

**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: 001-38470

**Unity Biotechnology, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**285 East Grand Ave.  
South San Francisco, CA**  
(Address of principal executive offices)

**26-4726035**

(I.R.S. Employer  
Identification No.)

**94080**

(Zip Code)

**Registrant's telephone number, including area code: (650) 416-1192**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	UBX	The Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 October 31, 2024, the registrant had 16,850,350 shares of common stock outstanding.

### Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of 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 on Form 10-Q are statements that could be deemed forward-looking statements reflecting the current beliefs and expectations of management with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. These statements are often identified by the use of words such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “if,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” “until,” and similar expressions or variations. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our plans to develop and commercialize UBX1325 (foselutoclax) or any future product candidates;
- our expectations regarding the potential benefits, activity, effectiveness, and safety of our drug candidates;
- our ongoing and planned clinical trials, including expectations with regard to the results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies;
- our predictions about the results of future or ongoing clinical trials, including predictions based on results from a clinical trial;
- our preclinical, clinical and regulatory development plans for our drug candidates, including the timing or likelihood of regulatory filings and approvals for our drug candidates;
- our expectations with regard to our ability to acquire, discover and develop additional drug candidates and advance such drug candidates into, and successfully complete, clinical studies;
- our expectations regarding the potential market size and size of the potential patient populations for our drug candidates, if approved for commercial use;
- our intentions and our ability to establish collaborations and/or partnerships;
- the timing and amount of any milestone payments we are obligated to make pursuant to our existing license agreements and any future license or collaboration agreements that we may enter into;
- our commercialization, marketing and manufacturing capabilities and expectations;
- our intentions with respect to the commercialization of our drug candidates;
- the pricing and reimbursement of our drug candidates, if approved;
- the implementation of our business model and strategic plans for our business and drug candidates, including additional indications that we may pursue;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates, including the projected terms of patent protection;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing, and our ability to obtain additional capital;
- our ability to maintain compliance with the minimum required closing bid price and the other standards for continued listing on the Nasdaq Global Select Market;
- our ability to remediate a material weakness in our internal control over financial reporting;
- developments and projections relating to our competitors and our industry, including competing therapies;
- our financial performance;

- macroeconomic trends and uncertainty, including high interest rates, rising inflation and the potential for local and/or global economic recession; and
- other risks and uncertainties, including those listed under the caption “Risk Factors”.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management’s beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections, and other information concerning our industry, our business and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by third parties, industry, medical and general publications, government data, and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

## Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission, or SEC, before making investment decisions regarding our common stock.

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, make it difficult to assess our future viability.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, other operations or commercialization efforts.
- Our financial condition raises substantial doubt as to our ability to continue as a going concern.
- We may not be able to maintain compliance with the continued listing requirements of Nasdaq and, if so, we would be subject to delisting.
- Our core therapeutic approach to slow, halt, or reverse diseases of aging is based on our understanding of cellular senescence. Utilizing senolytic molecules to treat diseases of aging is a novel therapeutic approach, which exposes us to unforeseen risks and makes it difficult to predict the time and cost of drug development and potential for regulatory approval.
- Our business is currently dependent on the successful development and regulatory approval of UBX1325.
- Other than UBX1325, all of our other programs are preclinical and face significant development risk.
- We rely on third-party suppliers to manufacture preclinical and clinical supplies of our drug candidates and we intend to continue to rely on third parties to produce such preclinical and clinical supplies as well as commercial supplies of any approved product. The loss of these suppliers, costs and availability of inputs or supplies, supply issues, or the failure of those manufacturers or suppliers to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- We face significant competition in an environment of rapid technological and scientific change, and our drug candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete.
- Our senolytic medicine platform and any future products that we commercialize could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our products. Even if we obtain regulatory approval for a drug candidate, our products will remain subject to regulatory scrutiny.
- We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our ability to accurately report the results of our operations and financial condition. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

**UNITY BIOTECHNOLOGY, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
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**PART I. FINANCIAL INFORMATION**

