of Series D convertible preferred stock, net of issuance costs	6,982	-
Proceeds from issuance of Series E convertible preferred stock, net of issuance costs	80,246	-
Payments made for deferred offering costs	(1,416)	-
Payments made for deferring financing costs related to issuance of Series D convertible preferred stock	-	(69)
Other	-	(25)
Net cash provided by financing activities	86,117	4,903
Net increase (decrease) in cash, cash equivalents and restricted cash	64,487	(16,300)
Cash, cash equivalents and restricted cash at beginning of period	17,487	32,543
Cash, cash equivalents and restricted cash at end of period	$ 81,974	$ 16,243
Supplemental Disclosure of Cash Flow Information:		
Purchases of property and equipment in accounts payable and accrued expenses and other liabilities	$ 159	$ —
Initial measurement of right-of-use assets and lease liabilities for operating lease	$ 536	$ —
Remeasurement of right-of-use assets and lease liabilities for lease modification	$ 390	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ 516	$ —

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed balance sheets that sum to the total of the same such amounts shown in the condensed statements of cash flows (in thousands):

	September 30, 2021	**September 30, 2020**
Cash and cash equivalents, end of period	$ 81,829	$ 11,302
Short-term restricted cash, end of period	20	4,866
Long-term restricted cash, end of period	125	75
Cash, cash equivalents and restricted cash at end of period	$ 81,974	$ 16,243

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

1. Description of Business

Aura Biosciences, Inc. is a clinical-stage biotechnology company leveraging its novel targeted oncology platform to develop a potential new standard of care across multiple cancer indications, with an initial focus on ocular and urologic oncology. Within these condensed financial statements, unless the context otherwise requires, references to the Company or Aura refer to Aura Biosciences, Inc. The Company's proprietary platform enables the targeting of a broad range of solid tumors using Virus-Like Particles, or VLPs, that can be conjugated with drugs or loaded with nucleic acids to create Virus-Like Drug Conjugates, or VDCs. The Company's VDCs are largely agnostic to tumor type and can recognize a surface marker, known as HSPGs, that are specifically modified and more broadly expressed on many tumors. The Company is developing AU-011, its first VDC product candidate for the first line treatment of primary choroidal melanoma, a rare disease with no drugs approved. The Company is also developing AU-011 for additional ocular oncology indications and in non-muscle invasive bladder cancer. Aura's team combines expertise in cancer cell biology, ophthalmology, and targeted therapies together with experience in the development and commercialization of orphan products for significant unmet medical needs. Aura's headquarters are located in Cambridge, Massachusetts.

The Company's operations to date have consisted primarily of conducting research and development and raising capital.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, the successful development and commercialization of products, fluctuations in operating results and financial risks, need for additional financing or alternative means of financial support or both to fund its current operating plan, protection of proprietary technology and patent risks, compliance with government regulations, dependence on key personnel and collaborative partners, competition, customer demand, management of growth, and the effectiveness of marketing by the Company.

Liquidity and Going Concern

Through September 30, 2021, the Company has funded its operations primarily with proceeds from the initial closing and additional closings of its convertible preferred stock financings. The Company has incurred recurring losses and negative cash flows from operations since its inception, including net losses of $23.6 million and $17.3 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, the Company had cash and cash equivalents of $82.0 million and an accumulated deficit of $140.5 million. The Company expects to continue to generate operating losses for the foreseeable future.

On November 2, 2021, the Company completed its initial public offering, or the IPO, in which it issued and sold 6,210,000 shares of common stock, including the full exercise of the underwriters' option to purchase additional shares at a price to the public of $14.00 per share for aggregate gross proceeds of $86.9 million. The Company received approximately $77.9 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses.

As of November 24, 2021, the issuance date of these condensed financial statements, the Company expects that its cash and cash equivalents and total net proceeds from the IPO of $77.9 million will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of these condensed financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

Impact of COVID-19

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government- imposed travel restrictions on travel between the United States, Europe and certain other countries. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as certain worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the pandemic and its effects on the Company's business and operations are uncertain.

The Company is monitoring the potential impact of COVID-19 on its business and condensed financial statements. The effects of the public health directives and the Company's work-from-home policies may negatively impact productivity, disrupt its business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on its ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact business, results of operations and financial condition, including its ability to obtain financing.

To date, the Company has not incurred impairment losses in the carrying values of its assets as a result of the pandemic and are not aware of any specific related event or circumstance that would require the Company to revise its estimates reflected in the condensed financial statements.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business and prospects. The extent to which the COVID-19 pandemic will directly or indirectly impact its business, results of operations, financial condition, and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. In management's opinion, the accompanying unaudited condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows.

Unaudited Interim Financial Information

The accompanying condensed balance sheet as of September 30, 2021, the condensed statements of operations and comprehensive loss, condensed statement of convertible preferred stock and stockholders' deficit for the three and nine months ended September 30, 2021 and 2020, and the condensed statements of cash flows for the nine months ended September 30, 2021 and 2020 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2021 and the results of its operations for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the nine months ended September 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2021 and 2020 are also unaudited. The unaudited condensed results of operations are not necessarily indicative of the operating results that may occur for the full fiscal year ending December 31, 2021. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission, or the SEC. Management believes that the disclosures provided here are adequate to make the information presented not misleading when these unaudited condensed financial statements are read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2020. The balance sheet data as of December 31, 2020 was derived from the Company's audited financial statements included in the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 1, 2021.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2020, filed with the SEC as a part of the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 1, 2021. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies except as noted below.

Cash Equivalents

Cash equivalents are highly liquid investments with an original maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds that invest in U.S. Treasury obligations and government funds with commercial banks and financial institutions.

Leases

Prior to January 1, 2021, the Company accounted for leases in accordance with ASC 840, Leases. At lease inception, the Company determined if an arrangement was an operating or capital lease. For operating leases, the Company recognized rent expense, inclusive of rent escalation, holidays and lease incentives, on a straight-line basis over the lease term. The difference between rent expense recorded and the amount paid was charged to deferred rent. The Company presented lease incentives as deferred rent and amortized the incentives as a reduction to rent expense on a straight-line basis over the lease term. The Company classified deferred rent as current and noncurrent liabilities based on the portion of the deferred rent that was scheduled to mature within the proceeding twelve months.

Effective January 1, 2021, the Company accounts for leases in accordance with ASU No. 2016-02, *Leases (Topic 842) ("ASC 842")*. At contract inception, the Company determines if an arrangement is or contains a lease. A lease conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If determined to be or contain a lease, the lease is assessed for classification as either an operating or finance lease at the lease commencement date, defined as the date on which the leased asset is made available for use by the Company, based on the economic characteristics of the lease. For each lease with a term greater than twelve months, the Company records a right-of-use asset and lease liability.

The Company adopted the new leasing standard effective January 1, 2021, using the modified retrospective transition approach which uses the effective date, or January 1, 2021, as the date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840. ASC 842 provides several optional practical expedients in transition. The Company has elected to apply the package of practical expedients requiring no reassessment of whether any expired or existing contracts are or contain leases, the lease classification of any expired or existing leases, or the capitalization of initial direct costs for any existing leases.

A right-of-use asset represents the economic benefit conveyed to the Company by the right to use the underlying asset over the lease term. A lease liability represents the obligation to make lease payments arising from the lease. The Company elected the practical expedient to not separate lease and non-lease components for all classes of underlying assets and therefore measures each lease payment as the total of the fixed lease and associated non-lease components. Lease liabilities are measured at lease commencement and calculated as the present value of the future lease payments in the contract using the rate implicit in the contract, when available. If an implicit rate is not readily determinable, the Company uses an incremental borrowing rate measured as the rate at which the Company could borrow, on a fully collateralized basis, a commensurate loan in the same currency over a period consistent with the lease term at the commencement date. Right-of-use assets are measured as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor. The lease term is measured as the noncancelable period in the contract, adjusted for any options to extend or terminate when it is reasonably certain the Company will extend the lease term via such options based on an assessment of economic factors present as of the lease commencement date. The Company elected the practical expedient to not recognize leases with a lease term of twelve months or less.

Components of a lease are split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) are allocated, based on the respective relative fair values, to the lease components and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

The Company's operating leases are presented in the condensed balance sheet as operating lease right-of-use assets, classified as noncurrent assets, and operating lease liabilities, classified as current and noncurrent liabilities. Operating lease expense is recognized on a straight-line basis over the lease term. Variable costs associated with a lease, such as maintenance and utilities, are not included in the measurement of the lease liabilities and right-of-use assets but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common stock financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. As of September 30, 2021, the Company had deferred offering costs of $1.6 million.

Recently Adopted Accounting Pronouncements

Upon adoption of ASC 842, the Company recorded lease liabilities and their corresponding right-of-use assets based on the present value of lease payments over the remaining lease term. The adoption of ASC 842 resulted in the recognition of operating lease liabilities of $0.6 million and operating lease right-of-use assets of $0.5 million and the derecognition of deferred rent liabilities of $0.02 million on the Company's balance sheet as of January 1, 2021. The adoption impact relates to the Company's existing operating lease for operating and laboratory space. The adoption of ASC 842 did not have a material impact on the Company's statements of operations and comprehensive loss or statements of cash flows.

3. Fair Value of Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of September 30, 2021 and December 31, 2020 (in thousands):

Description	September 30, 2021	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
Assets				
Money market funds	$ 79,829	$ 79,829	$ —	$ —
Total financial assets	$ 79,829	$ 79,829	$ —	$ —
Liability				
Warrant liability	$ 71	$ —	$ —	$ 71
Total financial liabilities	$ 71	$ —	$ —	$ 71

Description	December 31, 2020	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
Liability				
Warrant liability	$ 72	$ —	$ —	$ 72
Total financial liabilities	$ 72	$ —	$ —	$ 72

At September 30, 2021, the Company's cash equivalents include investments in money market funds that invest in U.S. Treasury obligations and government funds, the fair value of which is valued using level 1 inputs. The fair value of the warrant liability was determined based on Level 3 inputs and utilizing the Black-Scholes option pricing model (see Note 10). Significant changes to these assumptions would result in increases or decreases to the fair value of the warrant liability.

During the nine months ended September 30, 2021 and 2020, there were no transfers into or out of Level 3.

The following table set forth a summary of changes in the fair value of the Series B Warrants, which represents a recurring fair value measurement that is classified within Level 3 of the fair value hierarchy. Changes in fair value are recognized in other (expense) income as "Change in fair value of warrant liability" in the Company's condensed statements of operations and comprehensive loss (in thousands):

Series B Warrants (173,827 warrants)	
Fair value at December 31, 2020	$ 72
Change in fair value	(1)
Fair value at September 30, 2021	$ 71

4. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Assets under construction	$ 1,741	$ 1,154
IT equipment	73	—
Leasehold improvements	13	—
Lab equipment	5,085	4,708
Office furniture	63	64
Total property and equipment	$ 6,975	$ 5,926
Less—accumulated depreciation	(2,533)	(2,352)
Property and equipment, net	$ 4,442	$ 3,574

Depreciation expense was $0.2 million for the three months ended September 30, 2021 and 2020, and was $0.6 million for the nine months ended September 30, 2021 and 2020.

5. Prepaid Expenses and Other Current Assets

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

	September 30, 2021	December 31, 2020
Prepaid insurance	$ 80	$ 51
Prepaid research and development expenses	1,474	976
Other	55	16
Prepaid expenses and other current assets	$ 1,609	$ 1,043

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Accrued research and development expenses	$ 1,184	$ 750
Accrued compensation	1,569	1,023
Other	735	277
Accrued expenses and other current liabilities	$ 3,488	$ 2,050

7. Convertible Preferred Stock

As of September 30, 2021, the Company had 1,701,141 authorized, issued and outstanding shares of Series A Preferred stock, par value $0.00001, or the Series A, 3,298,732 authorized, issued and outstanding shares of Series A-1 Preferred stock, par value $0.00001, or the Series A-1, 4,325,021 authorized shares and 4,324,998 issued and outstanding shares of Series A-2 Preferred stock, par value $0.00001, or the Series A-2, and 22,705,646 authorized shares and 22,531,819 issued and outstanding shares of Series B Preferred stock, par value $0.00001, or the Series B, 58,109,711 authorized, issued and outstanding shares of Series C-1 Preferred stock, par value $0.00001, or the Series C-1, 33,218,192 authorized, issued and outstanding shares of Series C-2 Preferred stock, par value $0.00001, or the Series C-2, together with Series C-1, the Series C, 57,878,742 authorized, issued and outstanding shares of Series D-1 Preferred stock, par value $0.00001, or the Series D-1, and 24,598,481 authorized, issued and outstanding shares of Series D-2 Preferred stock, par value $0.00001, or the Series D-2, together with the Series D-1, the Series D, 102,671,041 authorized, issued, and outstanding shares of Series E Preferred stock, par value $0.00001, or the Series E, and together with the Series D, the Series C and the Series B, collectively the Senior Preferred Stock. All series of convertible preferred stock are collectively referred to as the Preferred Stock, each with a par value of $0.00001 per share.

