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, 2024

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.)**
80 Guest Street Boston, MA	**02135**
(Address of principal executive offices)	**(Zip Code)**

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

(Former Name or Former Address, if Changed Since Last Report)

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 ☒

As of November 7, 2024, the Registrant had 49,951,466 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, regulatory approval and commercialization of our product candidates.
- We are heavily dependent on the success of AU-011, or bel-sar, our only product candidate to date.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for bel-sar, 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 initiated but not yet completed a pivotal clinical trial nor have we 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.
- The U.S Food and Drug Administration's agreement to a Special Protocol Assessment with respect to the study design of our global Phase 3 trial of bel-sar for the treatment of early-stage choroidal melanoma does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process.
- We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and expect to continue to do so, 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 development and manufacturing organizations, or CDMOs, for the production of clinical supply of bel-sar and may continue to rely on CDMOs for the production of commercial supply of bel-sar, if approved. This reliance on CDMOs 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 bel-sar 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 bel-sar 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 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 nonclinical, 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 effects of macroeconomic conditions, including rising interest rates and inflation, on our business operations; 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 Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 25,407	$ 41,063
Marketable securities	148,970	185,087
Restricted cash and deposits	—	19
Prepaid expenses and other current assets	9,104	5,625
Total current assets	183,481	231,794
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	17,744	18,854
Other long-term assets	22	509
Property and equipment, net	3,325	3,150
Total Assets	$ 205,340	$ 255,075
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,991	1,787
Short-term operating lease liability	3,126	2,687
Accrued expenses and other current liabilities	9,597	7,883
Total current liabilities	14,714	12,357
Long-term operating lease liability	15,958	16,870
Total Liabilities	30,672	29,227
Commitments and Contingencies (Note 12)		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at September 30, 2024 and December 31, 2023, and 49,778,861 and 49,350,788 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	522,454	512,617
Accumulated deficit	(348,393)	(287,308)
Accumulated other comprehensive income	607	539
Total Stockholders' Equity	174,668	225,848
Total Liabilities and Stockholders' Equity	$ 205,340	$ 255,075

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

Aura Biosciences, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating Expenses:				
Research and development	$ 17,036	$ 15,428	$ 50,968	$ 44,952
General and administrative	6,196	5,060	17,341	15,256
Total operating expenses	23,232	20,488	68,309	60,208
Total operating loss	(23,232)	(20,488)	(68,309)	(60,208)
Other income (expense):				
Interest income, including amortization and accretion income	2,258	1,981	7,395	5,981
Other expense	(25)	(5)	(83)	(50)
Total other income	2,233	1,976	7,312	5,931
Loss before income taxes	(20,999)	(18,512)	(60,997)	(54,277)
Income tax provision, net	(43)	—	(88)	—
Net loss	$ (21,042)	$ (18,512)	$ (61,085)	$ (54,277)
Net loss per common share—basic and diluted	$ (0.42)	$ (0.48)	$ (1.23)	$ (1.43)
Weighted average common stock outstanding—basic and diluted	49,663,532	38,185,197	49,554,930	37,943,139
Comprehensive loss:				
Net loss	$ (21,042)	$ (18,512)	$ (61,085)	$ (54,277)
Other comprehensive items:				
Unrealized gain (loss) on marketable securities	790	89	68	(62)
Total other comprehensive income (loss)	790	89	68	(62)
Total comprehensive loss	$ (20,252)	$ (18,423)	$ (61,017)	$ (54,339)

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

Aura Biosciences, Inc.

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss) Amount	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2023	49,350,788	$ —	$ 512,617	$ (287,308)	$ 539	$ 225,848
Stock-based compensation expense	—	—	2,909	—	—	2,909
Employee Stock Purchase Plan issuance	12,314	—	95	—	—	95
Stock option exercises	51,180	—	158	—	—	158
Vesting of restricted stock	90,123	—	—	—	—	—
Unrealized loss on marketable securities	—	—	—	—	(521)	(521)
Net loss	—	—	—	(19,706)	—	(19,706)
Balance, March 31, 2024	49,504,405	—	515,779	(307,014)	18	208,783
Stock-based compensation expense	—	—	3,126	—	—	3,126
Employee Stock Purchase Plan issuance		—	—	—	—	—
Stock option exercises	24,245	—	83	—	—	83
Vesting of restricted stock	54,708	—	—	—	—	—
Unrealized loss on marketable securities	—	—	—	—	(201)	(201)
Net loss	—	—	—	(20,337)	—	(20,337)
Balance, June 30, 2024	49,583,358	—	518,988	(327,351)	(183)	191,454
Stock-based compensation expense	—	—	2,750	—	—	2,750
Employee Stock Purchase Plan issuance	12,163	—	82	—	—	82
Stock option exercises	127,433	—	634	—	—	634
Vesting of restricted stock	55,907	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	790	790
Net loss	—	—	—	(21,042)	—	(21,042)
Balance, September 30, 2024	49,778,861	$ -	$ 522,454	$ (348,393)	$ 607	$ 174,668

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss) Amount	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2022	37,771,918	$ —	$ 406,555	$ (210,900)	$ (72)	$ 195,583
Stock-based compensation expense	—	—	1,913	—	—	1,913
Employee Stock Purchase Plan issuance	6,635	—	56	—	—	56
Stock option exercises	21,549	—	145	—	—	145
Unrealized gain on marketable securities	—	—	—	—	27	27
Net loss	—	—	—	(17,466)	—	(17,466)
Balance, March 31, 2023	37,800,102	—	408,669	(228,366)	(45)	180,258
Stock-based compensation expense	—	—	1,931	—	—	1,931
Issuance of common stock under ATM facility	169,200	—	2,065	—	—	2,065
Stock option exercises	117,304	—	660	—	—	660
Unrealized loss on marketable securities	—	—	—	—	(178)	(178)
Net loss	—	—	—	(18,299)	—	(18,299)
Balance, June 30, 2023	38,086,606	—	413,325	(246,665)	(223)	166,437
Stock-based compensation expense	—	—	2,325	—	—	2,325
Employee Stock Purchase Plan issuance	8,276	—	72	—	—	72
Issuance of common stock under ATM facility	92,607	—	1,105	—	—	1,105
Stock option exercises	29,228	—	202	—	—	202
Unrealized gain on marketable securities	—	—	—	—	89	89
Net loss	—	—	—	(18,512)	—	(18,512)
Balance, September 30, 2023	38,216,717	$ —	$ 417,029	$ (265,177)	$ (134)	$ 151,718

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

Aura Biosciences, Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (61,085)	$ (54,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	932	971
Accretion on marketable securities	(3,890)	(2,853)
Stock-based compensation expense	8,785	6,169
Other	(5)	1
Non-cash lease expense	1,110	1,122
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,479)	3,059
Other long-term assets	486	(262)
Accounts payable	172	(1,497)
Accrued expenses and other liabilities	1,594	1,796
Operating lease liabilities	(473)	(689)
Net cash used in operating activities	(55,853)	(46,460)
Cash flows from investing activities:		
Purchases of property and equipment	(954)	(392)
Purchase of marketable securities	(59,103)	(88,847)
Maturities of marketable securities	99,183	65,396
Net cash provided by (used in) investing activities	39,126	(23,843)
Cash flows from financing activities:		
Proceeds from exercise of stock options	875	1,007
Proceeds from issuance of common stock under ATM facility, net of issuance costs	—	3,170
Proceeds from ESPP purchase	177	128
Net cash provided by financing activities	1,052	4,305
Net decrease in cash, cash equivalents and restricted cash	(15,675)	(65,998)
Cash, cash equivalents and restricted cash at beginning of period	41,850	122,370
Cash, cash equivalents and restricted cash at end of period	$ 26,175	$ 56,372
Supplemental disclosure of cash flow information:		
Purchases of property and equipment in accounts payable and accrued expenses and other liabilities	152	65
Initial measurement of right-of-use assets and lease liabilities for operating lease	—	20

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

	September 30,	
	2024	**2023**
Cash and cash equivalents, end of period	$ 25,407	$ 55,584
Short-term restricted cash, end of period	—	20
Long-term restricted cash, end of period	768	768
Cash, cash equivalents and restricted cash at end of period	$ 26,175	$ 56,372

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

1. Description of Business

Aura Biosciences, Inc., or the Company or Aura, is a clinical-stage biotechnology company developing precision therapies to treat solid tumors designed to preserve organ function. Within these unaudited condensed consolidated financial statements, unless the context otherwise requires, references to the Company or Aura refer to Aura Biosciences, Inc. and its subsidiaries on a consolidated basis. The Company's proprietary platform is designed to enable 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. VDCs are a novel class of drugs with a dual mechanism of action that promote cancer cell death by both the delivery of the cytotoxic payload to generate acute necrosis and activation of a secondary immune mediated response. The Company's initial focus is in ocular and urologic oncology, both areas of high unmet medical need where local targeted therapies may enable early intervention. The Company is evaluating the safety and efficacy of its lead candidate, bel-sar, as a potential vision-sparing therapy in an ongoing global Phase 3 CoMpass trial for the first-line treatment of adult patients with small choroidal melanoma and indeterminate lesions, or early-stage choroidal melanoma. Bel-sar is also being explored for metastases to the choroid and cancers of the ocular surface and is in Phase 1 clinical development in bladder cancer. The Company envisions the potential for development of bel-sar in additional therapeutic areas. Aura's headquarters are located in Boston, 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, collaborative partners, contract development and manufacturing organizations and other third-parties, competition, customer demand, management of growth, and the effectiveness of marketing by the Company.

Liquidity

Through September 30, 2024, the Company has funded its operations primarily with proceeds from the initial and additional closings of its convertible preferred stock financings, and through its initial public offering, or IPO, follow-on offerings and at-the-market offering, or ATM. On November 9, 2023, the Company issued and sold 11,000,000 shares of common stock at a price to the public of $9.00 per share for aggregate gross proceeds of $99.0 million, or the 2023 Follow-On Offering. The Company received approximately $92.6 million in net proceeds from the 2023 Follow-On Offering after deducting underwriting discounts and commissions and offering expenses. On November 1, 2022, the Company filed a shelf registration statement on Form S-3, or the 2022 Shelf, with the SEC in relation to the registration of up to an aggregate offering price of $250.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof. The Company also simultaneously entered into the Open Market Sale Agreement℠, or Sales Agreement, with Jefferies LLC, or the Sales Agent, to provide for the offering, issuance and sale by the Company of up to an aggregate of $75.0 million of common stock from time to time in the ATM under the 2022 Shelf and subject to the limitations thereof. In connection with the 2023 Follow-On Offering, on November 6, 2023, the Company delivered written notice to Jefferies that the Company was suspending and terminating the prospectus related to the shares issuable in the ATM pursuant to the terms of the Sales Agreement. On March 27, 2024, the Company filed a new shelf registration statement on Form S-3, or the 2024 Shelf, with the SEC in relation to the registration of up to an aggregate offering price of $350.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof, which superseded the 2022 Shelf. The 2024 Shelf included a prospectus supplement to provide for offerings in the ATM under the Sales Agreement. The Company issued no shares of common stock during the three and nine months ended September 30, 2024 under the ATM.

As of the issuance date of these unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2024, the Company expects that its cash and cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of these consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated 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 consolidated 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. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2024 and 2023 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, 2024. Certain information and footnote disclosures normally included in annual consolidated 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 consolidated financial statements are read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2023, in the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2024. There have been no changes to the Company's significant accounting policies except as noted below.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," which was subsequently amended in November 2018 through ASU No. 2018-19, "Codification Improvements to Topic 326, Financial Instruments—Credit Losses." ASU No. 2016-13 will require entities to estimate lifetime expected credit losses for trade and other receivables, net investments in leases, financing receivables, debt securities and other instruments, which will result in earlier recognition of credit losses. Further, the new credit loss model will affect how entities in all industries estimate their allowance for losses for receivables that are current with respect to their payment terms. ASU No. 2018-19 further clarifies that receivables arising from operating leases are not within the scope of Topic 326. Instead, impairment from receivables of operating leases should be accounted for in accordance with Topic 842, Leases. As per the latest ASU 2020-02, FASB deferred the timelines for certain small public and private entities, thus the new guidance was adopted by the Company for the annual reporting period beginning January 1, 2023, including interim periods within that annual reporting period. The standard will apply as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The Company adopted this standard on January 1, 2023 and the standard did not have a material impact on its results of operations, financial condition, and financial statement disclosures.

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, 2024 and December 31, 2023 (in thousands):

Description	September 30, 2024	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 24,896	$ 24,896	$ —	$ —
Marketable securities:				
U.S. Government agencies	148,970	—	148,970	—
Total financial assets	$ 173,866	$ 24,896	$ 148,970	$ —

Description	December 31, 2023	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 40,551	$ 40,551	$ —	$ —
Marketable securities:				
Commercial paper	9,137	—	9,137	—
Corporate bonds	6,187	—	6,187	—
U.S. Government agencies	166,002	—	166,002	—
Yankee bonds	2,982	—	2,982	—
Asset-backed securities	779	—	779	—
Total financial assets	$ 225,638	$ 40,551	$ 185,087	$ —

4. Property and Equipment, Net

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

	September 30, 2024	December 31, 2023
Assets under construction	$ 518	$ 391
IT equipment	307	289
Leasehold improvements	471	—
Lab equipment	7,996	7,506
	$ 9,292	$ 8,186
Less—accumulated depreciation	(5,967)	(5,036)
Property and equipment, net	$ 3,325	$ 3,150

Depreciation expense was $0.3 million and $0.4 million for the three months ended September 30, 2024 and 2023, respectively. In addition, depreciation expense was $0.9 million and $1.0 million for the nine months ended September 30, 2024 and 2023, respectively.

5. Prepaid Expenses and Other Current Assets

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

	September 30, 2024	December 31, 2023
Prepaid insurance	$ 353	$ 1,817
Prepaid research and development expenses	5,333	1,399
Other	3,418	2,409
Prepaid expenses and other current assets	$ 9,104	$ 5,625

6. Marketable Securities

Marketable securities consist of the following (in thousands):

	September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Government agencies	$ 148,363	$ 607	$ —	$ 148,970
Total	$ 148,363	$ 607	$ —	$ 148,970

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 9,144	$ —	$ (7)	$ 9,137
Corporate bonds	6,186	3	(2)	6,187
U.S. Government agencies	165,453	563	(14)	166,002
Yankee bonds	2,985	—	(3)	2,982
Asset-backed securities	780	—	(1)	779
Total	$ 184,548	$ 566	$ (27)	$ 185,087

As of September 30, 2024, the Company had no marketable securities with unrealized losses. The current credit ratings are all within the guidelines of the investment policy of the Company and the Company does not expect the issuers to settle any security at a price less than the amortized cost basis of the investment. The Company does not intend to sell the investments and it is not probable that the Company will be required to sell the investments before recovery of their amortized cost basis.

As of September 30, 2024, no marketable securities with contractual maturities of one year or less were in an unrealized loss position.

As of September 30, 2024, the Company had marketable securities with a fair value of $30.1 million that had maturities of one to two years.

There were no impairments of the Company’s assets measured and carried at fair value during the nine months ended September 30, 2024.

7. Accrued Expenses and Other Current Liabilities

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

	September 30, 2024	December 31, 2023
Accrued research and development expenses	$ 4,169	$ 3,445
Accrued compensation	4,368	3,503
Other	1,060	935
Accrued expenses and other current liabilities	$ 9,597	$ 7,883

8. Stockholders' Equity

The Company had 150,000,000 authorized shares of common stock, par value $0.00001 per share, of which 49,778,861 and 49,350,788 shares were issued and outstanding at September 30, 2024 and December 31, 2023, respectively.

In addition, the Company had 10,000,000 authorized shares of preferred stock, par value $0.00001 per share, all of which shares of preferred stock are undesignated. No authorized shares of preferred stock were issued and outstanding at September 30, 2024 and December 31, 2023.