Series D-2 Offering

On June 25, 2020, the Company entered into a Series D-2 Convertible Preferred Stock Purchase Agreement, or the Series D-2 Agreement, with certain investors to sell up to 24,598,481 shares of the Series D-2 stock at a purchase price of $0.6911 per share. The Series D-2 Agreement provides for two closings, the first on October 1, 2020, and the second upon the achievement or waiver of certain milestone events. The Company sold 14,469,710 shares of the Series D-2 on October 1, 2020, at the first tranche closing for gross proceeds of $10.0 million.

On March 5, 2021, the Company completed the second tranche of the Series D-2 offering and issued 10,128,771 shares of the Series D-2 at a purchase price of $0.6911 per share for gross proceeds of $7.0 million.

Costs incurred in connection with the Series D-2 offering totaled $0.1 million and were recorded as a reduction of proceeds from the Series D-2. The majority of offering costs were incurred during the year ended December 31, 2020. Offering costs incurred during the nine months ended September 30, 2021, were $0.02 million.

Series E Offering

On March 18, 2021, the Company completed its Series E offering and issued 102,671,041 shares of Series E stock, $0.00001 par value per share, at a purchase price of $0.7839 per share for gross proceeds of $80.5 million.

Costs incurred in connection with the Series E offering totaled $0.2 million during the nine months September 30, 2021 and were recorded as a reduction to the Series E convertible preferred stock.

The rights and privileges of the Company's Preferred Stock are as follows:

Voting

Except as otherwise required by law or by other provisions, holders of the Preferred Stock vote together with the holders of common stock as a single class. Holders of the Preferred Stock may cast the number of votes equal to the number of shares of common stock to which such shares of the Preferred Stock are convertible into.

Dividends

Series C, D, and E Dividends:

From and after the date of the issuance of any shares of the Series C-1, Series C-2, Series D-1, Series D-2, and Series E, dividends at the annual rate of seven percent (7%) per annum of the original share price per share accrue on such shares of the Series C-1, Series C-2, Series D-1, Series D-2, and Series E. Dividends accrue from day to day, whether or not declared, and are cumulative, but not compounding. Such dividends are only payable when and if declared by the Board of Directors (the "Board") or in the event of a Deemed Liquidation Event (as defined in the amended and restated Certificate of Incorporation). No other dividends may be declared or paid on any other class of stock unless the holders of the shares of the Series E then outstanding first receive, or simultaneously receive, their applicable dividend. As of September 30, 2021, $7.4 million, $3.2 million, $6.0 million, $1.0 million, and $3.0 million of cumulative dividends on the Series C-1, Series C-2, Series D-1, Series D-2, and Series E respectively, are included in the liquidation preference amount indicated on the balance sheet.

Series B Dividends:

From and after the date of the issuance of any shares of the Series B, dividends at the annual rate of $0.0869645 per share accrue on such shares of the Series B. Dividends accrue from day to day, whether or not declared, and are cumulative, but not compounding. Such dividends are only payable when and if declared by the Company's Board or in the event of a Deemed Liquidation Event (as defined in the amended and restated Certificate of Incorporation). No other dividends may be declared or paid on any other class of stock unless the holders of the shares of the Series B then outstanding first receive, or simultaneously receive, their applicable dividend. As of September 30, 2021, $10.9 million of cumulative dividends on the Series B are included in the liquidation preference amount indicated on the balance sheet.

Series A Dividends

From and after the date of the issuance of the Series A, Series A-1, and Series A-2, if the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of the Series A, Series A-1, and Series A-2 convertible preferred stock shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest dividend. No other dividends, or dividends on common stock payable in shares of common stock, may be declared or paid unless the holders of the Series A, Series A-1, and Series A-2 then outstanding first receive, or simultaneously receive, their applicable dividend. As of September 30, 2021, no dividends have been declared on the common stock or the Preferred Stock.

Liquidation Rights

In the event of a Deemed Liquidation Event, as defined in the Company's amended and restated Certificate of Incorporation, the assets of the Company will be distributed first to the holders of the Series E. The holders of the Series E will receive, in preference to all other stockholders, an amount equal to the sum of the Series E original issue price (equal to the cash price paid per share of $0.783900), plus unpaid dividends on such shares. Next, the holders of the Series D will receive, in preference to all other stockholders other than the Series E, an amount equal to the sum of the Series D original issue price, plus unpaid dividends on such shares. Next, the holders of the Series C will receive, in preference to all stockholders other than the Series E and D holders, an amount equal to the sum of the Series C original issue price plus unpaid dividends on such shares. Next, the holders of the Series B will receive, in preference to the holders of the Series A, Series A-1, Series A-2 and common stock, an amount equal to the sum of the Series B original issue price plus unpaid dividends on such shares. Next, the holders of the Series A, Series A-1, and Series A-2 will receive, in preference to the holders of common stock, an amount equal to the greater of their applicable liquidation preference or what they would have received had their shares converted into common stock. If the proceeds available are not sufficient to satisfy the full liquidation preference, the entire proceeds are to be distributed pro-rata among the Series E holders in proportion to the full preferential amount the Series E holders are entitled to receive.

Conversion

The Senior Preferred Stock converts into common stock on a one-for-one basis. Each share of the Series B, Series C-1, Series C-2, Series D-1, Series D-2, and Series E is convertible into the number of shares of common stock as is determined by dividing the respective original issue price by the conversion price in effect at the time of conversion. The Series E conversion price is set at $0.7839 per share, the Series D-1 and Series D-2 conversion price is set at $0.6911 per share, the Series C-1 conversion price is set at $0.5213 per share, the Series C-2 conversion price is set at $0.36491 per share, and the Series B conversion price is set at $1.24235 per share; none represents a beneficial conversion feature. Subject to certain exceptions, the Senior Preferred Stock has the benefit of anti- dilution protection on a weighted-average basis in the event that the Company sells stock at less than the applicable conversion price per share.

Each share of the Series A and Series A-1 was originally convertible into the number of shares of common stock determined by dividing the respective Series A and Series A-1 original issue price by the conversion price in effect at the time of conversion. The Series A conversion price was originally equal to $2.00 per share and the Series A-1 conversion price was originally equal to $2.4847 per share. As the Series A-2 was sold at $1.24235 per share, less than the per share prices of the Series A and Series A-1, anti-dilution protections were triggered. Pursuant to the anti-dilution protection terms, on February 24, 2015, the Series A conversion price was reduced from $2.00 to $1.8191 per share of common stock and the Series A-1 conversion price was reduced from $2.4847 to $2.1898 per share of common stock and, therefore, the Series A conversion ratio was changed from 1 to 1 to 1 to 1.099 and the Series A-1 conversion ratio was changed from 1 to 1 to 1 to 1.135. The Company evaluated the Series A and Series A-1 with the updated conversion ratios and determined that there was no beneficial conversion feature.

The Series A-2 converts into common stock on a one-for-one basis. The Series A-2 conversion price is set at $1.24235 per share and does not represent a beneficial conversion feature.

According to the terms of the Company's amended and restated Certificate of Incorporation, in the event that the applicable conversion price for any series of Senior Preferred Stock is reduced, then the applicable conversion price for each series of the Series A convertible preferred stock shall be uniformly and concurrently reduced.

Each share of the Preferred Stock will automatically convert into common stock upon (a) the occurrence of an event, specified by vote or written consent of certain stockholders or (b) the completion of a public stock offering involving a price per share of common stock of not less than $1.554975 per share, subject to certain adjustments, where such offering results in aggregate gross proceeds to the Company of at least $50.0 million and the common stock is listed for trading on either the New York Stock Exchange or the Nasdaq Stock Market.

The Company must reserve and keep available out of its authorized but unused capital stock such number of authorized shares of common stock to sufficiently effect the conversion of all outstanding Preferred Stock.

In considering the features of the convertible preferred stock, the Company determined that none of the features, including the conversion features, requires bifurcation during the nine months ended September 30, 2021 and 2020.

The conversion ratios for the Series A was changed to 13.700 to 1.099, Series A-1 was changed to 13.7 to 1.135 , and the Series A-2 through the Series E was changed to 13.7 to 1 upon the Company's filing of its amendment to its amended and restated Certificate of Incorporation on October 22, 2021 (see Note 16).

8. Common Stock

The Company had 470,183,383 and 232,697,999 authorized shares of common stock, par value $0.00001 per share, of which 442,717 and 381,123 shares were issued and outstanding as of September 30, 2021 and December 31, 2020, respectively.

9. Stock-Based Compensation

On January 15, 2009, the Company's Board adopted the 2009 Long-Term Incentive Stock Option Plan (the "2009 Plan") for the issuance of stock-based compensation to both employees and non- employees. The awards under this plan typically vest over a 24, 36 or 48-month period, depending on the option agreement and have a 10-year term. On December 12, 2018, the 2009 Plan expired, and the Company adopted the Aura Biosciences, Inc. 2018 Equity Incentive Plan (the "2018 Plan" and collectively with the 2009 Plan, the "Plans"). No options were modified in conjunction with the expiration of the 2009 Plan. The options granted under the 2009 Plan continue to be outstanding in accordance with their original terms. The 2018 Plan will expire in 2028. Under the 2018 Plan, Aura may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and stock rights.

The Board is authorized to administer the 2018 Plan. In accordance with the provisions of the 2018 Plan, the Board determines the terms of Aura options and other awards issued pursuant thereto, including the following:

- which employees, directors and consultants shall be granted awards;
- the number of shares of common stock subject to options and other awards;
- the exercise price of each option, which generally shall not be less than fair market value of the common stock on the date of grant;
- the termination or cancellation provisions applicable to options;
- the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and
- all other terms and conditions upon which each award may be granted in accordance with the 2018 Plan.

In addition, the Board or any committee to which the Board delegates authority may, with the consent of the affected plan participants, re-price or otherwise amend outstanding awards consistent with the terms of the 2018 Plan. On March 18, 2021, the Board approved an increase to the 2018 Plan available option pool of 2,346,228 options. With this increase and the transfer of the available options from the 2009 Plan, there were 650,795 options available for grant under the 2018 Plan at September 30, 2021.

The following table summarizes the combined stock option activity under the 2009 and the 2018 Plan for the nine months ended September 30, 2021:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	1,512,129	$ 3.84	7.77	$ 1,174
Granted	1,883,480	6.13	-	-
Exercised	(61,594)	4.95	-	-
Cancelled or forfeited	(169,066)	4.50	-	-
Outstanding at September 30, 2021	3,164,949	$ 5.15	8.60	$ 14,053
Exercisable at September 30, 2021	1,024,453	$ 3.85	6.75	$ 5,849

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2021 and 2020 is $3.97 and $2.74 per share, respectively. The total intrinsic value of options exercised was $0.01 million and $0.02 million for the nine months ended September 30, 2021 and 2020, respectively.

The Company has elected to use the Black-Scholes option pricing model to determine the fair value of options granted and generally recognizes the compensation cost of stock-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of stock-based payment awards utilizing the Black-Scholes option pricing model is affected by the estimated fair value of the Company's common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate, and expected dividends.

The fair value of the stock options issued for the three and nine months ended September 30, 2021 and 2020 was measured with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Weighted average risk-free interest rate	1.00%	0.33%	1.06%	0.58%
Expected term (years)	6.06	5.67	6.02	6.03
Expected volatility	73.36%	73.71%	74.21%	74.16%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

The Company recorded stock-based compensation expense as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 157	$ 47	$ 263	$ 153
General and administrative	397	144	747	404
Total	$ 554	$ 191	$ 1,010	$ 557

As of September 30, 2021, there was $7.9 million of unrecognized compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.61 years.

10. Series B Warrants

In February 2015 and May 2015, the Company issued warrants to purchase 1,650,098 and 887,536 shares of the Series B convertible preferred stock, respectively, at an exercise price of $1.24235 per share. Each Series B Warrant was immediately exercisable and expires in ten years from the original date of issuance. Pursuant to FASB ASC Topic 480, *Distinguishing Liabilities from Equity*, the Series B Warrants were classified as a liability and are re-measured to fair value at each balance sheet date and immediately prior to exercise. The Series B Warrants were converted into warrants to purchase 12,686 shares of common stock upon the completion of the IPO in November 2021.

A total of 173,827 of the Series B Warrants remained outstanding at September 30, 2021 and December 31, 2020.

The warrants were valued using the Black-Scholes option pricing model. The estimated fair value of the warrants and the significant assumptions used were as follows:

Series B Warrants	September 30, 2021	December 30, 2021
Series B estimated fair value	$ 1.12	$ 1.17
Volatility	79.50%	74.07%
Expected term (years)	3.5	4.2
Risk free rate	0.76%	0.27%
Dividend yield	7.00%	7.00%

During the nine months ended September 30, 2021, the change in fair value of the warrant liability was deemed immaterial.

11. Compensation

In January 2012, the Company adopted the Aura Biosciences 401(k) Profit Sharing Plan and Trust (the "401(k) Plan") for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. The Company makes matching contributions of 100% of the first 6% of employee contributions. The Company made matching contributions in the amount of $0.2 million and $0.1 million for the nine months ended September 30, 2021 and 2020, respectively.

12. Commitments and Contingencies

Lease Commitments

The Company has historically entered into lease arrangements for its facilities. As of December 31, 2020, the Company had one operating lease for its office and laboratory facility with required future minimum payments. The lease does not contain any options to renew, terminate, or purchase the underlying asset, and was set to expire on July 31, 2022. As part of its adoption of ASC 842, the Company recorded a right-of-use asset and operating lease liability for this lease as of the effective date.

On March 31, 2021, the Company executed an amendment to the facility lease which included an extension of the expiration date of the original leased premises, the addition of 4,516 square feet of laboratory space with an expected commencement date of May 1, 2021, and the addition of 1,000 square feet of laboratory space with an expected commencement date of June 15, 2021. The lease term for the original and new spaces will expire on July 31, 2023, with an option to renew for an additional 12 months.

Upon the execution of the amendment, which was deemed to be a lease modification, the Company re-evaluated the assumptions made at the original lease commencement date. The Company determined the amendment consists of two separate contracts under ASC 842. One contract is related to the modification of term for the original space, and the other is related to a new right-of-use for the two additional spaces, which are to be accounted for as new leases. The Company remeasured the lease liability and corresponding right-of-use asset for the original space as of the effective date of the amendment to reflect the extended term and recorded in the second quarter of 2021 an additional right-of-use asset and lease liability upon lease commencement of each of the additional space.

The Company also leases office and laboratory equipment for which the related expense is immaterial.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's leases for the three and nine months ended September 30, 2021 (in thousands):

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Lease Cost		
Financing lease costs:		
Amortization of finance right-of-use assets	$ -	$ 11
Operating lease costs	154	370
Variable lease costs	90	233
Total lease costs	$ 244	$ 614
Cash paid for amounts included in the measurement of lease liability—finance leases		$ 15
Cash paid for amounts included in the measurement of lease liability—operating leases		$ 367
Weighted-average remaining lease term—operating leases (years)		1.83
Weighted-average discount rate—finance leases		7.94%
Weighted-average discount rate—operating leases		3.51%

The following table reconciles the future minimum commitments to the Company's operating lease liabilities at September 30, 2021 (in thousands):

	Operating lease payments as of September 30, 2021
2021 (excluding nine months ended September 30, 2021)	$ 153
2022	625
2023	377
Total lease payments	1,155
Less: interest	(35)
Total operating lease liabilities at September 30, 2021	1,120
Less: current portion of lease liabilities	607
Lease liabilities, net of current portion	$ 513

In May 2021, the Company paid in full its finance lease.

Laser Purchasing Commitment

On April 5, 2019, the Company entered into a purchase agreement for equipment with future commitments payable in three installments of €0.2 million each. The first two installments of €0.2 million were paid by the Company in April 2019 and August 2019. Upon receipt of the laser systems, the Company will assess whether the laser systems have an alternative future use and, if so, will capitalize the lasers as a component of fixed assets.

License Agreements

The Company has entered into the following key agreements that relate to the core technology under development:

LI-COR Exclusive License and Supply Agreement

In January 2014, the Company entered into an Exclusive License and Supply Agreement, or the LI-COR Exclusive License Agreement, with LI-COR, Inc., or LI-COR, for the license of IRDye 700DX and related licensed patents for the treatment and diagnosis of ocular cancers in humans, and as amended in January 2016, July 2017, April 2018 and April 2019. LI-COR is a related party owning shares of the Company's capital stock. The LI-COR Exclusive License Agreement required a one-time upfront license issue fee of $0.1 million and requires aggregate milestone payments of up to $0.2 million upon certain regulatory and development milestones. The Company is also required to pay LI-COR low-single digit royalties on net sales. The term of the LI-COR Exclusive Agreement expires on a country-by-country basis, until the longer of (i) ten years from the first commercial sale of a licensed product in such country and (ii) the last to expire valid claim in such country. The Company recognized no expenses related to this agreement and related amendments for the nine months ended September 30, 2021 and 2020, respectively.

LI-COR Non-Exclusive License and Supply Agreement

In December 2014, the Company entered into a Non-Exclusive License Agreement, or the 2014 Non-Exclusive Agreement, for LI-COR to supply IRDye 700DX to the Company for the treatment and diagnosis of non-ocular cancers in humans. Under the 2014 Non-Exclusive Agreement, the Company paid a license issue fee of $0.03 million on the effective date. The Company must also pay LI-COR a non-refundable, non-creditable fee of $0.03 million per each licensed product upon pre-IND designation, as defined, of such licensed product. During the term, the Company must pay LI-COR low-single digit royalties on net sales. LI-COR receives 10% of all sublicensee income within 30 days of the Company's receipt from the sublicensee. The 2014 Non-Exclusive Agreement also required the Company to make certain payments upon the achievement of specified development and commercial milestones of up to $0.4 million in the aggregate.

Life Technologies Corporation

In December 2014, the Company entered into a non-exclusive, perpetual license agreement with Life Technologies Corporation, or Life Technologies, which allows the use of their HEK293 cell lines to manufacture Aura's products. Under this agreement the Company is required to pay an initial license fee of $0.1 million for each product. An annual development fee of $0.1 million is due within a year from the payment of the initial license fee and due annually until the earlier of (i) payment of a commercialization fee or (ii) all development work is terminated. The commercialization fee is a one-time, non-refundable, non-creditable fee of $0.3 million due upon receipt of approval of a licensed product. In the event of a change of control of an above 50% change in voting share, there will be a change of control fee of $0.2 million. The Company recorded a derivative liability due an increased probability of payment assessed in June 2021 to account for the change of control fee. Such amount was reduced to nil during the three months ended September 30, 2021 as the probability of a change of ownership above 50% of voting shares for the pending IPO was deemed probable not to occur. During the nine months ended September 30, 2021 and 2020, the Company recognized $0.03 million of expenses related to this agreement.

National Institute of Health (NIH)-Biologic Materials License Agreement

In December 2010, the Company entered into a Biologic Materials License Agreement with National Institutes of Health, or the NIH, for a non-exclusive right to use materials described in Schiller et al., Virology 2004 Apr.10, 321(2):205-16, which required a one-time non-refundable license issuance fee of $0.02 million. No future milestone payments or royalties are due under this agreement.

National Institute of Health (NIH)-Collaboration Research and Development Agreement

In July 2011, the Company entered into a Collaboration Research and Development Agreement, or CRADA, with Dr. John Schiller at the NIH, for a period of two years with the rights to an exclusive license to all technology generated within the collaboration. Under the agreement, the Company was required to make annual payments each year to fund the research activities, with the first payment due within 30 days of the effective date and subsequent payments due within 30 days of the anniversary date. This agreement was further amended in 2012, 2013, 2014, 2015, 2016, 2018 and most recently in September of 2020. During 2011-2020, the Company paid an aggregate of $0.3 million in research collaboration fees, $0.04 million of which was paid in 2020.

In September 2020, the Company executed the seventh amendment to the CRADA agreement. In this amendment the term of this agreement is extended until September 30, 2022, and the Company paid $0.03 million on the tenth anniversary of the CRADA agreement which occurred in July of 2021.

National Institute of Health (NIH)-Exclusive Patent License Agreement

In 2013, the Company entered into an exclusive patent license agreement that required the Company to pay a license issue royalty fee of $0.1 million and reimburse the NIH for any patent expenses incurred. Under the agreement, the Company is required to make low single-digit percentage royalty payments based on specified levels of annual net sales of licensed products subject to certain specified reductions. The Company is required to make development and regulatory milestone payments up to $0.7 million in the aggregate and sales milestone payments up to $0.6 million in the aggregate. The Company is also required to pay NIH a mid-single to low teen-digit percentage of any sublicensing revenue the Company receives. Additionally, the Company's payment obligations to NIH are subject to an annual minimum royalty payment of low five figures. As of September 30, 2021, the Company has paid NIH approximately $0.4 million in aggregate milestones under the NIH license agreement. In addition to milestones under the agreement, the Company reimburses the NIH for any patent filing costs incurred. As of September 30, 2021, the Company has reimbursed the NIH approximately $0.3 million in aggregate. The Company accrued $0.03 million and $0.02 million in patent licensing reimbursement fees as of September 30, 2021 and December 31, 2020.

In 2015, 2018 and 2019, the Company amended its exclusive patent license to include updates on the status of the commercial development and update/expand the list of licensed patents and patent applications. Each of those amendments required a $0.03 million payment that the Company paid.

Inserm

In November 2009, the Company entered into an exclusive, royalty-bearing license agreement with Inserm-Transfert of France for use of its patents. The agreement expires on a country by country basis based on the last to expire of any patent encompassed within the scope of the patent rights or 10 years from the date of the first commercial sale by the Company, whichever is later. There are potential milestone payments of €0.5 million ($0.5 million at December 31, 2020) in the aggregate associated with this agreement. The IND filing milestone of €0.01 million was accrued in 2016 and paid in 2017 by the Company. The milestones for the successful Phase I, II and III clinical trials are based on receiving a final report and achieving the primary endpoints defined in that trial and those milestones have not been achieved as of September 30, 2021. Upon the sublicense by the Company of a product for which royalties are payable under this agreement, low- to mid-single-digit royalty payments would be due by the Company. If Aura sublicenses the delivery platform for use with multiple drugs, low- to mid-teen payments on receipts would be due by the Company. The non-milestone payments in this agreement are subject to an anti-stacking clause. The Company did not incur any expense in the period ended September 30, 2021 and 2020.

Clearside

In July 2019, the Company entered into an exclusive license agreement with Clearside Biomedical, Inc., or Clearside, for the license of Clearside's Suprachoroidal Microneedle Technology for use in the treatment of indeterminate lesions, and choroidal tumors. Upon execution of the license agreement, the Company paid Clearside an upfront payment of $0.1 million which was expensed as incurred. Under the Clearside license agreement, the Company is required to pay milestones up to $21.0 million in the aggregate to Clearside upon the achievement of specified regulatory and development milestones, and upon the achievement of certain commercial sales milestones The Company is also required to pay low single digit royalties on net sales. If the Company sublicenses a product for which royalties are payable, then the Company is required to pay the greater of 20% received or low single digit royalties on net sales. The Company has made no milestone or royalty payments as of September 30, 2021.

The Clearside license agreement expires on a country-by-country basis upon the later of the last to expire patent or ten years from the date of the first commercial sale of a product.

13. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

The Company has calculated basic and diluted net loss per share for the three and nine months ended September 30, 2021 and 2020 as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (8,838)	$ (3,631)	$ (23,617)	$ (17,299)
Less: Accruals of dividends of preferred stock	(3,668)	(1,948)	(9,627)	(5,802)
Net loss attributable to common stockholders—basic and diluted	$ (12,506)	$ (5,579)	$ (33,244)	$ (23,101)
Denominator:				
Weighted-average common stock outstanding	441,448	376,738	426,604	362,735
Net loss per share attributable to common stockholders—basic and diluted	(28.33)	(14.81)	(77.93)	(63.69)

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share for the periods presented because their effect would have been antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Convertible preferred stock on as if converted basis	22,550,561	13,260,868	22,550,561	13,260,868
Stock options to purchase common stock	3,164,949	1,412,791	3,164,949	1,412,791
Warrants to purchase preferred stock	12,686	12,686	12,686	12,686
Total potential dilutive shares	25,728,196	14,686,345	25,728,196	14,686,345

14. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2021 as the Company incurred losses for the nine months ended September 30, 2021, and is forecasting additional losses through the remainder of fiscal year ending December 31, 2021, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2021. Therefore, no federal or state income taxes are expected and none have been recorded at this time. Income taxes have been accounted for using the liability method.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a full valuation allowance, since the Company does not currently believe that realization of its deferred tax assets is more likely than not.

As of September 30, 2021, the Company had no unrecognized income tax benefits that would reduce the Company's effective tax rate if recognized.

15. Related Parties

During the nine months ended September 30, 2021 and 2020, the Company incurred $0.4 million and $0.3 million in expenses to a stockholder that provided research and development related services. Of these amounts, $0.01 and $0.1 million were in accrued expenses as of September 30, 2021 and 2020.

16. Subsequent Events

Subsequent events have been evaluated through the date of filing of the unaudited condensed financial statements. The Company has identified the following subsequent events that require disclosure:

A. Election of Automatic Conversion of Preferred Stock

On October 7, 2021, the required convertible preferred stockholders authorized the automatic conversion of all shares of convertible preferred stock in an initial public offering, subject to the price per share of the common stock in the Company's sale of shares of common stock to the public in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75.0 million of gross proceeds to the Company and such shares being listed on the Nasdaq Stock Market, or a Public Offering, being at least $0.94068 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), (ii) subject to and effective upon the closing of the Public Offering and (iii) subject to the Public Offering being consummated no later than February 28, 2022.

B. Reverse Stock Split

On October 22, 2021, the Company effected a reverse stock split of the Company's common stock on a 1-for-13.7 basis, or the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company's convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. Accordingly, all common stock share and per share amounts, for all periods presented in these condensed financial statements, have been retroactively adjusted, to reflect this reverse stock split and adjustment of the convertible preferred stock conversion ratios.

C. Initial Public Offering

On November 2, 2021, the Company completed its IPO, in which it issued and sold 6,210,000 shares of common stock, including the full exercise of the underwriters' option to purchase additional shares at a price to the public of $14.00 per share for aggregate gross proceeds of $86.9 million. The Company received approximately $77.9 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses.

D. 2021 Stock Option and Incentive Plan

The 2021 Stock Option and Incentive Plan, or the 2021 Plan, was adopted by the Board on October 7, 2021, approved by the Company's stockholders on October 22, 2021 and became effective on November 1, 2021. The 2021 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The number of shares initially reserved for issuance under the 2021 Plan was 3,352,166, which will automatically increase on January 1, 2022 and each January 1 thereafter, by 5% of the outstanding number of shares of common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee. The maximum number of shares of common stock that may be issued in the form of incentive stock options shall not exceed the initial limit, cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the annual increase for such year or 3,352,166 shares of common stock.

E. 2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan, or the ESPP, was adopted by the Board on October 7, 2021, approved by the Company's stockholders on October 22, 2021 and became effective on November 1, 2021. A total of 335,217 shares of common stock were initially reserved for issuance under this plan, which will automatically increase on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) 335,217 shares of common stock, (ii) 1% of the outstanding number of shares of common stock on the immediately preceding December 31 or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP.

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

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biotechnology company leveraging our novel targeted oncology platform to develop a potential new standard of care across multiple cancer indications, with an initial focus on ocular and urologic oncology. Our proprietary platform enables the targeting of a broad range of solid tumors using Virus-Like Particles, or VLPs, that can be conjugated with drugs or loaded with nucleic acids to create Virus-Like Drug Conjugates, or VDCs. Our VDCs are largely agnostic to tumor type and can recognize a surface marker, known as heparin sulfate proteoglycans, or HSPGs, that are specifically modified and broadly expressed on many tumors. We are focusing our initial development of VDCs to treat tumors of high unmet need in ocular and urologic oncology. AU-011, our first VDC candidate, is being developed for the first line treatment of primary choroidal melanoma, a rare disease with no drugs approved. We have completed a Phase 1b/2 trial using intravitreal administration that has demonstrated a statistically significant growth rate reduction in patients with prior active growth and high levels of tumor control with visual acuity preservation in a majority of patients, as assessed using clinical endpoints in alignment with feedback from the FDA. These data supported advancement into a Phase 2 dose escalation trial, where we are currently evaluating suprachoroidal, or SC, administration of AU-011. We plan to present six to twelve months safety and efficacy data from this trial in 2022. We intend to select the route of administration and initiate a pivotal trial in the second half of 2022. We are also developing AU-011 for additional ocular oncology indications and plan to file an IND in the United States in the second half of 2022 for choroidal metastases. Leveraging our VDCs' broad tumor targeting capabilities, we also plan to initiate a Phase 1a trial in non-muscle invasive bladder cancer, or NMIBC, our first non-ophthalmic solid tumor indication, in the second half of 2022 and present Phase 1a data from this trial in 2023.

We were incorporated as a Delaware corporation in 2009 and our headquarters are located in Cambridge, Massachusetts. Since our inception, we have focused our efforts on identifying and developing potential product candidates, conducting preclinical studies and clinical trials, organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, conducting discovery, research and development activities and providing general and administrative support for these operations. We do not have any product candidates approved for sale and have not generated any revenue to date. We have funded our operations primarily through the sale of convertible preferred stock, common stock, and convertible debt. From inception through September 30, 2021, we have raised an aggregate of approximately $218.5 million of gross proceeds primarily from private placements of our equity and convertible debt securities as well as through the issuance of our common stock. In November 2021, we issued and sold 6,210,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares at a price to the public of $14.00 per share for aggregate gross proceeds of $86.9 million in our IPO. We received approximately $77.9 million in net proceeds after deducting underwriting discounts, commissions and offering expenses

We have incurred significant operating losses in every year since our inception in 2009 and have not generated any revenue. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were $23.6 million and $17.3 million for the nine months ended September 30, 2021 and 2020, respectively, and $22.2 million for the year ended December 31, 2020. As of September 30, 2021, we had an accumulated deficit of $140.5 million. In addition, our losses from operations may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We anticipate that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical studies and clinical trials of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company following the completion of the IPO. We expect that our expenses and capital requirements will increase substantially if and as we:

- conduct our current and future clinical trials of AU-011;
- progress the preclinical and clinical development of new indications;
- establish our manufacturing capability, including developing our contract development and manufacturing relationships;
- seek to identify and develop additional product candidates;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing and commercialization efforts;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

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 equity offerings, debt financings, collaborations or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain marketing approval for our product candidates. The lengthy process of securing marketing approvals for new drugs requires the expenditure of substantial resources. Any delay or failure to obtain regulatory approvals would materially adversely affect the development efforts of our product candidates and our business overall. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2021, we had cash and cash equivalents of $82.0 million. In November 2021, we issued and sold 6,210,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares at a price to the public of $14.00 per share for aggregate gross proceeds of $86.9 million in our IPO. We received approximately $77.9 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses. We believe that the anticipated net proceeds from the IPO, together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 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" below.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic continues to present substantial public health and economic challenges around the world, and to date has led to the implementation of various responses, including government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures.

We continue to closely monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, we have taken steps to minimize the current environment's impact on our business and strategy, including devising contingency plans and securing additional resources from third party service providers. For the safety of our employees and families, we have introduced enhanced safety measures for scientists to be present in our labs and increased the use of third party service providers for the conduct of certain experiments and studies for research programs. To date, we've only encountered minor delays in our manufacturing process due to a supply chain constraint with one of our vendors.

Beyond the impact on our pipeline, the extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain COVID-19 or treat its impact, including vaccination campaigns, among others. If we or any of the third parties with whom we engage, however, were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition. 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. See “Risk Factors” for a discussion of the potential adverse impact of the COVID-19 pandemic on our business, financial condition and results of operations.

Components of Our Results of Operations

Revenue

Since inception, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for one or more of our product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements. We cannot predict if, and when, or to what extent, we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our AU-011 program, and include:

- employee-related expenses, including salaries, related-benefits and stock-based compensation expense for employees engaged in research and development functions;
- fees paid to consultants for services directly related to our product development and regulatory efforts;
- expenses associated with conducting preclinical studies performed by ourselves, outside vendors or academic collaborators;
- expenses incurred under agreements with contract research organizations, or CROs, as well as consultants that conduct and provide supplies for our preclinical studies and clinical trials;
- the cost of manufacturing AU-011, including the potential cost of CMOs that manufacture product for use in our preclinical studies and clinical trials and perform analytical testing, scale-up and other services in connection with our development activities;
- costs associated with preclinical activities and development activities;
- costs associated with our intellectual property portfolio;
- costs related to compliance with regulatory requirements; and
- allocated expenses for utilities and other facility-related costs.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. 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 in our financial statements as prepaid or accrued research and development expenses. We allocate our direct external research and development costs across the entire AU-011 program. Preclinical expenses consist of external research and development costs associated with activities to support our current and future clinical programs, but are not allocated by specific indications due to the overlap of the potential benefit of those efforts across the entire AU-011 program.

Research and development activities are central to our business. We expect that our research and development expenses will increase for the foreseeable future as we continue clinical development for AU-011 and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include allocated expenses for rent and maintenance of facilities and other operating costs not included in research and development.

We expect that our general and administrative expenses will increase in the near-term as we continue to build a team to support our administrative, accounting and finance, communications, legal and business development efforts. Following this offering, we expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services; director and officer insurance costs; and investor and public relations costs.

Other Income (Expense)

Our other income (expense) consists of changes in the fair value of our warrant liability and derivative, gain/loss on disposal of fixed assets, and interest income on our invested cash balances.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items. As of December 31, 2020, we had federal and state gross operating loss carryforwards of $106.1 million and $89.3 million, respectively, which may be used to offset future taxable income, if any. Federal gross operating loss carryforwards of $44.2 million begin to expire in 2029 and go through 2037 and federal gross operating loss carryforwards of $61.9 million do not expire. The state gross operating loss carryforwards begin to expire in 2030. As of December 31, 2020, we had federal and state research and development tax credit carryforwards of $3.8 million and $1.1 million, respectively, which may be used to offset future income tax liabilities and begin to expire in 2029 and 2027, respectively. Due to the degree of uncertainty related to the ultimate use of the deferred tax assets, we have fully reserved these tax benefits, as the determination of the realization of the deferred tax benefits was not determined to be more likely than not.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 6,365	$ 2,850	$ 3,515
General and administrative	2,530	781	1,749
Total operating expenses	8,895	3,631	5,264
Loss from operations	(8,895)	(3,631)	(5,264)
Other income (expense):			
Change in fair value of derivative liability	52	-	52
Interest income, including amortization of discount	5	-	5
Total other income (expense)	57	-	57
Net loss and comprehensive loss	$ (8,838)	$ (3,631)	$ (5,207)

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Preclinical	$ 489	$ 655	$ (166)
Clinical trials	950	613	337
Manufacturing development	1,376	(85)	1,461
Personnel/overhead expenses	3,550	1,667	1,883
Total research and development expenses	$ 6,365	$ 2,850	$ 3,515

Research and development expenses increased to $6.4 million for the three months ended September 30, 2021 from $2.9 million for the three months ended September 30, 2020, primarily due to progression of clinical trials and ongoing manufacturing development costs for AU-011. In addition, research and development expenses related to personnel increased from growing headcount due to the progression of clinical trials.