Financings

On March 27, 2024, the Company filed the 2024 Shelf with the SEC in relation to the registration of up to an aggregate offering price of $350.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof, which superseded the 2022 Shelf. The 2024 Shelf included a prospectus supplement to provide for offerings in the ATM under the Sales Agreement. The Company issued no shares of common stock during the nine months ended September 30, 2024 under the ATM.

On November 9, 2023, the Company issued and sold 11,000,000 shares of common stock at a price to the public of $9.00 per share for aggregate gross proceeds of $99.0 million in the 2023 Follow-On Offering. The Company received approximately $92.6 million in net proceeds from the 2023 Follow-On Offering after deducting underwriting discounts and commissions and offering expenses.

On November 1, 2022, the Company filed the 2022 Shelf with the SEC in relation to the registration of up to an aggregate offering price of $250.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof. The Company also simultaneously entered into the Sales Agreement with the Sales Agent to provide for the offering, issuance and sale by the Company of up to an aggregate of $75.0 million of common stock from time to time in the ATM under the 2022 Shelf and subject to the limitations thereof. The Company issued 261,807 shares of common stock at an average price of $12.49 for aggregate gross proceeds of $3.3 million during the year ended December 31, 2023 under the ATM.

9. Stock-Based Compensation

2018 Stock Option and Incentive Plan

On December 12, 2018, the Company adopted the Aura Biosciences, Inc. 2018 Equity Incentive Plan, or the 2018 Plan. 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 of Directors, or the Board, has determined not to make any further awards under the 2018 Plan as of November 2, 2021. However, the 2018 Plan will continue to govern outstanding equity awards granted thereunder.

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 increased on January 1, 2022 and will continue to increase 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. On January 1, 2024, the shares reserved for issuance was increased to 9,414,162 shares. With the transfer of the available options from the 2018 Plan to the 2021 Plan, there were 4,109,828 options and restricted stock units available for grant under the 2021 Plan at September 30, 2024.

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 increased on January 1, 2022 and will continue to increase 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. On January 1, 2024, the shares reserved for issuance was increased to 1,282,856 shares. The purchase price of the shares under the ESPP are at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the purchase date. As of September 30, 2024, 1,258,379 shares were available to be issued under the ESPP. The Company recognized $0.01 million share-based compensation expense related to the ESPP for the three months ended September 30, 2024. The Company recognized $0.06 million share-based compensation expense related to the ESPP for the nine months ended September 30, 2024.

Stock Options

The Board is authorized to administer the 2021 Plan. In accordance with the provisions of the 2021 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 2021 Plan.

In addition, the Board may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. 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 2021 Plan.

The following table summarizes stock option activity under the 2018 Plan and 2021 Plan for the nine months ended September 30, 2024:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	5,030,351	$ 8.46	7.54	$ 10,353
Granted	1,446,630	7.74		
Exercised	(202,858)	4.32		
Cancelled/Forfeited	(527,682)	10.86		
Outstanding at September 30, 2024	5,746,441	$ 8.20	7.22	$ 11,033
Exercisable at September 30, 2024	3,189,078	$ 7.74	5.96	$ 8,671

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2024 and 2023 was $5.85 and $7.81 per share, respectively. The fair value of options vested during the nine months ended September 30, 2024 and 2023 was $6.4 million and $4.8 million, respectively. The total intrinsic value of options exercised was $0.8 million and $1.0 million for the nine months ended September 30, 2024 and 2023, respectively.

The fair value of the stock options issued for the three and nine months ended September 30, 2024 and 2023 was measured with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	3.89%	4.22%	3.93%	3.68%
Expected term (years)	6.08	6.08	6.05	6.03
Expected volatility of the underlying stock	88.82%	87.35%	88.61%	85.38%
Expected dividend rate	—%	—%	—%	—%

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions. Unvested restricted stock units may not be sold or transferred by the holder.

A summary of the restricted stock units activity during the nine months ended September 30, 2024 is as follows:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	1,093,402	$ 10.27
Granted	976,345	7.74
Vested/Released	(200,738)	10.40
Forfeited	(229,711)	10.15
Unvested at September 30, 2024	1,639,298	$ 8.77

As a result of the 2021 Plan, the Company granted restricted stock units which vest in increments of 25% annually over a period of four years. For the nine months ended September 30, 2024, 200,738 restricted stock units vested with a fair value of $2.1 million.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 1,175	$ 1,090	$ 4,194	$ 2,565
General and administrative	1,575	1,235	4,591	3,604
Total	$ 2,750	$ 2,325	$ 8,785	$ 6,169

As of September 30, 2024, there was $14.8 million of unrecognized compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.57 years.

As of September 30, 2024, there was $11.6 million of unrecognized compensation expense related to restricted stock units, which is expected to be recognized over a weighted-average period of 2.96 years.

10. Common Stock Warrants

In February 2015 and May 2015, the Company issued warrants to purchase 1,650,098 and 887,536 shares of Series B convertible preferred stock, respectively, at an exercise price of $1.24235 per share (the “Series B Warrants”). Each Series B Warrant was immediately exercisable and expires 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 were re-measured to fair value at each balance sheet date. A total of 173,827 of the Series B Warrants were outstanding and were converted into warrants to purchase 12,686 shares of common stock with an exercise price of $17.03 upon the completion of the IPO in November 2021. As a result, the 12,686 common stock warrants were converted into equity instruments and remain outstanding as of September 30, 2024.

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 for each of the three months ended September 30, 2024 and 2023. The Company made matching contributions in the amount of $0.7 million and $0.6 million for the nine months ended September 30, 2024 and 2023, respectively.

12. Commitments and Contingencies

Lease Commitments

The Company has historically entered into lease arrangements for its facilities. The Company has one operating lease for its office and laboratory facility with required future minimum payments as of September 30, 2024.

On May 16, 2022, the Company entered into an office and laboratory lease in Boston, Massachusetts with an initial 10-year term and one renewal option to extend the lease for an additional seven years. The lease commenced on August 1, 2022, and estimated payments due under the initial term total $35.2 million. The lease requires a letter of credit totaling $0.8 million which is classified as long-term restricted cash and deposits on the consolidated balance sheet. The landlord will reimburse the Company up to $0.5 million for certain costs related to expansion of the laboratory space. As of September 30, 2024, the Company has completed the expansion and has incurred and been fully reimbursed for $0.5 million of expenses.

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, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Lease Cost				
Operating lease costs	$ 867	$ 880	$ 2,642	$ 2,641
Variable lease costs	272	221	912	664
Short-term lease costs	—	2	—	6
Total lease costs	$ 1,139	$ 1,103	$ 3,554	$ 3,311

Cash paid for amounts included in the measurement of lease liabilities—operating leases	$ 2,005	$ 2,209
Weighted-average remaining lease term—operating leases (years)	7.84	8.84
Weighted-average discount rate—operating leases	10.71%	10.71%

The following table reconciles the future minimum commitments to the Company's operating lease liabilities at September 30, 2024 (in thousands):

	Operating lease payments as of September 30, 2024
2024	$ 816
2025	3,306
2026	3,405
2027	3,507
2028	3,611
Thereafter	13,823
Total lease payments	28,468
Less: interest	(9,384)
Total lease liabilities at September 30, 2024	19,084
Less: current portion of lease liabilities	3,126
Lease liabilities, net of current portion	$ 15,958

License Agreements

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

Rakuten License and Supply Agreement

In May 2024, the Company received notice from LI-COR, Inc., or LI-COR, that as of April 16, 2024, LI-COR assigned, and Rakuten Medical, Inc., or Rakuten, assumed, the 2014 Exclusive Agreement and the 2014 Non-Exclusive Agreement (each described below), each originally entered into by and between the Company and LI-COR. The 2014 Exclusive Agreement and 2014 Non-Exclusive Agreement were not otherwise modified by this assignment and assumption and remain in effect.

2014 Exclusive Agreement

In January 2014, the Company entered into an Exclusive License and Supply Agreement, or the 2014 Exclusive Agreement, with LI-COR for the license of IRDye 700DC and related licensed patent (now expired) for the treatment and diagnosis of ocular cancers in humans, as amended in January 2016, July 2017, April 2018 and April 2019. The 2014 Exclusive Agreement required a one-time upfront license issue fee of $0.1 million and aggregate milestone payments of up to $0.2 million upon certain regulatory and development milestones. The Company is also required to pay Rakuten low-single digit royalties on net sales. The term of the 2014 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, 2024 and 2023, respectively.

2014 Non-Exclusive Agreement

In December 2014, the Company entered into a Non-Exclusive License Agreement, or the 2014 Non-Exclusive Agreement, with LI-COR for the supply of IRDye 700DX to the Company for the treatment and diagnosis of non-ocular solid tumor 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 Rakuten a non-refundable, non-creditable fee of $0.03 million per each licensed product upon pre-IND designation, as defined of such licensed product, aggregate milestone payments of up to $0.3 million upon certain regulatory and development milestones; and during the term, the Company must pay Rakuten a low-single digit percentage royalty on net sales. Rakuten 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 aggregate. During the nine months ended September 30, 2024 and 2023, the Company recognized no milestones related to this agreement.

Life Technologies Corporation License Agreements

In December 2014, the Company entered into a non-exclusive, perpetual license agreement with Life Technologies Corporation, or the Life Technologies, which allows for five licensed 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 payment of the initial license fee and due annually or 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, there will be a change of control fee of $0.2 million.

In January 2022, the Company entered into the First Amendment to the non-exclusive, perpetual license agreement with Life Technologies for use of the license in an additional indication. The cost of this amendment was a one-time fee of $0.05 million. During the nine months ended September 30, 2024 and 2023, the Company recognized no expenses related to this agreement.

Effective in September 2022, the Company entered into a new non-exclusive, perpetual license agreement with Life Technologies for licensed products. Under this agreement, the Company is required to pay an initial license fee of $0.4 million for the first licensed product and $0.5 million for each additional licensed product. In addition, the agreement allows the Company the right to sublicense which would lead to a $0.2 million payment for each sublicense per licensed product and a $0.03 million payment for use of the cell line document package. In the event of a change of control, there will be a change of control fee of $0.5 million. During the nine months ended September 30, 2024 and 2023, the Company recognized no expenses related to 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 this agreement, the Company is required to make annual payments of $0.03 million to fund the research activities, the first payment of which was paid within 30 days of the effective date. Subsequent payments are due within 30 days of the anniversary of the effective date. This agreement was first amended in 2012, 2013, 2014, 2015, 2016, 2018 and in September of 2020. During the nine months ended September 30, 2024 and 2023, the Company paid no research collaboration fees related to this agreement.

A seventh amendment was made in October 2020, requiring payment of $0.04 million within 30 days of October 1, 2020, and another $0.03 million within 30 days of the 10th anniversary of the CRADA, which was paid in July 2021. This seventh amendment extended the term of the CRADA to September 30, 2022. The Company recognized no milestones related to this agreement and related amendments for the nine months ended September 30, 2024 and 2023.

An eighth amendment was effective in September 2022, requiring payment of $0.04 million within 30 days of November 1, 2022, and payment of another $0.03 million within 30 days of the 12th anniversary of the CRADA, which was in August 2023. This eighth amendment extended the term of the CRADA to September 30, 2024. During the nine months ended September 30, 2024 and 2023, the Company recognized $0 million and $0.03 million of expenses, respectively, related to this agreement.

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

In September 2013, the Company entered into an exclusive patent license agreement, or the NIH Exclusive License Agreement, with the NIH, that required the Company to pay a license issue royalty 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 of up to $0.7 million in aggregate and sales milestone payments up to $0.6 million in the aggregate. The Company is also required to pay the NIH a mid-single to low teen-digit percentage of any sublicensing revenue the Company receives. Additionally, the Company's payment obligations to the NIH are subject to an annual minimum royalty payment of low five figures. The Company recognized no patent licensing fees for the nine months ended September 30, 2024 and 2023, respectively.

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-Transfert License Agreement

In November 2009, the Company entered into an exclusive, royalty-bearing patent license agreement with Inserm-Transfert of France. The agreement expires on a country by country basis based on the last to expire any patent encompassed within the scope of the patent rights or 10 years from the date of the first commercial sales by the Company, whichever is later. 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; the Phase I and Phase II milestones have been achieved as of September 30, 2024. Upon the sublicense by the Company of a product for which royalties are payable under the agreement, low- to mid-single-digit royalty payments would be due by the Company. The non-milestone payments in this agreement are subject to an anti-stacking clause. The Company incurred approximately $0.1 million and $0 million in expenses related to milestones in the nine months ended September 30, 2024 and 2023, respectively.

Clearside License Agreement

In July 2019, the Company entered into an exclusive license agreement, or the Clearside 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 Clearside 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 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 to mid-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 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.

The Company recognized $0 million and $0.4 million in expenses related to this agreement and related amendments for the nine months ended September 30, 2024 and 2023, respectively.

13. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss per common share 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, 2024 and 2023 as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (21,042)	$ (18,512)	$ (61,085)	$ (54,277)
Denominator:				
Weighted-average common stock outstanding—basic and diluted	49,663,532	38,185,197	49,554,930	37,943,139
Net loss per common share—basic and diluted	$ (0.42)	$ (0.48)	$ (1.23)	$ (1.43)

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:

	Nine Months Ended September 30,	
	2024	2023
Stock options to purchase common stock	5,746,441	4,732,590
Restricted stock units that vest into common stock	1,639,298	852,049
Warrants to purchase common stock	12,686	12,686
Total potential dilutive shares	7,398,425	5,597,325

14. Income Taxes

For the nine months ended September 30, 2024 and 2023, the Company recorded an income tax provision of $0.1 million and $0 million, resulting in an effective tax rate of 0.1% and 0%, respectively. The income tax provision for the nine months ended September 30, 2024 is attributable to state income taxes. The difference in the statutory rate and the effective tax rate is primarily the result of the valuation allowance recorded against the Company's net deferred tax assets.

Due to the Company's history of losses since inception, there is not enough positive evidence at this time to support a position 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, 2024, the Company had no unrecognized income tax benefits that would reduce the Company's effective tax rate if recognized.

15. Subsequent Events

Subsequent events have been evaluated through the date of filing of the unaudited condensed consolidated financial statements. The Company has identified no subsequent events that require disclosure.

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 titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biotechnology company developing precision therapies to treat solid tumors designed to preserve organ function. Our proprietary platform is designed to enable 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. VDCs are a novel class of drugs with a dual mechanism of action that promote cancer cell death by both the delivery of the cytotoxic payload to generate acute necrosis and activation of a secondary immune mediated response. Bel-sar, our lead VDC candidate, consists of a human papilloma virus, or HPV, derived VLP conjugated to hundreds of infrared laser-activated molecules. The VDC is designed in a way that prevents the conjugation from interfering with tumor binding enabling its selectivity to tumor cells but not to normal cells. Laser activation of bel-sar is designed to result in precise tumor cell killing with minimal damage to surrounding healthy tissues.

We are evaluating the safety and efficacy of bel-sar as a potential vision-sparing therapy in an ongoing global Phase 3 CoMpass trial for the first-line treatment of adult patients with small choroidal melanoma and indeterminate lesions, or early-stage choroidal melanoma. Bel-sar is also being explored for metastases to the choroid and cancers of the ocular surface and is in Phase 1 clinical development in bladder cancer. While our initial focus is in ocular and urologic oncology, we envision the potential for development of bel-sar in additional therapeutic areas.

Early-Stage Choroidal Melanoma

We are developing bel-sar as a potential first line vision-sparing treatment option for early intervention in small choroidal melanoma and indeterminate lesions, avoiding the need for radiotherapy and reducing the risk for metastasis for these patients. There are no U.S Food and Drug Administration, or FDA, -approved therapies for primary choroidal melanoma. There are three common treatments routinely used as standard of care, or SoC, for local control of choroidal melanoma: plaque brachytherapy; proton beam irradiation; and enucleation, or removal of the affected eye, each of which represent invasive surgical procedures and are associated with significant vision loss. We have received Orphan Drug Designation, or ODD, for the treatment of early-stage choroidal (also referred to as uveal) melanoma from the FDA and the European Medicines Agency, or EMA, and Fast Track designation from the FDA for the treatment of early-stage choroidal melanoma.

Our ongoing Phase 3 CoMpass trial in adult patients with small choroidal melanoma and indeterminate lesions is designed as a superiority trial comparing bel-sar versus sham delivered via suprachoroidal, or SC, injection followed by laser light activation. The trial is a global, randomized, multi-center, masked study. It is intended to enroll approximately 100 patients randomized 2:1:2 to receive the high dose regimen of bel-sar, low dose regimen of bel-sar or a sham control. The primary endpoint is time to tumor progression, and the first key secondary endpoint is a composite time to event analysis. Endpoints will only compare the bel-sar high dose regimen to sham when the last patient completes 15 months of follow up. The trial has a power of >90% to meet the primary endpoint. (ClinicalTrials.gov ID: NCT06007690)

We have received written agreement from the FDA under a Special Protocol Assessment, or SPA, for the design and planned analysis of the global Phase 3 CoMpass trial. Since there is no drug approved for the treatment of primary choroidal melanoma, we have aligned with FDA that a statistically significant difference on the primary endpoint will provide support from a regulatory perspective to meet the requirement of clinical effectiveness. Based on the SPA, the FDA has agreed that the design and planned analysis of the study can adequately address objectives in support of a regulatory submission.

Bel-sar has shown clinical benefit and has been generally well-tolerated in clinical trials to date. Phase 2 end of study results evaluating bel-sar for the first-line treatment of early-stage choroidal melanoma were presented at The Retina Society Annual Meeting on September 12, 2024, in Lisbon, Portugal. The Phase 2 study (ClinicalTrials.gov ID: NCT04417530) was an open-label, ascending single and repeat dose escalation trial in patients with early-stage choroidal melanoma designed to evaluate the safety, tolerability and efficacy of up to three cycles of bel-sar treatment. The trial included both single and multiple ascending dose cohorts, with a total of 22 patients enrolled. Patients were closely monitored over a twelve-month follow-up period to assess tumor control, visual acuity preservation and tumor growth rate. The Phase 2 end of study results demonstrated that bel-sar achieved an 80% tumor control rate (n=8/10) among Phase 3-eligible patients who received the therapeutic regimen, with complete cessation of growth following treatment among responders (post-treatment average growth rate of 0.011 mm/yr among responders compared to 0.351 mm/yr prior to study entry; $p<0.0001$). Visual acuity preservation was achieved in 90% of these ten patients. Importantly, 80% of these ten patients were at high risk for vision loss with tumors close to the fovea or optic disc, highlighting the potential for vision preservation with this novel class of drugs. Of note, the current standard of care is radiotherapy, which leads to visual acuity of <20/200 (the cutoff for legal blindness) in the treated eye in up to 87% of patients. The safety profile of bel-sar was highly favorable in all participants regardless of dose. There were no treatment-related serious adverse events reported. Ocular treatment-related adverse events were mild (Grade 1), included anterior chamber inflammation (18%) or cell (9%) and resolved without sequelae. The vast majority (~70%) of the anterior chamber inflammation/cell events were self-limited, requiring no treatment, and resolved in a median of six days. For those events that did require treatment, topical steroid eye drops, administered for a median of six days, achieved complete resolution of the inflammation. Eye pain occurred in 9% of patients and was mild (Grade 1). Importantly, no treatment-related posterior inflammation events (no vitritis, choroiditis, retinitis, retinal pigment epithelium changes or vasculitis) were reported. The Phase 2 results are a significant achievement considering the typically poor prognosis associated with choroidal melanoma, a rare and life-threatening ocular cancer, where there are no approved vision-preserving therapies to date.

Metastases to the Choroid

Metastases to the choroid, where different types of primary cancers from elsewhere in the body (e.g., breast and lung cancer) metastasize to the eye, is an even more common cause of intraocular malignancy than primary choroidal melanoma. There is a high unmet need in these patients, as current therapy consists primarily of external radiotherapy, which comes with a very high treatment burden and ocular morbidity. As such, an easier-to-apply treatment that preserves vision is needed. These patients are treated by the same ocular oncologists that treat choroidal melanoma, and SC administration of bel-sar followed by laser light activation will be the mode of administration studied in this indication. We have an open Investigational New Drug application, or IND, in the United States and have received Fast Track designation from the FDA's Division of Oncology. We have activated the first sites in a Phase 2 clinical trial in metastases to the choroid and aim to enroll the first patients in 2024, with initial data anticipated in 2025.

Cancers of the Ocular Surface

We are also evaluating the development of bel-sar in other eye cancer indications like cancers of the ocular surface. Ocular surface tumors are tumors that start in the conjunctiva and are treated by the same ocular oncologists that treat choroidal melanoma and metastases to the choroid. These tumors are life threatening and are diagnosed early, when they are not yet metastatic, not unlike choroidal melanoma. Ocular surface tumors are known to be immunologically 'hot', that is, susceptible to control through normal immune mechanisms and immune-modulating therapies. This could allow us to benefit from the immune activation that is part of our mechanism of action, as we have demonstrated with bladder tumors. There are currently no drugs approved for cancers of the ocular surface, and patients are treated with surgery and off-label chemotherapy.

Bladder Cancer

We are developing bel-sar for bladder cancer and have an ongoing Phase 1 clinical trial for the treatment of non-muscle invasive bladder cancer, or NMIBC, and muscle invasive bladder cancer, or MIBC. Bladder cancer is the most common malignancy involving the urinary system and is the eighth most common cause of cancer death in men in the United States. While metastatic bladder cancer has several approved therapies, there are limited options for the treatment of intermediate and high-risk NMIBC.

We have generated nonclinical in vivo data that supports that bel-sar's dual mechanism of action can lead to cytotoxicity and long-term antitumor immunity which may further reduce the risk of recurrence and metastases. We have also shown that bel-sar is highly synergistic with checkpoint inhibitors that are already approved for a subset of patients with NMIBC. We believe this immune response can play an important role in bladder cancer, given that bladder cancer has a well-documented response to immune activation.

We received Fast Track designation from the FDA for bel-sar for the treatment of NMIBC in June 2022, and in September 2023, we updated the protocol for our Phase 1 study to include patients with MIBC. The ongoing Phase 1 trial (ClinicalTrials.gov ID: NCT05483868) is a two-part, open-label clinical trial, designed to assess the safety and feasibility of bel-sar as a monotherapy. The study treatment is administered seven to 12 days before the scheduled transurethral resection of bladder tumor, or TURBT, the standard of care procedure. The participants are followed for safety monitoring over a 56-day period. The trial is also evaluating bel-sar's biological activity with histopathological evaluation of tissue samples collected at the time of TURBT (regardless of tumor response) with evaluation of focal necrosis and immune changes in the tumor microenvironment.

On October 17, 2024, we announced positive early data from our ongoing Phase 1 clinical trial of bel-sar in patients with NMIBC. Part 1 (n=5) of the trial is complete, with patients receiving a single bel-sar dose without light activation. Part 2 (n=10) of the trial is designed to include ten patients. Included in this data are eight patients from Part 2 of the study with a confirmed tumor at time of treatment and having received either 100ug or 200ug of bel-sar as a single dose. Of these eight patients, five had low grade disease and three had high grade disease. Seven of these eight patients had a history of recurrent bladder cancer and had undergone multiple TURBTs and adjuvant treatments such as Bacillus Calmette-Guerin, or BCG, mitomycin, gemcitabine, cetrelimab and tamoxifen prior to trial enrollment. Ten of 13 study participants in this data had low grade disease, approximating the 70% incidence of this patient population among all NMIBC patients. The other three study participants in this data had high grade disease. In the safety analysis as of the September 9, 2024, data cut-off date (n=12), bel-sar was well-tolerated, with less than 10% of patients reporting Grade 1 and no Grade 2 or higher drug-related adverse events reported. No serious adverse events were reported, and no significant differences between the light-activated and non-light activated cohorts were observed with regard to safety events as of the data cut-off date. The data in these eight patients receiving bel-sar with light activation showed clinical activity detectable as soon as seven days after a single low dose of bel-sar with light activation. This was demonstrated by histopathological evidence of clinical complete response, necrosis, immune activation or visual tumor shrinkage observed on cystoscopy. For this analysis, "clinical complete response" was defined as the absence of tumor cells on histopathologic evaluation. Of the patients with low grade disease, four out of five exhibited a clinical complete response (one of four based on local pathology with central review ongoing), with no tumor cells detected in histopathological evaluation post-treatment in the target and in several non-target bladder tumors. Two of three of the patients with high grade disease demonstrated visual tumor shrinkage observed on cystoscopy, while tumor cells were still present on histopathological evaluation. Immune activation was noted in all patients in both treated target and untreated non-target bladder tumors with infiltration of effector CD8+ and CD4+ T-cells (where immune staining was available). This data provides evidence of a bladder urothelial field effect with a single low dose of bel-sar with light activation, potentially indicating a broader immune response in the bladder beyond the target tumor in these patients. We plan to continue development of bel-sar in bladder cancer with an initial focus on low grade, intermediate risk NMIBC patients, through a planned Phase 1b/2 trial expansion to test additional doses and treatment regimens with the opportunity to assess early durability of response at three months. In parallel, we are planning regulatory discussions on the design of the next trial with the goal of expediting clinical development in this patient population. We expect data from the Phase 1b/2 trial expansion in NMIBC in 2025.

We were incorporated as a Delaware corporation in 2009 and our headquarters are located in Boston, 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 warrants. From inception through September 30, 2024, we have raised an aggregate of approximately $419.4 million of gross proceeds primarily from private placements of our equity and convertible preferred stock as well as through the issuance of our common stock. On November 9, 2023, we issued and sold 11,000,000 shares of common stock at a price to the public of $9.00 per share for aggregate gross proceeds of $99.0 million, or the 2023 Follow-On Offering. We received approximately $92.6 million in net proceeds from the 2023 Follow-On Offering after deducting underwriting discounts and commissions and offering expenses. On December 5, 2022, we issued and sold 7,705,000 shares of common stock, including the full exercise of the underwriters' option to purchase additional shares at a price to the public of $12.00 per share, for aggregate gross proceeds of $92.5 million, or the 2022 Follow-On Offering. We received approximately $86.7 million in net proceeds from the 2022 Follow-On Offering after deducting underwriting discounts, commissions and offering expenses. On November 1, 2022, we filed a shelf registration statement on Form S-3, or the 2022 Shelf, with the Securities and Exchange Commission, or the SEC, in relation to the registration of up to an aggregate offering price of $250.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof. We also simultaneously entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or the Sales Agent, to provide for the offering, issuance and sale by us of up to an aggregate of $75.0 million of its common stock from time to time in "at-the-market" offerings, or the ATM, under the 2022 Shelf and subject to the limitations thereof. In connection with the 2023 Follow-On Offering, on November 6, 2023, we delivered written notice to Jefferies that we were suspending and terminating the prospectus related to the shares issuable in the ATM pursuant to the terms of the Sales Agreement. Other than the termination of the prospectus, the Sales Agreement remains in full force and effect. As of November 6, 2023, we had issued 993,996 shares of common stock at an average price of $12.50 under the ATM. On March 27, 2024, we filed a new shelf registration statement on Form S-3, or the 2024 Shelf, with the SEC in relation to the registration of up to an aggregate offering price of $350.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof, which superseded the 2022 Shelf. The 2024 Shelf included a prospectus supplement to provide for offerings in the ATM under the Sales Agreement. We issued no shares of common stock during the nine months ended September 30, 2024 under the ATM.

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 $61.1 million and $54.3 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $348.4 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 incur additional costs associated with operating as a public company. We expect that our expenses and capital requirements will increase substantially if and as we:

- conduct our current and future clinical trials of bel-sar;
- 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, 2024, we had cash and cash equivalents and marketable securities of $174.4 million. We believe that our existing cash and cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2026. 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.

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 bel-sar program, and include:

- employee-related expenses, including salaries, 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 and clinical trials 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 bel-sar, including the potential cost of CDMOs 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 clinical 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 bel-sar 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 bel-sar 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 bel-sar 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. We expect to incur increased expenses associated with our growth, 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 accretion, interest income and realized losses on marketable securities, interest income on our invested cash balances, and gains and losses on disposals of equipment.

Income Tax Provision, Net

For the year ending December 31, 2023, we recorded a $0.1 million tax provision related to the current state income taxes. Since our inception, we have not recorded any U.S. federal benefits for our net operating loss carryforwards or research and development tax credits, due to the uncertainty of realizing a benefit from those items. As of December 31, 2023, we had federal gross operating loss carryforwards of approximately $174.4 million which may be available to offset future taxable income, of which $44.2 million begin to expire in 2029 and go through 2037 and $130.2 million do not expire. The state gross operating loss carryforwards of $148.5 million, which may be available to offset future taxable income and which would begin to expire in 2030, except for $0.7 million of state NOLs that do not expire. We had foreign gross operating loss carryforwards of $0.1 million, which may be available to offset future taxable income and which do not expire. As of December 31, 2023, we had federal and state research and experimentation credit carryforwards of $8.2 million and $2.3 million, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2029 and 2028, 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, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 17,036	$ 15,428	$ 1,608
General and administrative	6,196	5,060	1,136
Total operating expenses	23,232	20,488	2,744
Loss from operations	(23,232)	(20,488)	(2,744)
Other income (expense):			
Interest income, including amortization of discount	2,258	1,981	277
Other expense	(25)	(5)	(20)
Total other income	2,233	1,976	257
Loss before income taxes	(20,999)	(18,512)	(2,487)
Income tax provision, net	(43)	—	(43)
Net loss	$ (21,042)	$ (18,512)	$ (2,444)

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Preclinical	$ 163	$ 271	$ (108)
Clinical trials	4,429	5,553	(1,124)
Manufacturing development	4,532	2,968	1,564
Personnel/overhead expenses	7,912	6,636	1,276
Total research and development expenses	$ 17,036	$ 15,428	$ 1,608

Research and development expenses increased to $17.0 million for the three months ended September 30, 2024 from $15.4 million for the three months ended September 30, 2023, primarily due to manufacturing and development costs for bel-sar and higher personnel expenses related to growth of our company.

General and Administrative Expenses

General and administrative expenses increased to $6.2 million for the three months ended September 30, 2024 from $5.1 million for the three months ended September 30, 2023, primarily driven by personnel expenses, as well as increases in general corporate expenses related to growth of our company.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 50,968	$ 44,952	$ 6,016
General and administrative	17,341	15,256	2,085
Total operating expenses	68,309	60,208	8,101
Loss from operations	(68,309)	(60,208)	(8,101)
Other income (expense):			
Interest income, including amortization of discount	7,395	5,981	1,414
Other expense	(83)	(50)	(33)
Total other income	7,312	5,931	1,381
Loss before income taxes	(60,997)	(54,277)	(6,720)
Income tax provision, net	(88)	—	(88)
Net loss	$ (61,085)	$ (54,277)	$ (6,808)

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Preclinical	$ 304	$ 767	$ (463)
Clinical trials	15,146	15,298	(152)
Manufacturing development	11,042	10,842	200
Personnel/overhead expenses	24,476	18,045	6,431
Total research and development expenses	$ 50,968	$ 44,952	$ 6,016

Research and development expenses increased to $51.0 million for the nine months ended September 30, 2024 from $45.0 million for the nine months ended September 30, 2023, primarily due to higher personnel expenses related to growth of our company.

General and Administrative Expenses

General and administrative expenses increased to $17.3 million for the nine months ended September 30, 2024 from $15.3 million for the nine months ended September 30, 2023, primarily driven by personnel expenses, as well as increases in general corporate expenses related to growth of our company.