General and Administrative Expenses

General and administrative expenses increased to $2.5 million for the three months ended September 30, 2021 from $0.8 million for the three months ended September 30, 2020. General and administrative expenses include $0.4 million and $0.1 million of stock-based compensation for the three months ended September 30, 2021 and 2020, respectively. The increase was primarily related to an increase in personnel expenses due to an increase in headcount, as well as general increases in audit, legal, consulting and facilities expenses in anticipation of becoming a public company.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 17,182	$ 14,499	$ 2,683
General and administrative	6,441	2,798	3,643
Total operating expenses	23,623	17,297	6,326
Loss from operations	(23,623)	(17,297)	(6,326)
Other income (expense):			
Change in fair value of warrant liability	1	-	1
Interest income (expense), including amortization of discount	8	(2)	10
Loss from disposal of assets	(3)	-	(3)
Total other income (expense)	6	(2)	8
Net loss and comprehensive loss	$ (23,617)	$ (17,299)	$ (6,318)

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Preclinical	$ 759	$ 2,078	$ (1,319)
Clinical trials	2,441	2,458	(17)
Manufacturing development	5,587	4,238	1,349
Personnel/overhead expenses	8,395	5,725	2,670
Total research and development expenses	$ 17,182	$ 14,499	$ 2,683

Research and development expenses increased to $17.2 million for the nine months ended September 30, 2021 from $14.5 million for the nine months ended September 30, 2020, due to ongoing manufacturing development costs for AU-011 and higher personnel expenses from growing headcount due to the progression of clinical trials.

General and Administrative Expenses

General and administrative expenses increased to $6.4 million for the nine months ended September 30, 2021 from $2.8 million for the nine months ended September 30, 2020. General and administrative expenses include $0.7 million and $0.4 million of stock-based compensation for the nine months ended September 30, 2021 and 2020, respectively. The increase was primarily related to an increase in personnel expenses due to an increase in headcount, as well as general increases in audit, legal, consulting and facilities expenses in anticipation of becoming a public company.

Liquidity and Capital Resources

To date we have funded our operations primarily through the sale of convertible preferred stock, common stock, and convertible debt. Through September 30, 2021, we have raised an aggregate of approximately $218.5 million of gross proceeds primarily from private placements of our equity and convertible debt securities and warrants, as well as through the issuance of our common stock. In November 2021, we issued and sold a total of 6,210,000 shares in our IPO of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $14.00 per share for aggregate gross proceeds of $86.9 million. We received approximately $77.9 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses.

As of September 30, 2021, we had cash and cash equivalents of $82.0 million and an accumulated deficit of $140.5 million. Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized our product candidate for any of its multiple indications, which is in various phases of preclinical and clinical development, depending on the indication, and we do not expect to generate revenue from sales of any products for the foreseeable future, if at all. Since our inception we have incurred losses and negative cash flows from operations and expect these conditions to continue for the foreseeable future.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (20,324)	$ (20,564)
Net cash used in investing activities	(1,306)	(639)
Net cash provided by financing activities	86,117	4,903
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 64,487	$ (16,300)

Operating Activities

During the nine months ended September 30, 2021, net cash used in operating activities was $20.3 million, primarily due to our net loss of $23.6 million partially offset by the non-cash charge related to stock compensation expense of $1.0 million and an increase in accrued expenses and other liabilities related to personnel expenses and clinical trials.

During the nine months ended September 30, 2020, net cash used in operating activities was $20.6 million, primarily due to our net loss of $17.3 million and a decrease in accrued expenses and other liabilities and accounts payable due to growth in our business, the advancement of our product candidates, and the timing of vendor invoicing and payments partially offset by non-cash charges related to $0.5 million in stock-based compensation expense.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2021 and 2020 was $1.3 million and $0.6 million, respectively, due to purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2021, net cash provided by financing activities was $86.1 million from net proceeds from the sale of Series E and second tranche of the Series D-2 and proceeds from stock options exercises, offset by payments made for deferred offering costs.

During the nine months ended September 30, 2020, net cash provided by financing activities was $4.9 million from the advanced net proceeds from the sale of the first tranche of the Series D-2 which was issued in October 2020 and proceeds from stock option exercises.

Funding Requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of AU-011 and any other product candidates we may acquire or develop and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our current and future product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or terminate our research and development programs or future commercialization efforts. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain, skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. As of September 30, 2021, we had cash and cash equivalents of $82.0 million. In November 2021, we issued and sold 6,210,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares at a price to the public of $14.00 per share for aggregate gross proceeds of $86.9 million in our IPO. We received approximately $77.9 million in net proceeds after deducting underwriting discounts, commissions and offering expenses. Based on our research and development plans, we believe that our existing cash and cash equivalents, will be sufficient to fund our operations into 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.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations from the sale of additional equity or debt financings, or other capital which comes in the form of strategic collaborations, licensing, or other arrangements. In the event that additional financing is required, we may not be able to raise it on terms acceptable to us, or at all. If we raise additional funds through the issuance of equity or convertible debt securities, it may result in dilution to our existing stockholders. Debt financing or preferred equity financing, if available, may result in increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations.

If we raise funds through strategic collaboration, licensing or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. Our ability to raise additional funds 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 and otherwise. 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2020.

		Payments Due by Period			
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
		(in thousands)			
Operating lease commitments(1)	$ 571	$ 360	$ 211	$ —	$ —
Total	$ 571	$ 360	$ 211	$ —	$ —

(1) Amounts in the table above reflect payments due for our lease of office space in Cambridge, Massachusetts, that expires in July 2023.

There were no material changes to our contractual obligations and commitments during the nine months ended September 30, 2021, from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 1, 2021.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our annual financial statements included in the final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 1, 2021, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our condensed financial statements.

Research and Development Costs

We expense all costs in performing research and development activities in the periods in which they are incurred. Research and development expenses include salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to nonemployees and entities that conduct certain research and development activities on our behalf and expenses incurred in connection with license agreements. Non-refundable advance payments for goods or services that will be used for rendered or future research and development activities are deferred and amortized over the period that the goods are delivered, or the related services are performed, subject to an assessment of recoverability.

As part of the process of preparing our condensed financial statements, we are required to estimate our accrued research and development expenses. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We account for our stock-based compensation as expense in the statements of operations and comprehensive loss based on the awards' grant date fair values. We account for forfeitures as they occur by reversing any expense recognized for unvested awards.

We estimate the fair value of options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We use the simplified method as allowed by the SEC, Staff Accounting Bulletin, or SAB, No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock. The fair value of stock-based payments is recognized as expense over the requisite service period which is generally the vesting period.

Determination of the Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our Board, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the option grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of $4.25 per share as of December 6, 2019, $4.38 per share as of August 25, 2020 and December 31, 2020, $5.48 per share as of March 15, 2021 and $9.59 per share as of August 31, 2021.

In addition to considering the results of these third-party valuations, our Board considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or sale of our company in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

The fair value of our common stock is determined based on the quoted market price of our common stock on the date of option grant.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Recent Accounting Pronouncements

We early adopted ASU No. 2016-02, Leases (Topic 842) effective January 1, 2021 as disclosed in Note 2 to our condensed financial statements. The adoption of ASC 842 resulted in the recognition of operating lease liabilities of $0.6 million and operating lease right-of-use assets of $0.5 million and the derecognition of deferred rent liabilities of $0.02 million on our balance sheet as of January 1, 2021.

A description of recently issued accounting pronouncements not yet adopted that may potentially impact our financial position and results of operations is also disclosed in Note 2 to our annual financial statements included in the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 1, 2021.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits that an "emerging growth company" may take advantage of the extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use the extended transition period under the JOBS Act. However, we did early adopt ASU No. 2016-02, Leases (*Topic 842*) effective January 1, 2021 as disclosed in Note 2 to our condensed financial statements. Accordingly, our financial statements may not be comparable to the financial statements of public companies that comply with such new or revised accounting standards. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest of: the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than $1.0 billion in non-convertible debt securities; or the last day of the fiscal year ending after the fifth anniversary of our IPO.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible 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 Quarterly Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2021, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this Quarterly Report was (a) reported within the time periods specified by the 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

Due to a transition period established by the SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ending December 31, 2021. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of September 30, 2021, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the 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.

Investing in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, as well as the other information in this Quarterly Report, including our condensed financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations". The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations and future prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position, and Additional Capital Needs

We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. Our net losses were $23.6 million and $17.3 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $140.5 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to increase significantly as we continue clinical development for AU-011 and continue to discover and develop additional product candidates. In addition, if we obtain regulatory approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. We will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to in the foreseeable future. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any product sales. We have no products approved for commercial sale, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- initiating and completing research regarding, and preclinical and clinical development of, AU-011 in primary choroidal melanoma and, additional oncology indications, other research programs from our VDC technology platform and any future product candidates;
- obtaining marketing approval for AU-011 and any future product candidates for which we complete clinical trials;
- transferring our manufacturing process to a commercial contract development and manufacturing organization for AU-011 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing AU-011 and any future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of AU-011 and any future product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates from our VDC technology platform;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if AU-011 or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market AU-011 or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for AU-011 and any future product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or terminate one or more of our research and development programs, future commercialization efforts, product development or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate and complete clinical trials of, and seek marketing approval for AU-011. Identifying and developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Even if one or more of AU-011 or any future product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we are currently conducting or anticipate. Other unanticipated costs may also arise. Because the design and outcome of our current and planned clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of AU-011 or any future product candidates that we develop. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

Based on our current operating plan, we believe that our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditures into 2024. Advancing the development of AU-011 and other research programs will require a significant amount of capital. Our existing cash and cash equivalents will not be sufficient to fund AU-011 through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize AU-011. Our estimate as to how long we expect our existing cash and cash equivalents to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Any additional fundraising efforts may divert our management from their day to day activities, which may adversely affect our ability to develop and commercialize product candidates. Disruptions in financial markets in general or more recently due to the COVID-19 pandemic may make equity and debt financings more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. To the extent that we raise additional capital through the sale of equity or convertible debt securities, each investor’s ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor’s rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day to day activities, which may adversely affect our ability to commercialize AU-011 if and when approved and develop our product candidates.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our clinical trials, research and development programs, future commercialization efforts or other operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, existing stockholder ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek commercial or development partners for our lead products or any future product candidate at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates.

We rely on our team's expertise in drug discovery, translational research and patient-driven precision medicine to develop our product candidates. Our business depends significantly on the success of this engine and the development and commercialization of the product candidates that we discover with this engine. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales in the near term, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of AU-011 in indeterminate lesions and primary choroidal melanoma and additional oncology indications, other research programs from our VDC technology platform, and any other future programs;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of AU-011, other research programs from our VDC technology platform, and any other future programs;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- Transferring our manufacturing process to a commercial CDMO, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates from our VDC technology platform;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

Risks Related to the Discovery and Development of our Product Candidates

We are heavily dependent on the success of AU-011, our only product candidate to date.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to development of AU-011 in multiple oncology indications, which is currently our only product candidate. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of AU-011. We can provide no assurance that AU-011 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of AU-011 or if AU-011 does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, recordkeeping, labeling, approval, licensure, sale, marketing, advertising, promotion and distribution of AU-011 is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for AU-011 in the United States, Europe and other major markets around the world will prevent us from commercializing and marketing AU-011 in such jurisdictions.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for AU-011, any approval might contain significant limitations related to use, including limitations on the stage or type of cancer AU-011 is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications, or requirement for a risk evaluation and mitigation strategy, or REMS. Any such limitations or restrictions could similarly impact any supplemental marketing approvals we may obtain for AU-011. Furthermore, even if we obtain regulatory approval for AU-011, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize AU-011, we may not be able to generate sufficient revenue to continue our business.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for AU-011, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We utilize third-party CROs and/or regulatory consultants to assist us in the regulatory approval process globally and expect to continue to do so in the future. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities and clinical sites by the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted Investigational New Drug application, or IND, Premarket Approval, or PMA, biologics license application, or BLA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Because the activity of AU-011 in ocular melanoma requires a drug delivery device and activation by a laser, the regulatory complexity of the product candidate is greater than for products that don't utilize a device, which creates uncertainties in the requirements for regulatory approval. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process, as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Our VDC product candidates are based on a technology that we are in the process of developing. We expect the novel nature of such product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials. Additionally, due to the COVID-19 pandemic, the conduct of Advisory Committee meetings may be disrupted or delayed and the impact that may have on the overall timing of regulatory approvals is uncertain.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We have not yet successfully initiated or completed any pivotal clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.

Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and Phase 1 and Phase 2 clinical trials for our product candidates, primarily related to our AU-011 program in indeterminate lesions and primary choroidal melanoma. We have not yet demonstrated an ability to successfully initiate or complete pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Furthermore, we may conduct our first pivotal trial based on an adaptive design, which could increase the time spent on or costs associated with this trial. We are in the process of transferring our intended commercial manufacturing process to our intended external contract development and manufacturing organization, or CDMO, commercial manufacturing site. During this transfer process, some modifications may be needed to ensure manufacturability and ability to scale-up the process to commercial batch sizes. We intend to perform an analytical comparability assessment between the current clinical process and the intended commercial process, however, if this analytical process comparability assessment is unsuccessful, clinical comparability may be required, which may result in delayed regulatory approval. We do not anticipate a change in formulation. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

We expect to focus our resources on the development of AU-011 in the near term. Developing, obtaining marketing approval for, and commercializing any future product candidates will require substantial additional funding and will be subject to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any future product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market any future product candidates for any indication, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

AU-011 is a biologic that requires the use of multiple devices, which may result in additional regulatory risks.

AU-011 is a novel biologic for which the intended use requires activation by a laser, which is regulated as a medical device. We plan to file a single BLA for the review and approval of this combination in our initial target indication of indeterminate lesions and small choroidal melanoma, but subsequent indications and delivery systems may require different or additional applications for marketing authorization. In addition, consistent with recent FDA guidance as seen with the approval of Xipere, Clearside Biomedical's SCS Microinjector® is also expected to be regulated as a medical device and suprachoroidal administration of AU-011 with this device is expected to constitute a combination product. As such, we may also include the SCS Microinjector in our BLA. There may be additional regulatory risks for biologic-device combination products. We may experience delays in obtaining regulatory approval of AU-011 given the increased complexity of the review process when approval of the product and a delivery device is sought under a single marketing application. In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device. Devices are subject to the FDA design control device requirements which comprise among other things, design verification, design validation, and testing to assess performance, cleaning, and robustness. Delays in or failure of the studies conducted by us, or failure of our company, our collaborators, if any, or our third-party providers or suppliers to maintain compliance with regulatory requirements could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in AU-011 reaching the market.

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

As product candidates proceed through preclinical 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, may be altered along the way in an effort to optimize processes and results. For example, we are planning to use Phase 2 drug product to initiate our first pivotal study and transitioning to the intended commercial drug product as soon as it available to conduct the second planned pivotal study. Such changes to a product candidate carry the risk that they will not achieve the intended objectives of optimizing the performance of the candidate. 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 the FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

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 or comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a given trial.

In addition, our competitors may in the future commence clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may choose instead to enroll in clinical trials of our competitors. Furthermore, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic, and we cannot accurately predict the extent and scope of such delays at this point. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit or enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. Our lead indication of Choroidal Melanoma is a rare disease and as such clinical trial recruitment estimates may be inaccurate and such recruitment may take longer than expected.

Patient enrollment may be affected by other factors, including:

- the severity of the disease under investigation;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of AU-011 in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the efforts to obtain and maintain patient consents and facilitate timely enrollment in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion;
- competing studies or trails with similar eligibility criteria;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- reporting of the preliminary results of any of our clinical trials; and
- factors we may not be able to control, including the impacts of the COVID-19 pandemic, that may limit patients, principal investigators or staff or clinical site availability.

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

We may in the future choose to conduct one or more 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 or comparable foreign regulatory authority 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 sole 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 U.S. population and the U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practices, or GCP, regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities 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 or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Even if we receive marketing approval for our current or future product candidates in the United States, we may never receive regulatory approval to market our current or future product candidates outside of the United States.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction.

For example, even if the FDA grants marketing approval of a product candidate, we may not obtain approvals in other jurisdictions, and comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among countries and can involve additional product candidate testing and administrative review periods different from those in the United States. The time required to obtain approvals in other countries might differ substantially from that required to obtain the FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding the FDA approval in the United States as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with regulatory requirements in international markets or fail to receive applicable marketing approvals, it would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

The results of preclinical studies and early clinical trials may not be predictive of future results.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials. AU-011 and any other product candidates we may develop may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. For example, AU-011 may not be effective at slowing or arresting tumor growth or may not preserve visual acuity in later stage trials. Even if AU-011 successfully slows or completely arrests tumor growth, this may not result in a reduction in the risk of metastasis. Additionally, any positive results generated in our ongoing clinical trials and preclinical studies would not ensure that we will achieve similar results in larger, pivotal clinical trials or in clinical trials of AU-011 in broader patient populations. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any product candidate to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of any other product candidates then under development and/or cause the FDA or other regulatory authorities to require additional testing before approving any other product candidates.

As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, the European Medicines Agency (EMA), or other regulatory agencies to market AU-011 or any future product candidate. Carrying out later-stage clinical trials is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel or sign a contract with a global clinical research organization to conduct the trials on our behalf. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to approval of AU-011 or future product candidates. 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 our product candidates.

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

From time to time, we may publicly disclose preliminary, interim or top-line data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. 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. Top-line data 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, top-line data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data 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. Adverse differences between interim data and final data could materially affect our business, financial condition, results of operations and growth prospects.

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 program, the approvability or commercialization of the particular product candidate and our company in general. Further, additional disclosure of interim data by us or by our potential competitors in the future could result in volatility in the price of our common stock. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or top-line data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could materially affect our business, financial condition, results of operations and growth prospects.

Additionally, we may utilize “open-label” trial designs or open-label extensions to our clinical trials in the future. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial or extension may not be predictive of future clinical trial results with AU-011 when studied in a controlled environment with a placebo or active control.

AU-011 or any future product candidates may cause or reveal significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval. In addition, if we obtain approval for any of our product candidates, significant adverse events, toxicities or other undesirable side effects may be identified during post-marketing surveillance, which could result in regulatory action or negatively affect our ability to market the product.

Adverse events or other undesirable side effects caused by or associated with treatment by AU-011 or our future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or other comparable foreign regulatory authorities. Although AU-011 has been evaluated in clinical trials, unexpected side effects may still arise in our ongoing or any future clinical trials. These side effects have included pigmentary changes around the tumor margin and vision loss.

During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, pivotal clinical trials or, in some cases, after they are made available to subjects on a commercial scale after approval.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product or require additional warnings on the label;
- additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- regulatory authorities may require additional warnings or limitations in the labeling, such as a contraindication, limitation of use, or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be subject to regulatory investigations and government enforcement actions; and
- our reputation may suffer.

Moreover, if AU-011 or any of our future product candidates is associated with undesirable or unexpected side effects in clinical trials, we may elect to abandon or 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 the product candidate, even if it is approved.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could materially affect our business, financial condition, results of operations, and growth prospects.

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

We may experience delays in initiating or completing our preclinical studies or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA's clearance to initiate clinical trials under future INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that require us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial;
- regulators or institutional review boards, or IRBs, or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- preclinical studies or 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 regulators may require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product research or development programs;
- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results across tumor types or indications;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- clinical trials of our product candidates may be delayed due to complications associated with the evolving COVID-19 pandemic;
- 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;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Moreover, principal investigators for our trials involving AU-011 or any future 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 or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the study. The FDA or comparable foreign regulatory authority 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 or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays, including those caused by the COVID-19 pandemic, also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may significantly harm our business, operating results, financial condition and prospects.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, compliance with applicable product tracking and tracing requirements, as well as continued compliance with current Good Manufacturing Practices, or cGMPs, and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, the FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we do not market our medicines for their approved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We may be unable to obtain orphan drug designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if our current product candidates and any future product candidates receive orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We have obtained orphan designation for AU-011 for the treatment of uveal melanoma, and we may seek additional orphan drug designations for some or all of our current or future product candidates in orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A breakthrough therapy designation or fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the United States.

We may seek breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We have obtained fast track designation for AU-011 for the treatment of choroidal melanoma, and we may seek additional fast track designations for other product candidates we may develop. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

Accelerated approval by the FDA, even if granted for our current or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct some aspects of our research, preclinical testing and clinical trials. We plan to use a clinical CRO for at least part of the potentially pivotal trial for AU-011 for the treatment of choroidal melanoma. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities reduces our control over these activities, but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, as well as the applicable legal, regulatory and scientific standards. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We are also required to register ongoing clinical trials and to post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Due to the rarity of ocular melanomas, we may engage clinical trial sites that have little experience in the conduct of clinical trials under GCPs. Even though we train the clinical trial sites, monitor the activities, and perform quality audits to assess and ensure compliance, we cannot ensure such compliance.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other biological product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

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

We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of AU-011 and may continue to rely on CMOs for the production of commercial supply of AU-011, if approved. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We currently do not have any manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future pre-clinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We are currently reliant on a single source for each of our regulatory starting materials, drug substance and drug product manufacturing for AU-011.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient, or API, necessary to produce AU-011 and future product candidates we may develop in the quantities needed for our clinical trials or, if AU-011 or any future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or APIs, including shortages caused by the purchase of such raw materials or API, by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of AU-011 or any future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business. To date, we have only encountered minor delays in our manufacturing process due to a supply chain constraint with one of our vendors

Reliance on third party manufacturers may expose us to different risks than if we were to manufacture clinical or commercial supply of our product candidates ourselves. The facilities used by third-party manufacturers to manufacture AU-011 or any future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. Some of our contract manufacturers may not have produced a commercially-approved product and therefore may not have obtained the requisite FDA approvals to do so. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. Additionally, any changes implemented by a new CMO could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of AU-011 and future product candidates and jeopardize our ability to commence product sales and generate revenue.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- lack of qualified backup suppliers for those components or materials that are currently purchased from a sole or single source supplier;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of AU-011 or any future product candidates for use in clinical trials or for commercial supply, including as a result of the COVID-19 pandemic;
- supply or service disruptions or increased costs that are beyond our control;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

AU-011 and any other product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Additionally, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more may be authorized in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or on terms acceptable to us. Our current and anticipated future dependence upon others for the manufacture of AU-011 or any other future product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks Related to Commercialization

If AU-011 or any future product candidates do not achieve broad market acceptance, the revenue that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if AU-011 and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable or may be significantly delayed in achieving profitability. Market acceptance of AU-011 and any future product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. If public perception is influenced by claims that the use of virus-like drug conjugates, or VDCs, is unsafe, whether related to our or our competitors' products, our products may not be accepted by the general public or the medical community. In addition, training clinicians to properly use AU-011 or any future product candidate that requires a similar laser and microinjector may create reluctance by clinicians to adopt our products, potentially adversely affecting our future sales and marketing efforts. Furthermore, such training increases our costs to generate sales associated with any such product. Future adverse events in targeted oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments.

Efforts to educate the medical community and third-party payors on the benefits of AU-011 and any future product candidates may require significant resources and may not be successful. If AU-011 or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of AU-011 and any future product candidates will depend on a number of factors, including:

- the efficacy of AU-011 and our virus-like particle, or VLP, technology, and any future product candidates;
- the prevalence and severity of adverse events associated with AU-011 and any future product candidates or those products with which they may be co-administered;
- the clinical indications for which AU-011 are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for AU-011 and any future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for AU-011 and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of AU-011 and any future product candidates and any products with which they are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third party payors, including government healthcare programs such as Medicare and Medicaid and other healthcare payors;
- the price concessions required by third-party payors to obtain coverage;
- the perception of physicians, patients, third-party payors and others in the medical community of the relative safety, efficacy, convenience, effect on quality of life and cost effectiveness of AU-011 compared to those of other available treatments;
- the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;
- the extent and strength of our marketing and distribution of AU-011 and any future product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to AU-011 and any future product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of AU-011 and any future product candidates, as well as competitive products;
- our ability to offer AU-011 and any future product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the publicity concerning our AU-011 or competing products and treatments;
- the actions of companies that market any products with which AU-011 and any future product candidates may be co-administered;
- the approval of other new products;
- adverse publicity about AU-011 and any future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We have never commercialized a product candidate and we currently have no sales, marketing or distribution capabilities and have no experience in marketing products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidate and undertaking preclinical studies and clinical trials of our product candidate. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We may not be successful in transitioning from a company with a development focus to a company capable of supporting commercial activities.

In addition to establishing internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. Further, if we enter into arrangements with third parties to perform sales and marketing services, our product revenues, if any, may be lower than if we were to market and sell any products that we develop ourselves. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

Furthermore, developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidate. We may not be able to build an effective sales and marketing organization in the United States, the European Union (EU) or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidate, we may have difficulties generating revenue from them.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

We may face competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. While we are not aware of anyone currently developing a treatment for choroidal melanoma, in the future our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than us. There are multiple companies that have drugs in clinical development for the treatment of NMIBC that are unresponsive to Bacillus Calmette-Guerin, such as Sesen Bio, Inc., FerGene, Inc., UroGen Pharma Ltd., CG Oncology, Inc. and ImmunityBio, Inc. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our potential competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaboration partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products, which may reduce or eliminate our commercial opportunity. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Even if we obtain regulatory approval of our product candidates, the availability and price of our potential future competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Business—Competition."