Liquidity and Capital Resources

To date we have funded our operations primarily through the sale of convertible preferred stock and warrants as well as common stock. Through September 30, 2024, we have raised an aggregate of approximately $419.4 million of gross proceeds primarily from private placements of our equity and convertible preferred stock and warrants, as well as through the issuance of our common stock. On November 9, 2023, we issued and sold 11,000,000 shares of common stock at a price to the public of $9.00 per share for aggregate gross proceeds of $99.0 million in the 2023 Follow-On Offering. We received approximately $92.6 million in net proceeds from the 2023 Follow-On Offering after deducting underwriting discounts and commissions and offering expenses. On December 5, 2022, we issued and sold 7,705,000 shares of common stock, including the full exercise of the underwriters' option to purchase additional shares at a price to the public of $12.00 per share for aggregate gross proceeds of $92.5 million in the 2022 Follow-On Offering. We received approximately $86.7 million in net proceeds from the 2022 Follow-On Offering after deducting underwriting discounts, commissions and offering expenses. On November 1, 2022, we filed the 2022 Shelf with the SEC in relation to the registration of up to an aggregate offering price of $250.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof. We also simultaneously entered into the Sales Agreement with the Sales Agent to provide for the offering, issuance and sale by us of up to an aggregate of $75.0 million of our common stock from time to time in the ATM under the 2022 Shelf and subject to the limitations thereof. In connection with the 2023 Follow-On Offering, on November 6, 2023, we delivered written notice to Jefferies that we were suspending and terminating the prospectus related to the shares issuable in the ATM pursuant to the terms of the Sales Agreement. As of November 6, 2023, we had issued 993,996 shares of common stock at an average price of $12.50 under the ATM. On March 27, 2024, we filed the 2024 Shelf with the SEC in relation to the registration of up to an aggregate offering price of $350.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof, which superseded the 2022 Shelf. The 2024 Shelf included a prospectus supplement to provide for offerings in the ATM under the Sales Agreement. We issued no shares of common stock during the nine months ended September 30, 2024 under the ATM.

Cash Flows

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

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (55,853)	$ (46,460)
Net cash provided by (used in) investing activities	39,126	(23,843)
Net cash provided by financing activities	1,052	4,305
Net decrease in cash, cash equivalents, and restricted cash	$ (15,675)	$ (65,998)

Operating Activities

During the nine months ended September 30, 2024, net cash used in operating activities was $55.9 million primarily due to our net loss of $61.1 million and an increase in prepaid expenses related to CRO costs associated with our Phase 3 trial of bel-sar in early-stage choroidal melanoma, partially offset by an increase in stock compensation expense.

During the nine months ended September 30, 2023, net cash used in operating activities was $46.5 million, primarily due to our net loss of $54.3 million and a decrease in accounts payable related to timing of vendor invoicing and payments, partially offset by an increase in stock compensation expense and prepaid expenses related to CRO costs associated with our Phase 3 trial of bel-sar in early-stage choroidal melanoma.

Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2024 was $39.1 million primarily due to maturities of marketable securities partially offset by purchases of marketable securities and property and equipment.

Net cash used in investing activities during the nine months ended September 30, 2023 was $23.8 million primarily due to purchases of marketable securities and property and equipment, partially offset by proceeds from sale and maturities of marketable securities.

Financing Activities

During the nine months ended September 30, 2024, net cash provided by financing activities was $1.1 million from proceeds from stock options exercises and issuance of common stock under the ESPP.

During the nine months ended September 30, 2023, net cash provided by financing activities was $4.3 million from proceeds from stock options exercises and issuance of common stock under the ATM and ESPP.

Funding Requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of bel-sar 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. In addition, we expect to incur additional costs associated with operating as a public company. 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;
- if our product candidates are approved, our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in businesses, products, and technologies; and
- unfavorable global economic conditions, which may exacerbate the magnitude of the factors discussed above.

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, 2024, we had cash and cash equivalents and marketable securities of $174.4 million. Based on our research and development plans, we believe that our existing cash and cash equivalents, will be sufficient to fund our operations into the second half of 2026. 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 preferred stock, 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. 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.

Material Cash Requirements

The following table summarizes our contractual obligations and commitments as of September 30, 2024.

		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)	$ 28,468	$ 3,282	$ 10,447	$ 7,486	$ 7,253
Total	$ 28,468	$ 3,282	$ 10,447	$ 7,486	$ 7,253

(1) Amounts in the table above reflect payments due for our lease of office and lab space in Boston, Massachusetts, that expires in August 2032.

Except as disclosed in the table above, we have no long-term debt or finance leases and no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase-order basis. We enter into contracts in the normal course of business with equipment and reagent vendors, CROs, CDMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. We have also acquired exclusive and non-exclusive rights to use, research, develop and offer for sale certain products and patents under license agreements. The license agreements obligate us to make payments to the licensors for license fees, milestones, license maintenance fees and royalties. These payments are not included in the preceding table as the amount and timing of such payments are not known.

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 consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our condensed consolidated 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 condensed consolidated 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. During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies from those described in the section titled "Management's Discussion and Analysis of Financial Condition and Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC.

Recent Accounting Pronouncements

We assessed the recent accounting pronouncements for the nine months ended September 30, 2024, and determined no pronouncements have material impact to the condensed consolidated financial statements.

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. Accordingly, our consolidated 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 $1.235 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 initial public offering, or IPO.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we will not be required to obtain a separate attestation of internal control over financial reporting from an outside auditor.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act 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 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 the desired control objectives and our 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 Interim Principal 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 Interim Principal Financial Officer have concluded that as of September 30, 2024, 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 Interim Principal Financial Officer, to allow timely decisions regarding any required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, 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, 2024, 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 unaudited condensed consolidated financial statements and related notes thereto 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 $61.1 million and $54.3 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $348.4 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 bel-sar 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 incur costs, and 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. To date, we have not generated any revenue from any product sales. Our ability to become profitable depends upon our ability to generate revenue. 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. Further, we 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, bel-sar in primary choroidal melanoma and additional oncology indications, including metastases to the choroid and bladder cancer as well as any other research programs from our VDC technology platform and any future product candidates;
- obtaining marketing approval for bel-sar and any future product candidates for which we complete clinical trials;
- transferring our manufacturing process to, and developing and maintaining it with, a CDMO for bel-sar and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing bel-sar and any future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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 bel-sar. 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 bel-sar 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 nonclinical 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 bel-sar 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 and marketable securities will be sufficient to fund our operating expenses and capital expenditures into the second half of 2026. Advancing the development of bel-sar and other research programs will require a significant amount of capital. Our existing cash and cash equivalents will not be sufficient to fund bel-sar through regulatory approval, and we anticipate needing to raise additional capital to complete the development and commercialization of bel-sar. 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 due to unfavorable global economic conditions and inflationary pressures 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 preferred stock, 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 bel-sar 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.

Recent volatility in capital markets may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new solutions, retain or expand our current levels of personnel, improve our existing solutions, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance our technological infrastructure and our existing solutions;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our businesses.

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, regulatory approval 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 bel-sar in small choroidal melanoma and indeterminate lesions and additional oncology indications, including but not limited to metastases to the choroid and bladder cancer, other research programs from our VDC technology platform, and any other future programs;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of bel-sar, 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, and developing or maintaining it with, a 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 bel-sar, 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 bel-sar 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 bel-sar. We can provide no assurance that bel-sar will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of bel-sar or if bel-sar 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 bel-sar is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for bel-sar in the United States, Europe and other major markets around the world will prevent us from commercializing and marketing bel-sar in such jurisdictions.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for bel-sar, any approval might contain significant limitations related to use, including limitations on the stage or type of cancer bel-sar 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 bel-sar. Furthermore, even if we obtain regulatory approval for bel-sar, 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 bel-sar, 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 bel-sar, 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 IND, Premarket Approval, or PMA, or 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 bel-sar 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 novel 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, 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 initiated but not yet completed a pivotal clinical trial nor have we commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, the EMA, or other regulatory agencies to market bel-sar or any future product candidate. Carrying out later-stage clinical trials is a complicated process. 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 bel-sar program in small choroidal melanoma and indeterminate lesions. We have not yet demonstrated an ability to successfully complete pivotal clinical trials, though we have an ongoing global Phase 3 trial in small choroidal melanomas and indeterminate lesions, 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. In order to complete later stage or pivotal trials, we are expanding our clinical operations, CMC 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 design, execute and complete necessary clinical trials in a way that leads to approval of bel-sar or future product candidates. We may require more time to enroll patients and incur greater costs than our competitors and may not succeed in obtaining global regulatory approvals of product candidates that we develop. Furthermore, we may conduct a pivotal trial based on an adaptive design, which could increase the time spent on or costs associated with this trial. We have transferred our manufacturing process to our intended external CDMO commercial manufacturer, but transfers to additional CDMOs may occur in the future. Further, some modifications to our manufacturing process may be needed to ensure manufacturability and ability to scale-up the process to commercial batch sizes and to meet worldwide regulatory standards for commercial manufacture. 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 or other studies may be required, which may result in delayed regulatory approval. We do not anticipate a change in formulation. However, failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates. 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, or obtain additional indications of our first product candidate, our commercial opportunity could be limited.

We expect to focus our resources on the development of bel-sar 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.

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

Bel-sar is a novel biologic for which the intended use in ocular oncology requires delivery to the suprachoroidal space, or SCS, and activation by a laser. For ocular oncology indications, we use Clearside Biomedical Inc.'s SCS Microinjector®, or the SCS Microinjector, to deliver bel-sar into the SCS. In the United States, we plan to submit a single BLA for the review and approval of this combination of bel-sar with the SCS Microinjector and the laser(s) in our initial target indication of small choroidal melanoma and indeterminate lesions, but subsequent indications and delivery systems may require different or additional applications for marketing authorization. The SCS Microinjector was approved by FDA in October 2021 as a constituent of the drug/device combination product XIPERE® (triamcinolone acetonide injectable suspension). There may be additional regulatory risks for biologic-device combination products. We may experience delays in obtaining regulatory approval of bel-sar given the increased complexity of the review process when approval of the product and a medical device is sought under a single BLA. 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. In the European Union, or EU, medical devices must be authorized under the EU's Medical Devices Regulation, which requires compliance with the general safety and performance requirements set forth in such legislation. 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 bel-sar 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. 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. For example, the EMA required additional testing to support drug substance characterization which led to a later than anticipated authorization to commence enrolling patients in our Phase 3 clinical trial under the EU Clinical Trial Regulation process.

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. 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 early-stage 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 bel-sar 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 trials 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 that may limit patients, principal investigators or staff or clinical site availability.

We are conducting a clinical trial outside the United States, and we may in the future conduct additional 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 are currently conducting a Phase 3 clinical trial and have, or anticipate to have, sites in the United States as well as in some or all of the following countries, among others: Ireland, the UK, Canada, Australia, Austria, Italy, Greece, South Korea, Israel, Germany, France, Spain, Denmark, Sweden, Belgium, Finland, and the Czech Republic. We also may in the future choose to conduct one or more additional clinical trials outside the United States, including in Europe. The acceptance of 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 United States 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 United States. 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 United States, 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. Bel-sar 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, bel-sar may not be effective at slowing or arresting tumor growth or may not preserve visual acuity in later stage trials. Even if bel-sar 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 bel-sar 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 that product candidate in other indications or patient populations or any other product candidates then under development and/or cause the FDA or other regulatory authorities to require additional testing before approving such product candidate or any other product candidates.

Interim, "top-line," and preliminary or early 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, early, 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 or early 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 continue to 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 bel-sar or any future product candidates when studied in a controlled environment with a placebo or active control.

Bel-sar 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 bel-sar 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 bel-sar 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, patients 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 patients. 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 patients 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 bel-sar 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 patients 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 board, 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 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;
- 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 bel-sar 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 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 expenses. Additionally, our product candidates, if approved, could be subject to post-marketing commitments/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. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. 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 and interpretations 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, interpretations 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. Moreover, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes.

We may be unable to obtain ODD for additional indications, 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. ODD must be requested before submitting an NDA or BLA. In the United States, ODD 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 ODD, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has ODD 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 bel-sar for the treatment of uveal melanoma from the FDA and EMA, and we may seek additional ODDs for bel-sar or some or all of our future product candidates in orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain ODD, 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.

Similarly, in the EU, the European Commission grants an orphan designation in respect of a product after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on a designation application. Orphan designation in the EU is granted to products where the sponsor can establish that (1) such product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than five in 10,000 persons in the EU when the application is made; or (ii) without incentives, it is unlikely that the marketing of the product would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition that has been authorized in the EU, or if such a method exists, the product in question would be of significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. Generally, if a product with an orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a ten-year period of marketing exclusivity, which precludes the EMA from approving another marketing authorization application for a similar medicinal product in the same indication for that time period, except in limited circumstances. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable such that market exclusivity is no longer justified. The European Commission introduced a legislative proposal in April 2023 that, if implemented, could reduce the current ten-year marketing exclusivity period in the EU for certain orphan medicines.

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 bel-sar for the treatment of choroidal melanoma, for the treatment of metastases to the choroid and for the treatment of NMIBC, and we may seek additional Fast Track designation 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 bel-sar 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, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, 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.

The FDA's agreement to a Special Protocol Assessment with respect to the study design of our global Phase 3 trial of bel-sar for the treatment of early-stage choroidal melanoma does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process.

We obtained agreement from the FDA on the design and planned analysis of our global Phase 3 trial of bel-sar for the treatment of early-stage choroidal melanoma through a SPA. An SPA agreement documents FDA's agreement that the design and planned analysis of a study can adequately address objectives in support of a regulatory submission. However, final determinations for marketing application approval are made after complete review of a marketing application and are based on the entire data in the application.

The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and/or planned analyses, are acceptable to support a regulatory submission.

Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts.

In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding by the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Moreover, if the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval of bel-sar for the treatment of small choroidal melanoma and indeterminate lesions.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and expect to continue to do so, 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, central reading centers, medical institutions and clinical investigators, to conduct some aspects of our research, preclinical testing and clinical trials. We are using a clinical CRO for the pivotal trial for bel-sar for the treatment of early-stage 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 CDMOs for the production of clinical supply of bel-sar and may continue to rely on CDMOs for the production of commercial supply of bel-sar, if approved. This reliance on CDMOs 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 preclinical 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 bel-sar.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient, or API, necessary to produce bel-sar and future product candidates we may develop in the quantities needed for our clinical trials or, if bel-sar 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 bel-sar 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 bel-sar 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 CDMOs 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 CDMO 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 CDMO 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 bel-sar 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 CDMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CDMO 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 CDMOs 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 manufacturers;
- 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 bel-sar or any future product candidates for use in clinical trials or for commercial supply;
- 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.

Bel-sar and any other product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. 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 bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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 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 bel-sar 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 bel-sar and any future product candidates may require significant resources and may not be successful. If bel-sar 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 bel-sar and any future product candidates will depend on a number of factors, including:

- the efficacy of bel-sar and our VLP technology, and any future product candidates;
- the prevalence and severity of adverse events associated with bel-sar and any future product candidates or those products with which they may be co-administered;
- the clinical indications for which bel-sar 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 bel-sar and any future product candidates that may be more restrictive than other competitive products;
- changes in the SoC for the targeted indications for bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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 bel-sar and any future product candidates, as well as competitive products;
- our ability to offer bel-sar 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 bel-sar or competing products and treatments;
- the actions of companies that market any products with which bel-sar and any future product candidates may be co-administered;
- the approval of other new products;
- adverse publicity about bel-sar 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 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 early-stage 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, such as Johnson & Johnson, UroGen Pharma Ltd., CG Oncology, Inc., ImmunityBio, Inc. and FerGene, 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 the section of our Annual Report on Form 10-K for the year ended December 31, 2023 titled "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. For more information, see the section of our Annual Report on Form 10-K for the year ended December 31, 2023 titled "Business—Government Regulation—Coverage and Reimbursement."

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. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, 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 bel-sar 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 bel-sar and any future product candidates has not been established with precision. Bel-sar is a VDC product candidate being developed for the first line treatment of early-stage 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 bel-sar is approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with choroidal melanoma, metastases to the choroid, and bladder cancer for which bel-sar 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. Bel-sar 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. For more information, see the section of our Annual Report on Form 10-K for the year ended December 31, 2023 titled “Business – Government Regulation – Health Care Laws and Regulations.”

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 General Data Protection Regulation, or GDPR, 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 the Health Insurance Portability and Accountability Act, or 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. For more information, see the section of our Annual Report on Form 10-K for the year ended December 31, 2023 titled “Business—Government Regulation—Health Care Reform & Legislative Updates.”

In the United States, there have been, and continue to be, a significant number of legislative initiatives to contain healthcare costs. The United States has also sought to implement 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. 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.

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 VLPs to target tumors and VDCs like bel-sar, 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 bel-sar 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 bel-sar 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 bel-sar, we may still not be able to make use or sell bel-sar 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 bel-sar 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 bel-sar or any future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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, bel-sar 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 bel-sar 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, bel-sar 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 bel-sar 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 bel-sar or a future product candidate, or forced to modify bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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 bel-sar 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 Rakuten (previously LI-COR) maintains its manufacture of IRDye 700DX® dye molecules (used in bel-sar) 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 bel-sar. 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 or subject to unauthorized access 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 cybersecurity incident or 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 the Boston area, 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.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 waste. 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. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow.

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 cybersecurity incidents or breaches, 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). We have established safeguards to do so in a secure manner in an effort 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 infrastructure, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access and misuse, 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 cybersecurity incidents or breaches 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 (including phishing attacks) 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, misuse or acquisition of information. Cyberattacks generally 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 on to process our information change frequently, and we may be unable to anticipate such techniques or implement adequate preventative measures or to stop or to adequately address cybersecurity incidents or breaches 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 cybersecurity incidents or breaches, may not be adequate to prevent or detect or adequately address service interruption, system failure or data loss.

Significant disruptions of our information technology systems or cybersecurity 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, as a result of increased hybrid work, a significant number of our employees and partners are working remotely, which increases the risk of a cybersecurity incident or breach or other data and cybersecurity issues. To the extent that any disruption or cybersecurity incident or breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure or misuse of or access to 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 cybersecurity incidents and breaches. 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 cybersecurity incidents or 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 cybersecurity incident or 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 cybersecurity incident or breach. In addition, our efforts to contain or remediate a cybersecurity 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 cybersecurity incidents or breaches may adversely affect our business. Unauthorized access to our information technology systems or infrastructure 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 cybersecurity incident or 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 HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. 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, which went into effect on January 1, 2020, established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Although there are limited exemptions for protected health information covered under HIPAA and clinical trial data, the CCPA may increase our compliance costs and potential liability. The CCPA was expanded on January 1, 2023, when the California Privacy Rights Act of 2020, or CPRA, became operative. The amendments introduced by the CPRA expanded the scope of the CCPA in a number of ways, including by providing California residents the ability to limit use of certain sensitive information, establishing restrictions on the retention of personal data, expanding the types of data breaches subject to the CCPA's private right of action and establishing a California Privacy Protection Agency to implement and enforce the legislation.

Similar comprehensive consumer privacy laws have been passed in numerous other states and a number of other states have proposed new privacy laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In addition, laws in all 50 U.S. states require businesses to provide notice to individuals if certain of their personal information has been disclosed as a result of a qualifying data breach or cybersecurity incident. There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. 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 GDPR, the EU member state implementing legislation, and the UK GDPR, may also apply to health-related and other personal data that we process, including, without limitation, personal data relating to clinical trial participants. The GDPR imposes strict obligations on the ability to process health-related and other personal data, 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. These obligations include, without limitation, several requirements relating to transparency related to communications with data subjects regarding the processing of their personal data, ensuring an appropriate legal basis or conditions applies to the processing of personal data, limitations on the retention of personal data, increased requirements pertaining to health data, 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 international transfer of personal data.

The GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to other regions outside the EEA/UK, or third countries, that have not been deemed to offer "adequate" privacy protections by the competent data protection authorities, including the United States in certain circumstances, unless a derogation exists or adequate international transfer safeguards (for example, the European Commission approved Standard Contractual Clauses, or the EU SCCs, and the UK International Data Transfer Agreement/Addendum, or the UK IDTA) are put in place. Where relying on the EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments on the transfers made pursuant to the EU SCCs and UK IDTA, on a case-by-case basis, to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred personal data as provided in the EEA and UK, and may be required to adopt supplementary measures if this standard is not met. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to process or transfer personal data from the EEA to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position.

Although the UK is regarded as one of the third countries under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EEA member states to the UK without additional safeguards. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process. The aim of the UK Bill is to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, the competent authorities in the EEA Member States interpret GDPR obligations slightly differently from country to country (particularly in relation to the processing of health data) and therefore we do not expect to operate in a uniform legal landscape in the EEA. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA.

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 (£17.5 million under UK GDPR) or 4% of their worldwide annual turnover, or revenue. Additionally, regulators could prohibit our use of personal data subject to the GDPR. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from infringement of 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. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. 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, cybersecurity incidents or data breaches. Moreover, clinical trial participants or patients 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. In addition, our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. We also expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act, or the AI Act, the world's first comprehensive AI law, is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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 on 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.

While we maintain product liability insurance, we anticipate that we will need to increase our insurance coverage as we conduct additional 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, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 51.0% 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, or NOL, 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 gross operating losses and tax credits may also be impaired or restricted under state law. As of December 31, 2023, we had federal gross operating loss carryforwards of approximately $174.4 million, state gross operating loss carryforwards of $148.5 million, and foreign gross operating loss carryforwards of $0.1 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 gross 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 gross 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 NOLs 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.

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 bel-sar 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, including inflationary pressures.

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, or 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, or 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 amended and restated 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 tenth 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, or Board, 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 tenth 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.

Future sales and issuances of our common stock or rights to acquire shares of our common stock, could result in additional dilution to the ownership of our stockholders and cause the market price of our common stock to decline significantly.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could be granted rights superior to our existing stockholders. In March 2024, we filed a registration statement on Form S-3 relating to the registration of our common stock, preferred stock, debt securities, warrants and units or any combination thereof. Concurrently with the filing of such registration statement, we filed an “at-the-market” offering prospectus supplement, which provides for the offering, issuance and sale by us of shares of our common stock from time to time for aggregate gross proceeds of up to $75 million in sales deemed to be “at-the-market offerings” as defined by the Securities Act. Any sale or issuance of securities pursuant to this registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline. Furthermore, new investors purchasing securities that we may issue and sell in the future could obtain rights superior to the rights of our existing stockholders.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of September 30, 2024, we have 49,778,861 shares of common stock outstanding. Significant portions of these shares are held by a small number of stockholders, including persons who were our stockholders prior to our IPO. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, certain shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered or intend to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. In addition, our directors, executive officers and certain affiliates may establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

General Risk Factors

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.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect our company, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on our company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to us and may have material adverse impacts on our business.

Unfavorable global economic or political 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 COVID-19 pandemic, which began in 2020, caused significant volatility and uncertainty in the U.S. and international markets. In addition, the current military conflict between Russia and Ukraine and the armed conflict in Israel and the Gaza Strip could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions that may be initiated by nations including the United States, the EU or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CDMOs and other third parties with which we conduct business. A severe or prolonged economic downturn or political unrest could result in a variety of risks to our business, including but not limited to 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, as amended, or Section 404, (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 $1.235 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 30. 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 your 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 the section of this Quarterly Report titled “Risk Factors” and the following:

- results of preclinical studies and results or enrollment of clinical trials of bel-sar or our future product candidates, or those of our potential future competitors or our existing or future collaborators;
- 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 bel-sar 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;
- natural disasters, pandemics and other calamities;
- acts of war or periods of widespread civil unrest, including the increasingly volatile global economic conditions resulting from the Russia-Ukraine conflict and the conflict in the Middle East; and
- general economic, industry, and market conditions, including inflationary pressures.

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 in substantial 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 devotes substantial time to 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.

Global economic uncertainty and unfavorable global economic conditions caused by political instability, changes in trade agreements and conflicts, such as the Russia-Ukraine conflict and the conflict in the Middle East, could adversely affect our business, financial condition, results of operations or prospects.

Our business, financial condition, results of operations or prospects could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, increased inflation, economic uncertainties in various global markets caused by political instability and conflict, such as the Russia-Ukraine conflict, the conflict in the Middle East and the 2024 presidential election in the United States, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our inability 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. 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.

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

(a) Recent Sales of Unregistered Equity Securities

None.

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

None.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) Executive Severance Plan

On November 10, 2024, the Compensation Committee (the "Committee") of our Board adopted an Executive Severance Plan for participating executives (the "Plan"). The Plan provides for severance payments and benefits to eligible executives (each, a "Covered Executive") in the event that we terminate the employment of a Covered Executive without Cause (as defined in the Plan) or if a Covered Executive resigns with Good Reason (as defined in the Plan) (such termination or resignation, a "Qualifying Termination"). Upon acceptance of participation in the Plan, the severance payments and benefits under the Plan shall supersede and replace any severance benefits under any individual employment agreement or offer letter previously entered into between us and a Covered Executive. At the time of the Plan's adoption, it was anticipated that the Covered Executives would initially be comprised of Elisabet de los Pinos, Ph.D., our Chief Executive Officer, J. Jill Hopkins, M.D., our Chief Medical Officer and President of R&D, Conor Kilroy, our General Counsel and Secretary, and Mark Plavsic, Ph.D., our Chief Technology Officer.

Under the terms of the Plan, upon a Qualifying Termination outside of the Change of Control Period (defined as the period beginning three months prior and ending 12 months following a Change of Control (as defined in the Plan)), a Covered Executive will be entitled to receive severance pay in the form of: (i) continuation of the Covered Executive's Base Salary (as defined in the Plan) for nine months (12 months in the case of Dr. de los Pinos), and (ii) payment to the group health plan provider or the Consolidated Omnibus Budget Reconciliation Act ("COBRA") provider of the employer cost of the COBRA premiums at the time of the Qualifying Termination applicable to the Covered Executive and his or her eligible dependents for a period of up to nine months (up to 12 months in the case of Dr. de los Pinos).

Upon a Qualifying Termination within the Change in Control Period, a Covered Executive will be entitled to receive severance pay in the form of: (i) a lump sum cash payment equivalent to 12 months (18 months in the case of Dr. de los Pinos) of the Covered Executive's Base Salary, (ii) a lump sum cash payment equivalent to one times (one and one-half times in the case of Dr. de los Pinos) the Covered Executive's Target Bonus (as defined in the Plan) plus the Covered Executive's Target Bonus pro-rated for the number of days of service during the year in which the Qualifying Termination occurs, (iii) payment to the group health plan provider or the COBRA provider of the employer cost of the COBRA premiums at the time of the Qualifying Termination applicable to the Covered Executive and his or her eligible dependents for a period of up to 12 months (18 months in the case of Dr. de los Pinos), and (iii) to cause equity awards with time-based vesting held by the Covered Executive to immediately become fully vested, exercisable or nonforfeitable. For equity awards held by a Covered Executive as of November 10, 2024, the effective date of the Plan, such awards shall immediately become fully vested, exercisable or nonforfeitable upon a Change of Control.

As described more fully in the Plan, in order to receive the foregoing benefits, a Covered Executive must execute a separation agreement and general release of claims in our favor and affirm his or her continuing obligations towards us, including his or her ongoing restrictive covenants.

The foregoing description of the Plan does not purport to be complete and is qualified in its entirety by reference to the complete text of the Plan, a copy of which is filed herewith as Exhibit 10.3 and incorporated herein by reference.

(c) Insider Trading Arrangements

None of our directors or officers, as defined in Rule 16a-1(f) under the Securities Act, adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, as defined in Item 408(c) of Regulation S-K, during the quarter ended September 30, 2024.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Tenth Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect, as amended by the Certificate of Amendment, dated June 20, 2024 (incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40971) filed on August 8, 2024).
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrant's Annual Report on Form 10-K (File No. 001-40971) filed on March 23, 2022).
4.1	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) filed on October 8, 2021).
10.1*†	Transition and Release Agreement, dated September 25, 2024, by and between Julie Feder and the Registrant.
10.2*†	Resignation and Consulting Agreement, dated September 25, 2024, by and between Julie Feder and the Registrant.
10.3*†	Executive Severance Plan, and form of participation agreement thereunder.
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 Interim 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 Interim 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 With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

† Indicates a management contract or any compensatory plan, contract or arrangement.

These certifications are furnished to the SEC pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and are deemed not filed for purposes of Section 18 of the Exchange Act nor shall they be deemed incorporated by reference in any filing under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

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

Aura Biosciences, Inc.

Date: November 12, 2024

By: /s/ Elisabet de los Pinos

Elisabet de los Pinos
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

By: /s/ Amy Elazzouzi

Amy Elazzouzi
Vice President, Finance
(Interim Principal Financial Officer and Interim Principal Accounting Officer)

Exhibit 10.1

September 25, 2024

PERSONAL AND CONFIDENTIAL

Julie Feder

Re: Transition and Release Agreement

Dear Ms. Feder:

This letter confirms your resignation from employment with Aura Biosciences, Inc. (the "Company"), effective October 25, 2024. As you know, your employment relationship with the Company is governed by your offer letter with the Company dated August 10, 2018 (the "Offer Letter"). As specified in Section 12 of the Offer Letter, you have been employed "at-will," meaning that you or the Company could end the employment relationship at any time and for any reason, subject to the terms of the Offer Letter.

As set forth in Section 11 of the Offer Letter, you are eligible to receive severance benefits in connection with a termination by the Company without Cause (as defined in the Offer Letter) if you enter into, do not revoke and comply with a Release (as defined in the Offer Letter). Although you have voluntarily resigned from your employment with the Company, if you enter into the Release Agreement below, the Company will provide you with the opportunity to remain an at- will employee of the Company during a transition period and then subsequently receive the severance benefits outlined in this letter.

With those understandings and regardless of whether you enter into the Release Agreement, the following bulleted terms and conditions apply in connection with the ending of your employment:

- The Company shall pay you salary, any accrued but unused vacation, and unpaid and properly documented business expenses accrued to you through the last day of your employment.

- Your eligibility to participate in the Company's group health plans as an active employee will end in accordance with the terms and conditions of the health plans on October 31, 2024. The Company shall provide you with the opportunity to continue group health coverage at your own expense under the law known as "COBRA", subject to your COBRA eligibility as applicable. You will be notified by separate memoranda of your rights under COBRA. The COBRA benefits offered by the Company to you will include health insurance, dental insurance and vision insurance at the same level as currently offered to employees of the Company.

- Your eligibility to participate in the Company's other employee benefit plans and programs will cease in accordance with the terms and conditions of each of those benefit plans and programs. Your rights to benefits, if any, are governed by the terms and conditions of those benefit plans and programs.

- In connection with the ending of your employment, you hereby (i) resign from your status as an employee, officer or other positions you occupy at the Company and resign from your status as an employee, officer, director or other positions you occupy at any subsidiary of the Company, in each case, effective as of the last day of your employment and (ii) agree to execute such documentation as the Company reasonably requires to effectuate such resignations.

- You are subject to continuing obligations under (i) your Confidential Information, Non-Solicitation and Invention Assignment Agreement (the "Restrictive Covenants Agreement"), (ii) Sections 10 (Non-disparagement) of the Offer Letter, (iii) the Resignation and Consulting

Agreement, which the Company provided to you on September 25, 2024 (the "Consulting Agreement"), and (iv) this Release Agreement (collectively, the "Ongoing Obligations"). The Ongoing Obligations, along with any other confidentiality and restrictive covenant obligations you have to any of the Releasees (as defined below) shall remain in full force and effect.