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be sufficient. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, particularly in light of the most recent presidential election, 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, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

If the market opportunity for AU-011 is smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The incidence and prevalence for target patient populations of AU-011 and any future product candidates has not been established with precision. AU-011 is a virus-like drug conjugate product candidate being developed for the first line treatment of primary choroidal melanoma. Our projections of both the number of people who have choroidal melanoma, as well as additional ocular oncology and bladder cancer indications, are based on our estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the patient criteria included in the final label, the indications for which AU-011 is approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with choroidal melanoma, choroidal metastases and NMIBC for which AU-011 may be approved as treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. AU-011 is our only product candidate and therefore our business is dependent on the market opportunity for our product.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons 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, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of 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. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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 or federal civil money penalties;
- the federal civil and criminal false claims laws and Civil Monetary Penalties Law, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the United States Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022 (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists & anesthesiologist assistants, and certified nurse-midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many states in the United States have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Current and future healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted and/or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay regulatory approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell a product for which we obtain regulatory approval. Changes in laws, regulations, statutes or the interpretation of existing laws and regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States, there have been, and continue to be, a significant number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education and Reconciliation Act, or collectively, the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the United States pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) 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. Since then, the ACA risk adjustment program payment parameters have been updated annually.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed on procedural grounds the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, President Biden signed an Executive Order on July 9, 2021, affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Further, on November 20, 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 would have applied to 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 U.S. District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. 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. On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. 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. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030, unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for the FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining the FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantage.

Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to our technology platform using HPV-derived virus-like particles to target tumors and VDCs like AU-011, as well as successfully defending these rights against third-party challenges and successfully enforcing these rights to prevent third-party infringement. We will only be able to protect AU-011 or a future product candidate derived from our platform from unauthorized use by third parties to the extent that valid and enforceable patents cover it. Our ability to maintain patent protection for AU-011 or a future product candidate is uncertain due to a number of factors, including that:

- others may design around our patent claims to produce competitive technologies, products or methods that fall outside of the scope of our patents;
- we may not obtain patent protection in all jurisdictions that may eventually provide us a significant business opportunity; and
- any patents issued to us may be successfully challenged by third parties.

Even with our patents covering AU-011, we may still not be able to make use or sell AU-011 or a future product candidate because of the patent rights of others. Others may have filed patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully commercialize AU-011 or a future product candidate.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications. These expenditures can be at numerous stages of prosecuting patent applications and over the lifetime of maintaining and enforcing issued patents. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Furthermore, we employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions we are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a 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, which would have a material adverse effect on our business.

Legal action that may be required to enforce our patent rights can be expensive and may involve the diversion of significant management time. There can be no assurance that we will have sufficient financial or other resources to file and pursue infringement claims, which typically last for years before they are concluded. In addition, these legal actions could be unsuccessful and result in the invalidation of our patents, a finding that they are unenforceable or a requirement that we enter into a licensing agreement with or pay monies to a third party for use of technology covered by our patents. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or have used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to successfully protect or enforce our intellectual property rights, our competitive position could suffer, which could harm our results of operations.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of AU-011 or any future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize AU-011 or any future product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. We may be unable to acquire or in-license any such proprietary rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive 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.

We rely on intellectual property licensed from third parties. We face risks with respect to such reliance, including the risk that, 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.

We are a party to a number of intellectual property license agreements that are important to our business. Our existing license agreements impose on us various diligence, milestone payment, royalty and other obligations. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted and related obligations under the license agreement and other interpretation-related issues;
- our licensor's right to license or sublicense patent and other rights to us, and whether and the extent to which the right is retained by a third party;
- whether and the extent to which our technology infringes on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other 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 AU-011 or any future product candidates, 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.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, disputes may arise regarding the payment of the royalties due to licensors in connection with our exploitation of the rights we license from them. Licensors may contest the basis of royalties we retained and claim that we are obligated to make payments under a broader basis. Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. In addition to the costs of any litigation we may face, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors. If disputes over intellectual property that we have licensed from third parties prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we or our collaborators may be unable to successfully manufacture and commercialize AU-011 or a future product candidate.

If we fail to comply with our obligations under the license agreements, our licensors may have the right to terminate these agreements, in which event we might not be able to manufacture or market AU-011 or a future product candidate. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our AU-011 or a future product candidate, thereby potentially extending the term of marketing exclusivity for such product, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of the FDA marketing approval of our product candidates, one or more of our owned, co-owned, or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the EU, AU-011 or a future product candidate may be eligible for term extensions based on similar legislation. In either jurisdiction, however, 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. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of biopharmaceutical and biotechnology companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the U.S. Patent and Trademark Office, or the USPTO, and its foreign counterparts are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. The U.S. patents and patent applications may also be subject to interference or derivation proceedings, and the U.S. patents may be subject to reexamination proceedings, post-grant review and/or *inter partes* review in the USPTO. International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post-grant review, *inter partes* review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

Furthermore, even if not challenged, our patents and patent applications may not prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to AU-011 or a future product candidate is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, AU-011 or a future product candidate.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology without providing any compensation to us, may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as the U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.

Our commercial success depends upon our ability to develop, manufacture, market and sell AU-011 or a future product candidate without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the biotechnology industry is common, including patent infringement lawsuits, interferences, oppositions, reexamination proceedings, post-grant review, and/or *inter partes* review before the USPTO and corresponding international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing AU-011 or a future product candidate, or forced to modify AU-011 or a future product candidate, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to AU-011 or a future product candidate that is the subject of the suit may be delayed or terminated. In addition, defending such claims may cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially could include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may in the future be subject to third-party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to further develop or commercialize AU-011 or a future product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering our technology or a product candidate, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and Europe, defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part of the patent protection on AU-011 or a future product candidate.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on AU-011 or a future product candidate in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions.

We have and have applied for patents in those countries where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where our ability to enforce our patent rights is not as strong as in the United States. These products may compete with any products that we may develop, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we chose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. As a result, many companies have encountered significant difficulties in protecting and defending intellectual property rights in certain jurisdictions outside the United States. Such issues may make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights.

Furthermore, 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, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing or 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 to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. 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.

If we or our licensors are unable to protect the confidentiality of the proprietary information related to our product or process, our business and competitive position would be harmed.

We and our licensors rely on confidentiality agreements to protect unpatented know-how, technology and other proprietary information related to our product and process, to maintain our competitive position. For example, our licensor Li-Cor maintains its manufacture of IRDye 700DX® dye molecules (used in AU-011) as a trade secret. Trade secrets and know-how can be difficult to protect. In particular, the trade secrets and know-how in connection with our development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry.

We seek to protect our proprietary information, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated proprietary information 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 are unwilling to protect trade secrets.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing AU-011. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our therapeutic programs and other proprietary technologies we may develop. Such an outcome could have a materially adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our proprietary information. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our proprietary information were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to our Business and Industry

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to pursue our business strategy will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biopharmaceutical industries depends upon our ability to attract, manage, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements for these individuals could harm our business. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, in a timely manner or at all. In particular, we have experienced a very competitive hiring environment in Cambridge, Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity incentive awards that vest over time. The value to employees of restricted stock awards and stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams are at-will employees and may terminate their employment with us on short notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior personnel across our organization.

The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Recently, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19 has spread to most countries across the world, including all 50 states within the United States, including Cambridge, Massachusetts, where our primary office and laboratory space is located. The coronavirus pandemic is evolving, and has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus, the emergence of new variance, acceptance of vaccines and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations in the United States, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we may experience delays in initiating IND-enabling studies, protocol deviations, enrolling our clinical trials, or dosing of patients in our clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which could be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently being affected by the COVID-19 pandemic. Some factors from the COVID-19 pandemic that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative affect on the operations of our third-party manufacturers;
- interruption in global shipping affecting the transport of clinical trial materials, such as drug product and conditioning drugs and other supplies used in our clinical trials;
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments;
- operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors;
- 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
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines.

We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring certain of our employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the SEC, or the FDA. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should the FDA determine that an inspection is necessary for approval of and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

These and other factors arising from COVID-19 could worsen in countries that are already afflicted with COVID-19 or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. 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. We also could incur significant costs associated with civil or criminal fines and penalties.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Changes in tax laws or in their implementation or interpretation may adversely affect us or our investors.

The rules dealing with the U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our internal information technology systems, or those of our third-party CROs, contractors, consultants or others who process sensitive information on our behalf, may fail or suffer security incidents, loss or leakage of data and other compromises, any of which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing such information, expose us to liability or otherwise adversely affect our business.

In the ordinary course of our business, we may collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information (including health information). It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We also have outsourced certain of our operations to third parties, and as a result we manage a number of third parties who have access to our information. Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks by sophisticated nation-state and nation-state supported actors or by malicious third parties (including the deployment of harmful malware (such as malicious code, viruses and worms), natural disasters, global pandemics, fire, terrorism, war and telecommunication and electrical failures, fraudulent activity, as well as security incidents from inadvertent or intentional actions (such as error or theft) by our employees, contractors, consultants, business partners, and/or other third parties, phishing attacks, ransomware, denial-of-service attacks, social engineering schemes and other means that affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure as well as lead to unauthorized access, disclosure or acquisition of information. Cyberattacks are increasing in their frequency, sophistication and intensity. The techniques used to sabotage or to obtain unauthorized access to our information technology systems or those upon whom we rely to process our information change frequently, and we may be unable to anticipate such techniques or implement adequate preventative measures or to stop security incidents in all instances. The recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our information technology systems, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service interruption, system failure or data loss.

Significant disruptions of our information technology systems or security incidents could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information including health information), and could result in financial, legal, business and reputational harm to us. If such disruptions 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. Further, the COVID-19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security incident results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed.

We may also be required to comply with laws, regulations, rules, industry standards, and other legal obligations that require us to maintain the security of personal data. We may also have contractual and other legal obligations to notify collaborators, our clinical trial participants, or other relevant stakeholders of security incidents. Failure to prevent or mitigate cyberattacks could result in unauthorized access to data, including personal data. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. Such disclosures are costly, could lead to negative publicity, may cause our collaborators or other relevant stakeholders to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach. In addition, the costs to respond to a cybersecurity event or to mitigate any identified security vulnerabilities could be significant, including costs for remediating the effects of such an event, paying a ransom, restoring data from backups, and conducting data analysis to determine what data may have been affected by the breach. In addition, our efforts to contain or remediate a security incident or any vulnerability exploited to cause an incident may be unsuccessful, and efforts and any related failures to contain or remediate them could result in interruptions, delays, harm to our reputation, and increases to our insurance coverage.

In addition, litigation resulting from security breaches may adversely affect our business. Unauthorized access to our information technology systems could result in litigation with our collaborators, our clinical trial participants, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our collaborators were disrupted, we could incur significant liability, which could negatively affect our business and damage our reputation.

Furthermore, we may not have adequate insurance coverage or otherwise protect us from, or adequately mitigate, liabilities or damages. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We are, or may become, subject to stringent and changing privacy and information security laws, regulations, standards, policies and contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such data privacy and security obligations could lead to government enforcement actions (which could include civil or criminal fines or penalties), a disruption of our clinical trials or commercialization of our products, private litigation, changes to our business practices, increased costs of operations, and adverse publicity that could otherwise negatively affect our operating results and business. Compliance or the failure to comply with such obligations could increase the costs of our products, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data (including personal and clinical trial data) is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. Moreover, we are subject to the terms of our privacy and security policies, representations, certifications, standards, publications, contracts and other obligations to third parties related to data privacy, security and processing. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, cause regulators to reject, limit or disrupt our clinical trial activities, result in increased expenses, reduce overall demand for our products, and make it more difficult to meet expectations of relevant stakeholders.

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations including, without limitation, laws that regulate personal data such as health data. For example, in the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state personal information laws (e.g., the California Consumer Privacy Act of 2018, or CCPA), 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), govern the collection, use, disclosure and protection of health-related and other personal data. These laws and regulations could apply to our operations, the operations of our collaborators, or other relevant stakeholders upon whom we depend. In addition, we may obtain personal data (including 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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPPA. Additionally, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA became effective on January 1, 2020, and gives California residents expanded rights to access and delete their personal data, opt out of certain personal data sharing and receive detailed information about how their personal data is used. The CCPA requires covered businesses to provide new disclosures to California residents. 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. Although there are limited exemptions for clinical trial data and the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, the CCPA may increase our compliance costs and potential liability. It is anticipated that the CCPA will be expanded on January 1, 2023, when the California Privacy Rights Act of 2020, or CPRA, becomes operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive information, establish restrictions on the retention of personal data, expand the types of data breaches subject to the CCPA's private right of action and establish a new California Privacy Protection Agency to implement and enforce the new law. In addition, other states have enacted or proposed data privacy laws. For example, Virginia recently passed its Consumer Data Protection Act and Colorado recently passed the Colorado Privacy Act, both of which differ from the CPRA and go into effect in 2023. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal data. As we expand our operations, these and similar laws may increase our compliance costs and potential liability.

Foreign data protection laws, such as, without limitation, the EU's GDPR and the EU member state implementing legislation, may also apply to health-related and other personal data that we process, including, without limitation, personal data relating to clinical trial participants. European data protection laws impose strict obligations on the ability to process health-related and other personal data of European data subjects, including in relation to security (which requires the adoption of administrative, physical and technical safeguards designed to protect such information), collection, use and transfer or personal data. European data protection laws may affect our use, collection, analysis, and transfer (including cross-border transfer) of such personal data. These include, without limitation, several requirements relating to transparency related to communications with data subjects regarding the processing of their personal data, obtaining the consent of the individuals to whom the personal data relates, limitations on the retention of personal data, increased requirements pertaining to health data, establishing a legal basis for processing, notification of data processing obligations or security incidents to the competent national data protection authorities and/or data subjects, the security and confidentiality of the personal data, various rights that data subjects may exercise with respect to their personal data, and strict rules and restrictions on the transfer of personal data outside of Europe (including from the European Economic Area (EEA), Switzerland and United Kingdom (UK)).

European data protection laws prohibit, without an appropriate legal basis, the transfer of personal data to countries outside of Europe, such as to the United States, which are not considered relevant authorities to provide an adequate level of data protection. A decision by the Court of Justice of the EU, or the "Schrems II" ruling, invalidated the EU-U.S. Privacy Shield Framework, and raised questions about whether the European Commission's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal data transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of personal data from Switzerland to the United States. The UK, whose data protection laws are similar to those of the EU, has similarly determined that the EU-U.S. Privacy Shield is not a valid mechanism for lawfully transferring personal data from the UK to the U.S. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular, applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place. However, the nature of these additional measures is currently uncertain. Additionally, the European Commission recently adopted new SCCs that will repeal the SCCs adopted under the Data Protection Directive. This means we may need to update our contracts that involve the transfer of personal data outside of the EEA to the new SCCs. As supervisory authorities issue further guidance on personal data export mechanisms, including on the new SCCs, and/or start taking enforcement action, our compliance costs could increase, we may be subject to complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we conduct clinical trials, this could negatively impact our business.

Further, the UK's decision to leave the EU, often referred to as Brexit, and ongoing developments in the UK have created uncertainty regarding data protection regulation in the UK. Following December 31, 2020, and the expiry of transitional arrangements between the UK and EU, the data protection obligations of the GDPR continue to apply to UK-related Processing of personal data in substantially unvaried form under the so-called "UK GDPR" (i.e., the GDPR as it continues to form part of UK law by virtue of section 3 of the EU (Withdrawal) Act 2018, as amended). However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and EEA. Furthermore, the relationship between the UK and the EEA in relation to certain aspects of data protection law remains uncertain, including with respect to regulation of data transfers between the EU member states and the UK. On June 28, 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers (other than those carried out for the purposes of the UK immigration control) of personal data from the EEA to the UK to continue without restriction for a period of four years ending June 27, 2025. After that period, the adequacy decision may be renewed, but, only if the UK continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the UK and could intervene at any point if the UK deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the UK will require a valid 'transfer mechanism' and we may be required to implement new processes and put new agreements in place, such as SCCs, to enable transfers of personal data from the EEA to the UK to continue.

The increase of foreign privacy and security legal frameworks with which we must comply, increases our compliance burdens and exposure to substantial fines and penalties for non-compliance. For example, under the GDPR, entities that violate the GDPR can face fines of up to the greater of 20 million euros or 4% of their worldwide annual turnover (revenue). Additionally, regulators could prohibit our use of personal data subject to the GDPR. The GDPR has increased our responsibility and potential liability in relation to personal data that we process, requiring us to put in place additional mechanisms to comply with the GDPR and other foreign data protection requirements.

We may also publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal data and/or other confidential information. Although we endeavor to comply with our published policies and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices.

Compliance with U.S. federal and state as well as foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure, or perceived failure, to comply with federal, state and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties, fines or penalties), private litigation, a diversion of management attention, adverse publicity and negative effects on our operating results and business. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations related to information security or security breaches. Moreover, clinical trial participants or subjects about whom we or our collaborators obtain information, as well as the providers who share this information with us, may limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, contracts or privacy notices or breached other obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and make it more difficult to meet expectations of or commitments to our relevant stakeholders.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, pandemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Any future acquisitions, in-licensing or strategic partnerships may increase our capital requirements, dilute our stockholders, divert our management's attention, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- spend substantial operational, financial and management resources in integrating new businesses, technologies and products;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third-party manufacturers could materially delay our operations.

We expect to significantly expand our organization, including building sales and marketing capability and creating additional infrastructure to support our operations as a public company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert or stretch our management and business development resources in a way that we may not anticipate. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any current or future product candidates that we may develop. Claims could also be asserted under the state consumer production acts. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any current or future product candidates 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;
- a diversion of management's time and resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- a decline in our stock price; and
- the inability to commercialize any current or future product candidates that we may develop.

We do not yet maintain product liability insurance, and we anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; the U.S. federal and state fraud and abuse laws, data privacy and security laws and other similar non-United States laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, 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 be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other United States federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Common Stock

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of September 30, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 62.2% of our outstanding common stock. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. As of December 31, 2020, we had federal net operating loss carryforwards of approximately $106.1 million, and state net operating loss carryforwards of $89.3 million. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating the U.S. federal and state taxable income. As a result, the amount of the net operating loss and tax credit carryforwards presented in our financial statements could be limited and may expire unutilized. Under current law, unused U.S. federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. For taxable years beginning after December 31, 2020, however, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in such taxable years.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. For a further description of our dividend policy, please refer to the section entitled "Dividend Policy."

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of AU-011 or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or our amended and restated certificate of incorporation or our amended and amended and restated bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws will further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the Federal Forum Provision). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

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 harm our business.

Anti-takeover provisions in our amended and restated Certificate of Incorporation and bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and, therefore, decrease the trading price of our common stock.

Our fourth amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a Board divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of the stockholders may be called only by the Board acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings of stockholders may not be called by any other person or persons;
- advance notice requirements for stockholder proposals and nominations for election to our Board;
- a requirement that no member of our Board may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and
- the authority of the Board to issue preferred stock on terms determined by the Board without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our fourth amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our Board or initiate actions that are opposed by the then-current Board and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our Board could cause the market price of our common stock to decline.

General Risks

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, the U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the current COVID-19 pandemic has caused significant volatility and uncertainty in the U.S. and international markets. See "Risks Related to our Business and Industry—The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates." A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our employees, independent contractors, consultants, academic collaborators, partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, academic collaborators, partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA, the EMA and comparable foreign regulatory authorities, provide true, complete and accurate information to the FDA, the EMA and comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain the FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, academic collaborators, partners and vendors, and the precautions we take to detect and prevent such activities 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 actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" and "smaller reporting companies" will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 or Section 404, as amended, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an "emerging growth company," we are only required to provide two years of audited financial statements and two years of selected financial data in our periodic reports.

We will remain an "emerging growth company" until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a "large accelerated filer," which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an “emerging growth company,” we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the independent auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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 share price may be more volatile.

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 benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an “emerging growth company” or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a “smaller reporting company” until (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million as of the prior June 30th. 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.

The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, you may not be able to sell their common stock at or above the price you paid for your common stock. The market price for our common stock may be influenced by many factors, including the other risks described in this section of the prospectus entitled “Risk Factors” and the following:

- results of preclinical studies and results or enrollment of clinical trials of AU-011 or our future product candidates, or those of our potential future competitors or our existing or future collaborators;
- the impact of the COVID-19 pandemic on our employees, trials, collaboration partners, suppliers, our results of operations, liquidity and financial condition;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of future competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for AU-011 or our future product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;

- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, pandemics and other calamities; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm 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 "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

In the past, securities class action litigation has often been brought against public companies following declines in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result insubstantial costs and a diversion of management's attention and our resources, which could harm our business.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act and rules implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an "emerging growth company," we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. In addition, for as long as we are a "smaller reporting company" with less than $100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the of the Sarbanes-Oxley Act of 2002. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In additional, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

However, any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

(a) Recent Sales of Unregistered Equity Securities

On November 2, 2021, upon the closing of our IPO, all 308,332,857 shares of our then-outstanding convertible preferred stock automatically converted into 22,550,561 shares of our common stock. The issuance of such common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

During the period between January 1, 2021 and September 30, 2021, we issued to certain of our employees, advisors and directors, options to purchase an aggregate of 1,883,480 shares of our common stock at an average exercise price of $6.13 per share. We deemed these issuances to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit or Section 4(a)(2) of the Securities Act as sales and offers not involving a public offering.

(b) Use of Proceeds from Initial Public Offering of Common Stock

On November 2, 2021, the Company completed its initial public offering, or the IPO, in which it issued and sold 5,400,000 shares of its common stock at a public offering price of $14.00 per share. The Company received net proceeds from the IPO of $67.3 million, after deducting underwriters' discounts, commissions and estimated offering-related costs. In connection with the IPO, the Company granted the underwriters a 30-day option to purchase an additional 810,000 shares. On November 8, 2021, the underwriters exercised the option in full and the Company issued 810,000 shares of common stock for aggregate net proceeds of $10.5 million after deducting underwriter discounts and commissions of $0.8 million.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333- 260156), which was declared effective by the SEC on October 28, 2021. Cowen and Company, LLC, SVB Leerink LLC, Evercore Group L.L.C. and BTIG, LLC acted as underwriters for the IPO.

No expenses incurred by the Company in connection with the IPO were paid directly or indirectly to (i) any of its officers or directors or their associates, (ii) any persons owning 10% or more of any class of its equity securities, or (iii) any of its affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from the IPO from those disclosed in the Prospectus. We plan to invest the funds received in cash equivalents and other marketable securities in accordance with our investment policy.

(a) 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.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description
3.2	Tenth Amended and Restated Certificate of Incorporation of Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrants' Current Report on Form 8-K (File No. 001-40971).
3.4	Amended and Restated Bylaws of Registrant, as currently in effect (incorporated by reference to Exhibit 3.4 of the Registrants' Current Report on Form 8-K (File No. 001-40971).
4.2	Fifth Amended and Restated Investors' Rights Agreement (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-260156)).
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 and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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.

Aura Biosciences, Inc.

Date: November 24, 2021

By: /s/ Elisabet de los Pinos

Elisabet de los Pinos
President and Chief Executive Officer

Date: November 24, 2021

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Exhibit 31.1

CERTIFICATION

I, Elisabet de los Pinos, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Aura Biosciences, 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.

Aura Biosciences, Inc.

Date: November 24, 2021

By: /s/ Elisabet de los Pinos

Elisabet de los Pinos

President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Julie Feder, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Aura Biosciences, 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.

Aura Biosciences, Inc.

Date: November 24, 2021

By: /s/ Julie Feder

Julie Feder

Chief Financial 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 on Form 10-Q of Aura Biosciences, Inc. (the "Company") for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of her knowledge:

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

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

Aura Biosciences, Inc.

Date: November 24, 2021

By: /s/ Elisabet de los Pinos
Elisabet de los Pinos
President and Chief Executive Officer

Date: November 24, 2021

By: /s/ Julie Feder
Julie Feder
Chief Financial Officer