- You are not eligible to receive any Bonus (as defined in the Offer Letter) for calendar year 2024 and you are not entitled to receive any other incentive compensation.

The remainder of this letter proposes the Release Agreement between you and the Company. You and the Company agree as follows:

1. Resignation Date; Transition Period

a. Resignation Date; Transition Period. Provided you enter into, do not revoke and comply with this Release Agreement, the Company will continue to employ you until October 25, 2024, unless, prior to that date, the Company terminates your employment due to (i) your breach of this Release Agreement (including without limitation your failure to provide the Transitional Services) or any of the Ongoing Obligations; or (ii) your engaging in other behavior that justified a for "Cause" termination as defined in the Offer Letter ((i) or (ii), a "Specified Termination"). Subject to the foregoing, the actual last date of your employment, whether it is October 25, 2024 or another date as stated above, is the "Resignation Date." The time period between the date of this letter and the Resignation Date shall be referred to as the "Transition Period."

b. Transitional Services; Compensation. Unless otherwise directed by the Company, during the Transition Period, you will (i) continue to perform your current full-time job duties in the position of Chief Financial Officer until October 25, 2024, (ii) assist the Company with the transition of your responsibilities, and (iii) perform any other duties as the Company in its reasonable discretion determines ((i), (ii) and (iii), the "Transitional Services"). For the avoidance of doubt, you must continue to comply with the Company's policies, including but not limited to the Company's Amended and Restated Insider Trading Policy. During the Transition Period, you will continue to receive your current base salary and you will continue to be eligible for regular employee benefits as currently in effect (subject to the terms of the Company's benefit plans), provided that (to avoid doubt) you will not be eligible for any bonuses during the Transition Period or related to your employment during 2024. Subject to the terms of the Equity Documents, your previously granted equity shall continue to vest during the Transition Period.

2. Severance Benefits

Provided you (i) enter into, do not revoke and comply with this Release Agreement, (ii) do not experience a Specified Termination prior to October 25, 2024, and (iii) reaffirm the terms of this Release Agreement including the general release in Section 4 so that it covers the period between the date of this Release Agreement and the Resignation Date by signing and returning the Certificate attached as Exhibit A hereto after the Resignation Date in accordance with the time frame provided in such Certificate, and such Certificate becomes effective, the Company shall provide you with the following "Severance Benefits":

a. Severance Pay: The Company shall pay you severance pay ("Severance Pay") by continuing your base salary (at the annual rate of $468,473.28 per year) effective for the ten (10) month period immediately following the Resignation Date (the "Severance Pay Period"). The Company shall pay you Severance Pay in installments on its regular payroll dates during the Severance Pay Period; provided that the Company shall not be obligated to pay any Severance Pay before the Certificate Effective Date (as defined in Exhibit A). If the Company does not make one or more payments of Severance Pay on a regular payroll date because the Certificate has not yet become effective, the

Company shall make all such delayed payments by the first payroll date when it is practicable to do so after the Certificate Effective Date.

b. Health Benefits/401k: If you elect COBRA continuation coverage, the Company shall pay the same portion of COBRA premiums that the Company pays for its active employees for the same level of group healthcare coverage as in effect for you on the Resignation Date until the earliest of the following: (i) the end of the nine (9) month period immediately following the Resignation Date (the "COBRA Period"); (ii) your eligibility for group medical care coverage through other employment; or (iii) the end of your eligibility under COBRA for continuation coverage for health care. You agree to notify the Company promptly if you become eligible for group medical care coverage through another employer. You also agree to respond promptly and fully to any reasonable requests for information by the Company concerning your eligibility for such coverage. You may continue coverage after the end of the COBRA Period at your own expense for the remainder of the COBRA continuation period, subject to continued eligibility. Notwithstanding the foregoing, if the Company determines at any time that its payments pursuant to this paragraph may be taxable income to you, it may convert such payments to payroll payments directly to you on the Company's regular payroll dates, which shall be subject to tax-related deductions and withholdings. In accordance with the Company's 401k plan, you may transfer your 401k account at any point following the Resignation Date.

c. Tax Treatment. The Company shall make deductions, withholdings and tax reports with respect to payments and benefits under this Release Agreement that it reasonably determines to be required. Payments under this Release Agreement shall be in amounts net of any such deductions or withholdings. Nothing in this Release Agreement shall be construed to require the Company to make any payments to compensate you for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

Your receipt of the Severance Benefits under this Release Agreement is conditioned on your continued compliance with the Consulting Agreement. If the Consulting Agreement is terminated for Cause (as defined in the Consulting Agreement), then your receipt of the Severance Benefits shall immediately cease and you will not be eligible for receive any additional Severance Benefits.

3. Equity

During the course of your employment, you were awarded a total of 146,285 Restricted Stock Units (the "Award") and stock options to purchase 559,658 shares of the Company's common stock (the "Option"), in each case under the Company's 2009 Amended and Restated Stock Option and Restricted Stock Plan, 2018 Equity Incentive Plan and 2021 Stock Option and Incentive Plan and associated restricted stock unit award agreements and stock option agreements (collectively, the "Equity Documents"). If you enter into and comply with this Release Agreement, and do not experience a Specified Termination prior to October 25, 2024, you will have 25,314 Restricted Stock Units of the Award vested and 359,748 shares of the Option vested. As of September 25, 2024, 3,900 of such vested Options were previously exercised by you. The remaining 120,971 Restricted Stock Units of the Award and 199,910 shares of the Option shall be unvested as of October 25, 2024 and shall become null and void as of such date, unless you enter into the Consulting Agreement under which your equity will continue to vest (as described below and in the Consulting Agreement). The vested and unexercised equity as of October 25, 2024, along with any other equity that may vest during the Consulting Period (as described in the Consulting Agreement) is collectively referred to herein as the "Vested Equity".

The Vested Equity shall continue to be subject to the terms and conditions of the Equity Documents, provided that you agree, effective as of September 25, 2024, to the following: (i) from September 25, 2024 through the expiration of your existing 10b5-1 Plan with Morgan Stanley (the "10b5-1 Plan"),

which is expected to occur on December 20, 2024 (the "Plan Termination Date"), you will not sell, directly or indirectly, any shares of Vested Equity other than pursuant to the 10b5-l Plan; and (ii) after the Plan Termination Date, you shall not sell, directly or indirectly, more than 5,000 shares of your Vested Equity during any 30 day period beginning on the Plan Termination Date, in each case, without the prior written approval of an authorized representative of the Company. In addition, you will continue to be eligible to participate in your 10b5-1 Plan during the Consulting Period through the Plan Termination Date, and agree not to amend or terminate the 10b5-1 Plan prior to the Plan Termination Date. After the Plan Termination Date, you shall not enter into a subsequent 10b5-1 trading plan but rather will be subject to the limitations set forth in clause (ii) above. In accordance with the Consulting Agreement, you are also eligible for continued vesting during the Consulting Period (as defined in the Consulting Agreement). For the avoidance of doubt, as provided in the Equity Documents, except in the event of disability, death or Cause, the three- month post-service relationship exercise period for any vested equity shall not begin until after your service relationship with the Company has ended (i.e. after the Consulting Period ends). For the avoidance of doubt, during the Transition Period, the Consulting Period and thereafter as specified in the Company's Amended and Restated Insider Trading Policy (the "Trading Policy"), you shall at all times comply with the Trading Policy.

4. Release of Claims

In consideration for, among other terms, the opportunity to continue your employment with the Company during the Transition Period and to receive the Severance Benefits, each of which you acknowledge you would otherwise not be entitled to, you voluntarily release and forever discharge the Company and its affiliated and related entities, their respective predecessors, successors and assigns, its and their respective employee benefit plans and fiduciaries of such plans, and the current and former officers, directors, managers, members, shareholders, employees, attorneys, accountants and agents of each of the foregoing in their official and personal capacities (collectively referred to as the "Releasees") generally from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown ("Claims") that, as of the date when you sign this Release Agreement, you have, ever had, now claim to have or ever claimed to have had against any or all of the Releasees. This release includes, without limitation, all Claims:

- relating to your employment by and resignation from employment with the Company;
- relating to your Offer Letter or the Equity Documents;
- of wrongful discharge or violation of public policy;
- of breach of contract;
- of retaliation or discrimination under federal, state or local law (including, without limitation, Claims of discrimination, retaliation or otherwise under the Americans with Disabilities Act, Title VII of the Civil Rights Act of 1964, and the Massachusetts Fair Employment Practices Act (M.G.L. c. 151B));
- under any other federal or state statute;
- for wages, bonuses, incentive compensation, commissions, stock, stock options, vacation pay or any other compensation or benefits, whether under Massachusetts Wage Act, M.G.L. c. 149, §§148-150C, or otherwise; and

- for damages or other remedies of any sort, including, without limitation, compensatory damages, punitive damages, injunctive relief and attorney's fees;

provided, *however*, that this release shall not affect your rights under this Release Agreement or under any "employee benefit plan," as that term is defined in Section 3(3) of the Employee Retirement Income Security Act, 29 U.S.C. §1002(3).

You acknowledge and represent that, except as expressly provided in this Release Agreement, the Company has paid or provided all salary, wages, bonuses, accrued vacation/paid time off, premiums, leaves, severance, reimbursable expenses, commissions, stock, stock options, equity awards, vesting, and any and all other benefits and compensation due to you.

You agree not to accept damages of any nature, other equitable or legal remedies for your own benefit or attorney's fees or costs from any of the Releasees with respect to any Claim released by this Release Agreement. As a material inducement to the Company to enter into this Release Agreement, you represent that you have not assigned any Claim to any third party.

5. Return of Property

In accordance with Section 3 of the Restrictive Covenants Agreement, you agree to return to the Company by the Resignation Date all Company property, including, without limitation, computer equipment, keys and access cards, credit cards and any documents (including electronic documents as well as hard copies) containing information concerning the Company, its business or its business relationships. You also commit to deleting and finally purging any duplicates of files or documents that may contain Company information from any computer or other device that remains your property after the Resignation Date. In the event that you discover that you continue to retain any such property, you shall return it to the Company immediately.

6. Non-disparagement

In accordance with Section 10 of the Offer Letter, you agree that you will not directly or indirectly, make or ratify any statement, public or private, oral or written, to any person that disparages, either professionally or personally, the Company or any of its affiliates, past and present, and each of them, as well as its and their trustees, directors, officers, members, managers, partners, agents, attorneys, insurers, employees, stockholders, representatives, assigns, and successors, past and present, and each of them. You represent that during the period since this Release Agreement was proposed to you, you have not made any such disparaging statements.

The Company agrees to direct its C-Suite executives not to make disparaging statements about you during such persons' employment with the Company.

7. Confidentiality of Agreement-Related Information

You agree, to the fullest extent permitted by law, to keep all Release Agreement-Related Information completely confidential. "Release Agreement-Related Information" means the negotiations leading to this Release Agreement and the terms of this Release Agreement. Notwithstanding the foregoing, you may disclose Release Agreement-Related Information to your spouse, your attorney and your financial advisors (if applicable), and to them only provided that they first agree for the benefit of the Company to keep Release Agreement-Related Information confidential. You represent that during the period since this Release Agreement was proposed to you, you have not made any disclosures that would have been contrary to the foregoing obligation if it had then been in effect. Nothing in this section shall be construed

to prevent you from disclosing Release Agreement-Related Information to the extent required by a lawfully issued subpoena or duly issued court order; provided that you provide the Company with advance written notice and a reasonable opportunity to contest such subpoena or court order.

8. Protected Disclosures and Other Protected Actions

Nothing contained in this Agreement, any other agreement with the Company (including without limitation the Ongoing Obligations), or any Company policy limits your ability, with or without notice to the Company, to: (i) file a charge or complaint with any federal, state or local governmental agency or commission (a "Government Agency"), including without limitation, the Equal Employment Opportunity Commission, the National Labor Relations Board or the Securities and Exchange Commission (the "SEC"); (ii) communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including by providing non-privileged documents or information; (iii) discuss or disclose information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful; or (iv) testify truthfully in a legal proceeding. Any such communications and disclosures must not violate applicable law and the information disclosed must not have been obtained through a communication that was subject to the attorney-client privilege (unless disclosure of that information would otherwise be permitted consistent with such privilege or applicable law). If a Government Agency or any other third party pursues any claim on your behalf, you waive any right to monetary or other individualized relief (either individually or as part of any collective or class action), but the Company will not limit any right you may have to receive an award pursuant to the whistleblower provisions of any applicable law or regulation for providing information to the SEC or any other Government Agency.

9. Defend Trade Secrets Act

For the avoidance of doubt, pursuant to the federal Defend Trade Secrets Act of 2016, you shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

10. Other Provisions

a. Termination and Return of Payments; Certain Remedies. If you materially breach any of your obligations under any Ongoing Obligation, in addition to any other legal or equitable remedies it may have for such breach, the Company shall have the right to: (i) terminate the Transition Period, (ii) cancel any equity that has vested during the Transition Period and instruct you to reimburse the Company for any proceeds resulting from the sale of any equity that vested during the Transition Period, and/or (iii) enforce the return of its non-wage payments to you or for your benefit under this Release Agreement. If the Company initiates (i), (ii) or (iii) in the preceding sentence due to a breach, you shall continue to be subject to the Ongoing Obligations. Without limiting the Company's remedies hereunder, if the Company prevails in any action to enforce this Release Agreement, then you shall be liable to the Company for reasonable attorneys' fees and costs incurred by the Company in connection with such action.

b. Enforceability. If any provision of this Release Agreement is held to be unenforceable, this Release Agreement will be deemed amended to the extent necessary to render the otherwise unenforceable provision, and the rest of the Release Agreement, valid and enforceable. If a court declines to amend this Release Agreement as provided herein, the invalidity or unenforceability of any provision of this Release Agreement shall not affect the validity or enforceability of the remaining provisions.

c. Waiver; Absence of Reliance. No waiver of any provision of this Release Agreement shall be effective unless made in writing and signed by the waiving party. In signing this Release Agreement, you are not relying upon any promises or representations made by anyone at or on behalf of the Company.

d. Jurisdiction; Governing Law; Interpretation. You and the Company hereby agree that the state and federal courts of Massachusetts shall have the exclusive jurisdiction to consider any matters related to this Release Agreement. With respect to any such court action, you submit to the jurisdiction and venue of such courts, you acknowledge that venue in such courts is proper and you waive any right to a jury with respect to any such action. This Release Agreement shall be interpreted and enforced under the laws of Massachusetts, without regard to conflict of law principles.

e. Entire Agreement. The Equity Documents and the Ongoing Obligations constitute the entire agreement between you and the Company and supersedes any previous agreements or understandings between you and the Company.

f. Time for Consideration; Effective Date. You acknowledge that you have knowingly and voluntarily entered into this Release Agreement and that the Company advises you to consult with an attorney before signing this Release Agreement. By entering into this Release Agreement, you acknowledge that you have been given the opportunity to consider this Release Agreement for twenty-one (21) days from your receipt of this Release Agreement before signing it (the "Consideration Period"). To accept this Release Agreement, you must return a signed original or a signed PDF copy of this Release Agreement so that it is received by the undersigned at or before the expiration of the Consideration Period. If you sign this Release Agreement before the end of the Consideration Period, you acknowledge that such decision was entirely voluntary and that you had the opportunity to consider this Release Agreement for the entire Consideration Period. For the period of seven (7) days from the date when you sign this Release Agreement, you have the right to revoke this Release Agreement by written notice to the undersigned, provided that such notice is delivered so that it is received at or before the expiration of the seven (7) day revocation period. This Release Agreement shall not become effective or enforceable during the revocation period. This Release Agreement shall become effective on the first business day following the expiration of the revocation period (the "Effective Date").

g. Counterparts. This Release Agreement may be executed in separate counterparts. When all counterparts are signed, they shall be treated together as one and the same document.

11. 409A

This Release Agreement is not intended to provide for any deferral of compensation subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and, to the maximum extent permitted by applicable law, amounts payable to you pursuant to Section 2 shall be made in reliance upon Treasury Regulation Section 1.409A-1(b)(9) (with respect to separation pay plans) or Treasury Regulation Section 1.409A-1(b)(4) (with respect to short-term deferrals). To the extent applicable, this Release Agreement shall be interpreted in accordance with Code Section 409A and Department of Treasury regulations and other interpretive guidance issued thereunder consistent with the foregoing intention. Each series of installment payments made under this Agreement is hereby designated as a series of "separate payments" within the meaning of Section 409A of the Code. Notwithstanding anything herein to the contrary, to the extent any payments to you hereunder constitute "non-qualified deferred compensation" subject to Section 409A of the Code or are intended to be exempt from Section 409A of the Code pursuant to Treasury Regulation Section 1.409A-1(b)(9), then, to the extent required by Section 409A of the Code or to satisfy such exception, no amount shall be payable pursuant to such sections unless your termination of employment constitutes a "separation from service" with the Company (as

such term is defined in Treasury Regulation Section 1.409A-1(h) and any successor provision thereto) (a "Separation from Service"). If you are a "specified employee" (as defined in Section 409A of the Code), as determined by the Company in accordance with Section 409A of the Code, on the date of your Separation from Service, to the extent that the payments or benefits under this Release Agreement constitute "non-qualified deferred compensation" subject to Section 409A of the Code and the delayed payment or distribution of all or any portion of such amounts to which you are entitled under this Release Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, then such portion deferred pursuant to this Section shall be paid or distributed to you in a lump sum on the earlier of (A) the date that is six (6) months following your Separation from Service, (B) the date of your death or (C) the earliest date as is permitted under Section 409A of the Code. Any remaining payments due under this Release Agreement shall be paid as otherwise provided herein. Further, in the event that the amounts payable under Section 2 constitute "non-qualified deferred compensation" subject to Section 409A of the Code and the timing of the delivery of this Release Agreement could cause such amounts to be paid in one or another taxable year, then, notwithstanding the payment timing set forth in such sections, such amounts shall not be payable until the later of (A) the payment date specified in such section or (B) the first business day of the taxable year following your Separation from Service. Any reimbursements or in-kind benefits payable under this Release Agreement shall be made in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv) and shall be paid on or before the last day of your taxable year following the taxable year in which you incurred the expenses. The reimbursements or in-kind benefits provided under this Release Agreement during any taxable year of yours will not affect such amounts provided in any other taxable year of yours, and your right to reimbursement for such amounts shall not be subject to liquidation or exchange for any other benefit. The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Release Agreement are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, Section 409A.

[*Signature Page Follows*]

Please indicate your agreement to the terms of this Release Agreement by signing and returning to the undersigned the original or a PDF copy of this letter within the time period set forth above.

Very truly yours,

Aura Biosciences, Inc.

By:

/s/ Elisabet de los Pinos
Name: Elisabet de los Pinos, Ph.D.
Title: CEO

You are advised to consult with an attorney before signing this Release Agreement. This is a legal document. Your signature will commit you to its terms. By signing below, you acknowledge that you have carefully read and fully understand all of the provisions of this Release Agreement and that you are knowingly and voluntarily entering into this Release Agreement.

/s/ Julie Feder	9/26/2024
Name: Julie Feder	Date:

Exhibit 10.2

September 25, 2024

PERSONAL AND CONFIDENTIAL

Julie Feder

Re: **Resignation and Consulting Agreement**

Dear Ms. Feder:

This letter confirms your resignation from your employment with Aura Biosciences, Inc. (the "Company") effective on October 25, 2024 (the "Resignation Date"). The Company is also offering you the opportunity to enter into a consulting relationship with the Company following the Resignation Date. The terms of the consulting engagement, should you accept this offer, are set forth below (the "Consulting Agreement").

1.Consulting Period; Services; Consideration. Provided you enter into, do not revoke and comply with the Transition and Release Agreement with the Company, which was provided to you on September 25, 2024 (the "Release Agreement"), the term of this Consulting Agreement and your services as a consultant for the Company shall commence immediately following the Resignation Date and, unless terminated earlier pursuant to Section 6 below, shall continue in effect through December 31, 2024 (the "Consulting Period"). During the Consulting Period, you shall provide to the Company the services reasonably requested by the Company that relate to your responsibilities during your employment (the "Services"), with such Services approximating ten (10) hours per month on average during the Consulting Period, unless otherwise mutually agreed by you and the Company. As consideration for your agreement to this Consulting Agreement, subject to the terms of the Company's Amended and Restated 2009 Stock Option and Restricted Stock Plan, 2018 Equity Incentive Plan and 2021 Stock Option and Incentive Plan, and the associated restricted stock unit award agreements and stock option agreements (the "Equity Documents"), your previously granted equity (the "Equity Grants") shall continue to vest during the Consulting Period, provided that you comply with the restrictions on your sale of Vested Equity (as defined in the Release Agreement) as set forth in Section 3 of the Release Agreement. Consultant hereby acknowledges and agrees that (i) to the extent any Equity Grants that are stock options are currently "incentive stock options", such shares must be exercised within three months following the date Consultant ceased being an employee of the Company to qualify as "incentive stock options", and (ii) after such three-month period, such shares shall automatically become non-qualified stock options. Consultant is encouraged to consult with a tax advisor regarding the tax treatment of Consultant's stock options.

2.Expenses. The Company shall reimburse you for reasonable and necessary out-of-pocket expenses incurred by you in the performance of the Services to the Company, provided such out-of-pocket expenses are approved in advance by the Company in writing and further supported by reasonable documentation.

3.Resignation from Other Positions. In connection with the ending of your employment, you hereby (i) resign from your status as an employee, officer or other positions you occupy at the Company and resign from your status as an employee, officer, director or other positions you occupy at any subsidiary of the Company, in each case, effective as of the last day of your employment and (ii) agree to execute such documentation as the Company reasonably requires to effectuate such resignations.

4.Ongoing Obligations. You are subject to continuing obligations under (i) your Confidential Information, Non-Solicitation and Invention Assignment Agreement (the "Restrictive Covenants

Agreement"), (ii) Section 10 (Non-disparagement) of your offer letter with the Company dated August 10, 2018, and (iii) the Release Agreement (collectively, the "Ongoing Obligations"). The Ongoing Obligations, along with any other confidentiality and restrictive covenant obligations you have to the Company, shall remain in full force and effect, and are incorporated by reference herein. Additionally, you shall continue to be subject to the terms of the Company's Amended and Restated Insider Trading Policy and any other policies applicable to consultants.

5.Independent Contractor. You agree that you are not, nor shall you be deemed to be at any time during the term of this Consulting Agreement, an employee of the Company. Your status and relationship with the Company shall be that of an independent contractor and consultant. You shall not state or imply, directly or indirectly, that you are empowered to bind the Company without the Company's prior written consent. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between you and the Company. You acknowledge and agree that you are obligated to pay all taxes, unemployment, disability insurance and workers' compensation payments applicable to you or the Services, and that you will not be eligible for any employee benefits, except as specified herein or in the Release Agreement, and expressly waive any entitlement to such benefits. You agree that the Services will be provided by you directly and not any other person or entity.

Except insofar as it would preclude you from providing the Services under this Consulting Agreement or violate a term of this Consulting Agreement or the Ongoing Obligations, you are free to perform services for any other person.

6.Cancellation of Services. The Company may, at any time, terminate the performance of all or any portion of the Services to be provided hereunder and either you or the Company may terminate this Consulting Agreement upon sixty (60) days prior written notice to the non terminating party stating its intention to terminate. The Company, however, may immediately terminate the Services and this Agreement for Cause. For purposes of this Consulting Agreement, "Cause" shall mean, as determined by the Company in good faith: (a) willful failure or refusal to perform the Services; (b) your material breach of any written agreement between you and the Company, including but not limited to this Consulting Agreement and the Ongoing Obligations; or (c) your gross negligence or willful misconduct that would reasonably be expected to result in material injury or reputational harm to the Company if you were to continue to be engaged by the Company.

7.Warranties of Consultant. You represent to the Company that (i) with respect to any information, know-how, knowledge or data disclosed by you to the Company in the performance of this Consulting Agreement, you have the full and unrestricted right to disclose the same; and (ii) you are free to undertake the services required by this Agreement, and there is, and shall be, no conflict of interest between your performance of this Consulting Agreement and any obligation you may have to other parties.

8.Indemnification. You shall indemnify and hold the Company, its affiliates and their respective directors, officers, agents and employees harmless from and against all claims, demands, losses, damages and judgments, including court costs and attorneys' fees, arising out of or based upon any breach or alleged breach by you of any obligation set forth in this Consulting Agreement, or your gross negligence or willful misconduct. You further agree to indemnify the Company and hold it harmless to the extent of any obligation imposed on the Company (i) to pay withholding taxes or any other applicable taxes or (ii) otherwise resulting from you being determined not to be an independent contractor.

9.Entire Agreement; Jurisdiction; Governing Law; Interpretation. This Consulting Agreement and the Ongoing Obligations constitute the entire agreement between you and the Company with respect to the matters contained herein, and supersede all proposals and agreements, written or oral, and all other communications between you and the Company relating to the subject matter of this Consulting

Agreement. You and the Company hereby agree that the state and federal courts of Massachusetts shall have the exclusive jurisdiction to consider any matters related to this Consulting Agreement. This Consulting Agreement shall be interpreted and enforced under the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles. This Consulting Agreement may not be modified or amended except in writing signed or executed by you and the Company. In case any provisions (or portions thereof) contained in this Consulting Agreement will, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Consulting Agreement, and this Consulting Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained herein.

10.Effective Date. To accept this Consulting Agreement, you must return a signed original or a signed PDF copy of this Consulting Agreement so that it is received by the General Counsel of the Company by 5:00 PM on September 26, 2024. This Consulting Agreement shall become effective on the day it becomes fully executed.

Please indicate your agreement to the terms of this Consulting Agreement by signing and returning to the Chief Executive Officer the original or a PDF copy of this Consulting Agreement within the time period set forth above.

Sincerely,

AURA BIOSCIENCES, INC.

By: /s/ Elisabet de los Pinos
Elisabet de los Pinos, PhD
Chief Executive Officer

I agree to the terms of this Consulting Agreement.

/s/ Julie Feder	9/26/2024
Julie Feder	Date

Exhibit 10.3

AURA BIOSCIENCES, INC.

EXECUTIVE SEVERANCE PLAN

1. Purpose. Aura Biosciences, Inc., a Delaware corporation (the "Company"), considers it essential to the best interests of its stockholders to foster the continuous employment of key management personnel. The Board of Directors of the Company (the "Board") recognizes, however, that, as is the case with many publicly-held corporations, the possibility of an involuntary termination of employment exists and that such possibility, and the uncertainty and questions that it may raise among management, may result in the departure or distraction of management personnel to the detriment of the Company and its stockholders. Therefore, the Board has determined that the Aura Biosciences, Inc. Executive Severance Plan (the "Plan") should be adopted to reinforce and encourage the continued attention and dedication of the Company's Covered Executives (as defined in Section 2 hereof) to their assigned duties without distraction. Nothing in this Plan shall be construed as creating an express or implied contract of employment and nothing shall alter the "at will" nature of the Covered Executives' employment with the Company.

2. Definitions. The following terms shall be defined as set forth below:

(a) *"Accounting Firm"* shall mean a nationally recognized accounting firm selected by the Company.

(b) *"Administrator"* means the Board or the Compensation Committee of the Board.

(c) "*Base Salary*" shall mean the higher of (i) the annual base salary in effect immediately prior to the Date of Termination (prior to any "Good Reason" reduction) or (ii) the annual base salary in effect immediately prior to the Change in Control (if applicable).

(d) "*Cause*" shall mean that the Covered Executive has: (i) violated the Covered Executive's fiduciary duty to the Company or committed any other act involving material dishonesty or fraud with respect to the Company; (ii) been indicted for or pled guilty or *nolo contendere* to a felony involving violence, conversion, theft or misappropriation of property of another, controlled substances, moral turpitude, or the regulatory good standing of the Company; (iii) engaged in grossly negligent or willful misconduct that the Company determines to be materially injurious to the Company; (iv) willfully violated any Company policy that harmed the Company or breached any material provision of any agreement between the Covered Executive and the Company; or (v) failed or refused to perform the Covered Executive's material duties or failed or refused to follow a lawful directive from the Board or, with respect to the Tier 2 Executives, the CEO, unrelated to a Disability. Further, before terminating the Covered Executive for Cause the Company will provide the Covered Executive in writing the reason for the Covered Executive's termination, and if the Company determines that the Covered Executive can cure, ten (10) business days to cure. For purposes of clarity, receiving a poor performance review is not Cause for purposes of this Plan. If the Covered Executive is given a cure period, the Company will only terminate the Covered Executive's employment if the Covered Executive failed to cure.

(e) "*Change in Control*" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the stock of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

(f) "*Change in Control Period*" shall mean the period beginning on the date three months prior to a Change in Control and ending on the one-year anniversary of the Change in Control.

(g) *"Code"* shall mean the Internal Revenue Code of 1986, as amended.

(h) "*Covered Executives*" shall mean the Tier 1 Executive and Tier 2 Executives, in each case, who meet the eligibility requirements set forth in Section 4 of the Plan.

(i) "*Date of Termination*" shall mean the date that a Covered Executive's employment with the Company (or any successor) ends, which date shall be specified in the Notice of Termination. Notwithstanding the foregoing, a Covered Executive's employment shall not be deemed to have been terminated solely as a result of the Covered Executive becoming an employee of any direct or indirect successor to the business or assets of the Company.

(j) "*Disability*" shall mean a physical or mental illness, impairment, or condition determined by a physician reasonably selected by the Covered Executive and the Company, and if an agreement on such selection cannot be reached, selected jointly by the two physicians identified by the Covered Executive and the Company, that prevents the Covered Executive from performing the essential functions of the Covered Executive's role, with or without a reasonable accommodation, for a period of 90 consecutive dates, or 180 days (which need not be consecutive) in any 12 month period. The determination of any such physician shall be final and conclusive for all purposes of this Plan.

(k) "*Effective Date*" shall mean the date the Plan is effective as set forth in Section 23 of the Plan.

(l) *"Existing Equity Awards*" shall mean any stock options, restricted stock units or other equity awards outstanding as of the Effective Date.

(m) *"Good Reason"* shall mean that the Covered Executive has completed all steps of the "Good Reason Process" following the occurrence of any of the following events without the Covered Executive's consent (each, a "*Good Reason Condition*"):

(i) a material diminution in the Covered Executive's responsibilities,

authority or duties;

(ii) a material diminution in the Covered Executive's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company;

(iii)a material breach by the Company of this Plan or any offer letter or employment agreement between the Covered Executive and the Company; or

(iv)a material change in the geographic location at which the Covered Executive provides services to the Company.

(n) "*Good Reason Process*" shall mean:

(i) the Covered Executive reasonably determines in good faith that a Good Reason Condition has occurred;

(ii) the Covered Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within sixty (60) days of the first occurrence of such condition;

(iii)the Covered Executive cooperates in good faith with the Company's efforts, for a period of not less than thirty (30) days following such notice (the "*Cure Period*"), to remedy the Good Reason Condition;

(iv)notwithstanding such efforts, the Good Reason Condition continues to exist at the end of the Cure Period; and

(v) the Covered Executive terminates his or her employment and provides the Company with a Notice of Termination with respect to such termination, each within sixty (60) days after the end of the Cure Period.

If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(o) "*Notice of Termination*" shall mean a written notice which shall indicate the specific termination provision in this Plan relied upon for the termination of a Covered Executive's employment and the Date of Termination.

(p) *"Participation Agreement"* shall mean an agreement between a Covered Executive and the Company that acknowledges the Covered Executive's participation in the Plan.

(q) *"Qualified Termination Event"* shall mean (i) a termination of the Covered Executive's employment by the Company other than for Cause, death or Disability or (ii) the Covered Executive's resignation from the Company for Good Reason.

(r) "*Restrictive Covenants Agreement*" shall mean the Confidential Information, Non-Solicitation, and Invention Assignment Agreement or similar agreement entered into between the Covered Executive and the Company.

(s) "*Target Bonus*" shall mean the Covered Executive's target annual cash incentive compensation at the higher of (i) the rate in effect for the year in which the Qualified Termination Event occurs (prior to any reduction that constituted "Good Reason") or (ii) at the rate in effect immediately prior to the Change in Control (if applicable).

(t) "*Tier 1 Executive*" shall mean the Company's Chief Executive Officer.

(u) "*Tier 2 Executives*" shall mean the individuals designated as such by the Administrator.

3. Administration of the Plan.

(v) Administrator. The Plan shall be administered by the Administrator.

(w) Powers of Administrator. The Administrator shall have all powers necessary to enable it properly to carry out its duties with respect to the complete control of the administration of the Plan. Not in limitation, but in amplification of the foregoing, the Administrator shall have the power and authority in its discretion to:

(i) construe the Plan to determine all questions that shall arise as to interpretations of the Plan's provisions;

(ii) determine which individuals are and are not Covered Executives, designate an individual as a Tier 2 Executive, determine the benefits to which any Covered Executives may be entitled in accordance with this Plan, the eligibility requirements for participation in the Plan and all other matters pertaining to the Plan;

(iii) adopt amendments to the Plan which are deemed necessary or desirable to comply with all applicable laws and regulations, including but not limited to Code Section 409A and the guidance thereunder;

(iv) make all determinations it deems advisable for the administration of the Plan, including the authority and ability to delegate administrative functions to a third party;

(v) decide all disputes arising in connection with the Plan; and

(vi) otherwise supervise the administration of the Plan.

(x) All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Covered Executives.

4. Eligibility. All Covered Executives who have executed and submitted to the Company a Participation Agreement, and satisfied such other requirements as may be

determined by the Administrator in accordance with this Plan, are eligible to participate in the Plan.

5. Termination Benefits Generally. In the event a Covered Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Covered Executive any earned but unpaid salary, unpaid expense reimbursements in accordance with Company policy, accrued but unused vacation or leave entitlement, and any vested benefits the Covered Executive may have under any employee benefit plan of the Company in accordance with the terms and conditions of such employee benefit plan (collectively, the "*Accrued Benefits*"), within the time required by law but in no event more than sixty (60) days after the Date of Termination.

6. Termination Not in Connection with a Change in Control. In the event a Qualified Termination Event occurs at any time other than during the Change in Control Period, with respect to such Covered Executive, in addition to the Accrued Benefits, subject to his or her execution of a separation agreement in a form and manner satisfactory to the Company containing, among other provisions, a general release of claims in favor of the Company and related persons and entities, confidentiality, return of property, non-disparagement and reaffirmation of the Restrictive Covenants Agreement and, in the Company's sole discretion and to the extent permitted by applicable law, a one-year post-employment non-competition agreement (it being understood that such one-year post-employment non-competition agreement shall not be required of any Covered Executive residing in California) (the "*Separation Agreement and Release*") and the Separation Agreement and Release becoming irrevocable, all within the time period set forth in the Separation Agreement and Release but in no event more than sixty (60) days after the Date of Termination, and subject to the Covered Executive complying with the Separation Agreement and Release, the Company shall:

(y) pay the Covered Executive an amount equal to twelve (12) months' Base Salary for the Tier 1 Executive and nine (9) months' Base Salary for each Tier 2 Executive; and

(z) if the Covered Executive was participating in the Company's group health and/or dental plans immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the group health or dental plan provider or the COBRA provider a monthly cash payment in an amount equal to the monthly employer contribution that the Company would have made to provide health and/or dental insurance to the Covered Executive and his or her eligible dependents' if the Covered Executive had remained employed by the Company, based on the premiums as of the Date of Termination, until the earliest of (i) twelve (12) months for the Tier 1 Executive and nine (9) months for each Tier 2 Executive, (ii) the date as of which the Covered Executive qualifies for alternative health coverage pursuant to other employment or (iii) the cessation of the Covered Executive's health continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health or dental plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Covered Executive for the time period specified above. Such payments, if to the Covered Executive, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Section 6(a) shall be paid out in a substantially equal installments in accordance with the Company's payroll practice over twelve (12) months for the Tier 1 Executive and nine (9) months for each Tier 2 Executive, commencing within sixty (60) days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid in the second calendar year no later than the last day of such 60-day period; provided further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Plan is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

7. Termination in Connection with a Change in Control. In the event a Qualified Termination Event occurs within the Change in Control Period, then with respect to such Covered Executive, in addition to the Accrued Benefits, subject to his or her execution and non-revocation of the Separation Agreement and Release, all within the time period set forth in the Separation Agreement and Release, but in no event more than sixty (60) days after the Date of Termination, the Company shall:

(aa) notwithstanding anything to the contrary in any applicable option agreement or other stock-based award agreement, cause 100% of the outstanding and unvested equity awards with time-based vesting held by the Covered Executive to immediately become fully vested, exercisable or nonforfeitable as of the later of the Date of Termination (or, if later, upon the Change in Control) and the effective date of the Release (the "*Accelerated Vesting Date*"). The termination or forfeiture of any of such equity awards will be delayed to the extent necessary to effectuate this provision and will not occur if the acceleration pursuant to this provision occurs. No additional vesting of such equity awards shall occur during the period between the Covered Executive's Date of Termination and the Accelerated Vesting Date. Notwithstanding the foregoing, any Existing Equity Awards shall be subject to Section 8 of the Plan;

(bb) pay to the Covered Executive an amount equal to the sum of (i) 150% of Base Salary for the Tier 1 Executive and 100% of Base Salary for each Tier 2 Executive, and (ii) 150% of the Target Bonus for the Tier 1 Executive and 100% of the Target Bonus for each Tier 2 Executive, and (iii) the Covered Executive's Target Bonus, pro-rated for the number of days of service provided by the Covered Executive during the year in which the Date of Termination occurs; and

(cc) if the Covered Executive was participating in the Company's group health and/or dental plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the group health or dental plan provider or the COBRA provider a monthly cash payment in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Covered Executive and his or her eligible dependents' if the Covered Executive had remained employed by the Company for eighteen (18) months for the Tier 1 Executive and twelve (12) months for each Tier 2 Executive, after the Date of Termination, based on the premiums as of the Date of Termination; provided, however, that if the Company reasonably determines that it cannot pay

such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Covered Executive for the time period specified above. Such payments, if to the Covered Executive, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Section 7(b) shall be paid out in a lump sum within sixty (60) days after the Date of Termination and the amounts payable under Section 7(c), as applicable, shall be paid out in a substantially equal installments in accordance with the Company's payroll practice over eighteen (18) months for the Tier 1 Executive and twelve (12) months for each Tier 2 Executive, commencing within sixty (60) days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid in the second calendar year no later than the last day of the 60-day period.

The provisions of this Section 7 shall apply in lieu of, and expressly supersede, the provisions of Section 6 if (i) the Covered Executive undergoes a Qualified Termination Event and (ii) the Date of Termination is within the Change in Control Period. For the avoidance of doubt, (i) in no event will the Covered Executive be entitled to severance pay and benefits under both Section 6 and Section 7 of this Plan, and (ii) if the Company has commenced providing severance pay and benefits to the Covered Executive under Section 6 prior to the date that the Covered Executive becomes eligible to receive severance pay and benefits under this Section 7, the severance pay and benefits previously provided to the Covered Executive under Section 6 shall reduce the severance pay and benefits to be provided under this Section 7. The provisions of this Section 7 shall terminate and be of no further force or effect after the Change in Control Period.

8. Existing Equity Awards. Notwithstanding anything to the contrary herein or in any applicable option agreement or other stock-based award agreement, upon a Change in Control, and subject to the Covered Executive's continued employment through the date of such Change in Control, 100% of any then outstanding Existing Equity Awards shall immediately become fully vested, exercisable or nonforfeitable as of the Change in Control.

9. Additional Limitation.

(dd) Anything in this Plan to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Covered Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Plan or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "*Aggregate Payments*"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Covered Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Covered Executive receiving a higher After Tax Amount (as defined below) than the Covered Executive would receive if the Aggregate Payments were not subject to such reduction. In the event of

such reduction, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (i) cash payments not subject to Section 409A of the Code; (ii) cash payments subject to Section 409A of the Code; (iii) equity-based payments and acceleration; and (iv) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ee) For purposes of this Section 9, the "*After Tax Amount*" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Covered Executive as a result of the Covered Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Covered Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes (if any) which could be obtained from deduction of such state and local taxes.

(ff) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 9(a) shall be made by the Accounting Firm, which shall provide detailed supporting calculations both to the Company and the Covered Executive within fifteen (15) business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Covered Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Covered Executive.

10.Restrictive Covenants Agreement. As a condition to participating in the Plan, each Covered Executive shall continue to comply with the terms and conditions contained in the Restrictive Covenants Agreements and such other agreement(s) as designated in the applicable Participation Agreement. If a Covered Executive has not entered into a Restrictive Covenants Agreement, he or she shall enter into such agreement prior to participating in the Plan.

11.Withholding. All payments made by the Company under this Plan shall be subject to any tax or other amounts required to be withheld by the Company under applicable law.

12.Section 409A.

(gg) Anything in this Plan to the contrary notwithstanding, if at the time of the Covered Executive's "separation from service" within the meaning of Section 409A of the Code, the Company determines that the Covered Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Covered Executive becomes entitled to under this Plan would be considered deferred compensation subject to the twenty (20) percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the

earlier of (i) six (6) months and one (1) day after the Covered Executive's separation from service, or (ii) the Covered Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(hh) The parties intend that this Plan will be administered in accordance with Section 409A of the Code and that all amounts payable hereunder shall be exempt from the requirements of such section as a result of being "short term deferrals" for purposes of Section 409A of the Code to the greatest extent possible. To the extent that any provision of this Plan is not exempt from Section 409A of the Code and ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner to comply with Section 409A of the Code. Each payment pursuant to this Plan is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Plan may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(ii) To the extent that any payment or benefit described in this Plan constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Covered Executive's termination of employment, then such payments or benefits shall be payable only upon the Covered Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(jj) All in-kind benefits provided and expenses eligible for reimbursement under this Plan shall be provided by the Company or incurred by the Covered Executive during the time periods set forth in this Plan. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(kk) The Company makes no representation or warranty and shall have no liability to the Covered Executive or any other person if any provisions of this Plan are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

13.Notice and Date of Termination.

(ll) Notice of Termination. A termination of the Covered Executive's employment shall be communicated by Notice of Termination from the Company to the Covered

Executive or vice versa in accordance with this Section 13.

(mm) Notice to the Company. Any notices, requests, demands, and other communications provided for by this Plan shall be sufficient if in writing and delivered in person or sent by registered or certified mail, postage prepaid, to a Covered Executive at the last address the Covered Executive has filed in writing with the Company, or to the Company at the following physical or email address:

Aura Biosciences, Inc.
Attention: General Counsel
80 Guest Street
Boston, MA 02135
Email: legaldepartment@aurabiosciences.com

14.No Mitigation. The Covered Executive is not required to seek other employment or to attempt in any way to reduce any amounts payable to the Covered Executive by the Company under this Plan.

15.Benefits and Burdens. This Plan shall inure to the benefit of and be binding upon the Company and the Covered Executives, their respective successors, executors, administrators, heirs and permitted assigns. In the event of a Covered Executive's death after a termination of employment but prior to the completion by the Company of all payments due to him or her under this Plan, the Company shall continue such payments to the Covered Executive's beneficiary designated in writing to the Company prior to his or her death (or to his or her estate, if the Covered Executive fails to make such designation).

16.Enforceability. If any portion or provision of this Plan shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Plan, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Plan shall be valid and enforceable to the fullest extent permitted by law.

17.Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Plan, or the waiver by any party of any breach of this Plan, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

18.Non-Duplication of Benefits and Effect on Other Plans. Notwithstanding any other provision in the Plan to the contrary, the benefits provided hereunder shall be in lieu of any other severance payments and/or benefits provided by the Company, including any such payments and/or benefits pursuant to an employment agreement or offer letter between the Company and the Covered Executive, other than as provided in Section 3(c) of the Company's 2021 Stock Option and Incentive Plan, as amended from time to time, or any equivalent provision of a successor equity plan of the Company.

19.No Contract of Employment. Nothing in this Plan shall be construed as giving any Covered Executive any right to be retained in the employ of the Company or shall affect the terms and conditions of a Covered Executive's employment with the Company.

20.Amendment or Termination of Plan. The Company may amend or terminate this Plan at any time or from time to time, but no such action shall adversely affect the rights of any Covered Executive without the Covered Executive's written consent.

21.Governing Law. This Plan shall be construed under and be governed in all respects by the laws of the State of Delaware, without giving effect to the conflict of laws principles.

22.Obligations of Successors. In addition to any obligations imposed by law upon any successor to the Company, any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company shall expressly assume and agree to perform this Plan in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

23.Effectiveness and Term. The Plan is effective as of November 10, 2024.

Executive Severance Plan Participation Agreement

[DATE]

[NAME]
[ADDRESS]
[ADDRESS]

Re: Executive Severance Plan

Dear [NAME],

Aura Biosciences, Inc., a Delaware corporation (the "Company") is pleased to inform you that you have been designated as an eligible participant in the Company's Executive Severance Plan, as amended from time to time (the "Severance Plan"), a copy of which (excluding the exhibits thereto) is attached hereto as Exhibit A. You have been designated as a Tier [1][2] Executive under the Severance Plan.

Under certain circumstances, you will be eligible for certain severance benefits as described in the Severance Plan. Any and all such severance benefits are subject to the terms and conditions of the Severance Plan.

As a condition to participate in the Severance Plan, you hereby acknowledge that the severance benefits that may be provided to you under the Severance Plan will supersede and replace any severance benefit plan, policy or practice previously maintained by the Company or any of its affiliates that may have been applicable to you and any severance benefits under any individually negotiated employment agreement, offer letter agreement or equity award agreement between you and the Company or any of its affiliates, as may be amended from time to time, but other than Section 3(d) of the Company's 2021 Stock Option and Incentive Plan, as amended from time to time, or any equivalent provision of a successor equity plan of the Company. In addition, as a condition to participate in the Severance Plan, you hereby acknowledge that you will continue to comply with the [Confidential Information, Non-Solicitation and Invention Assignment Agreement] entered into between you and the Company on [DATE].

Please review the information in this letter and the Severance Plan carefully. If you have any questions regarding the letter or the Severance Plan, please contact [NAME] at [email].

To accept the terms of this letter and participate in the Severance Plan, please sign and date this letter in the space provided below and return the signed copy to [NAME] by [DATE] (the "Expiration Date"). If you do not return the signed copy by the Expiration Date, the terms of this letter shall be null and void and you may not participate in the Severance Plan.

Aura Biosciences, Inc.

____
Name:
Title:

Agreed and Accepted:

____
Name:
Date:

Exhibit A

Aura Biosciences, Inc. Executive Severance Plan

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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 12, 2024

By: /s/ Elisabet de los Pinos

Elisabet de los Pinos
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Amy Elazzouzi, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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 12, 2024

By: /s/ Amy Elazzouzi

Amy Elazzouzi
Vice President, Finance
(Interim Principal Financial Officer and Interim Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Aura Biosciences, Inc. (the "Company") for the period ended September 30, 2024 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 12, 2024

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

Date: November 12, 2024

By: /s/ Amy Elazzouzi
Amy Elazzouzi
Vice President, Finance
(Interim Principal Financial Officer and Interim Principal Accounting Officer)