**Item 1. Condensed Financial Statements**

**Unity Biotechnology, Inc.**  
**Condensed Balance Sheets**  
(In thousands, except for share amounts and par value)

	September 30, 2024 (Unaudited)	December 31, 2023 <sup>(1)</sup>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 8,898	\$ 19,803
Short-term marketable securities	20,139	23,398
Prepaid expenses and other current assets	1,226	3,404
<b>Total current assets</b>	<b>30,263</b>	<b>46,605</b>
Property and equipment, net	4,414	5,082
Operating lease right-of-use assets	11,359	12,981
Long-term restricted cash	896	896
Other long-term assets	200	126
<b>Total assets</b>	<b>\$ 47,132</b>	<b>\$ 65,690</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,804	\$ 1,380
Accrued compensation	1,704	1,841
Accrued and other current liabilities	5,276	4,619
<b>Total current liabilities</b>	<b>8,784</b>	<b>7,840</b>
Operating lease liability, net of current portion	20,698	23,539
Warrant liability	3,506	5,913
<b>Total liabilities</b>	<b>32,988</b>	<b>37,292</b>
<b>Commitments and contingencies (Note 5)</b>		
<b>Stockholders' equity:</b>		
Convertible preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 16,850,350 and 16,784,969 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	516,006	512,773
Accumulated other comprehensive income (loss)	39	(24)
Accumulated deficit	(501,903)	(484,353)
<b>Total stockholders' equity</b>	<b>14,144</b>	<b>28,398</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 47,132</b>	<b>\$ 65,690</b>

<sup>(1)</sup>The balance sheet as of December 31, 2023 is derived from the audited financial statements as of that date.

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share amounts)  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 2,787	\$ 4,632	\$ 9,971	\$ 16,828
General and administrative	3,815	4,347	11,209	14,560
Impairment of long-lived assets	—	5,602	—	5,602
Total operating expenses	<u>6,602</u>	<u>14,581</u>	<u>21,180</u>	<u>36,990</u>
Loss from operations	(6,602)	(14,581)	(21,180)	(36,990)
Interest income	396	689	1,424	2,349
Interest expense	—	(566)	—	(2,451)
Gain (loss) on warrant liability	(215)	253	2,407	2,283
Other expense, net	(60)	(577)	(201)	(711)
Net loss	<u>(6,481)</u>	<u>(14,782)</u>	<u>(17,550)</u>	<u>(35,520)</u>
Other comprehensive (loss) gain				
Unrealized gain on marketable debt securities	74	81	63	196
Comprehensive loss	<u>\$ (6,407)</u>	<u>\$ (14,701)</u>	<u>\$ (17,487)</u>	<u>\$ (35,324)</u>
Net loss per share, basic and diluted	<u>\$ (0.38)</u>	<u>\$ (1.01)</u>	<u>\$ (1.04)</u>	<u>\$ (2.46)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>16,849,283</u>	<u>14,598,218</u>	<u>16,816,706</u>	<u>14,446,672</u>

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Condensed Statements of Stockholders' Equity**  
(In thousands, except share amounts)  
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2023</b>	<b>16,784,969</b>	<b>\$ 2</b>	<b>\$ 512,773</b>	<b>\$ (24)</b>	<b>\$ (484,353)</b>	<b>\$ 28,398</b>
Repurchase of early exercised shares	(3,336)	—	—	—	—	—
Vesting of restricted stock units	5,014	—	—	—	—	—
Stock-based compensation	—	—	1,394	—	—	1,394
Unrealized loss on available-for-sale marketable securities	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(5,790)	(5,790)
<b>Balances at March 31, 2024</b>	<b>16,786,647</b>	<b>\$ 2</b>	<b>\$ 514,167</b>	<b>\$ (38)</b>	<b>\$ (490,143)</b>	<b>\$ 23,988</b>
Issuance of common stock under 2018 ESPP	52,494	—	68	—	—	68
Vesting of restricted stock units	8,481	—	—	—	—	—
Stock-based compensation	—	—	974	—	—	974
Unrealized gain on available-for-sale marketable securities	—	—	—	3	—	3
Net loss	—	—	—	—	(5,279)	(5,279)
<b>Balances at June 30, 2024</b>	<b>16,847,622</b>	<b>\$ 2</b>	<b>\$ 515,209</b>	<b>\$ (35)</b>	<b>\$ (495,422)</b>	<b>\$ 19,754</b>
Vesting of restricted stock units	2,728	—	—	—	—	—
Stock-based compensation	—	—	797	—	—	797
Unrealized gain on available-for-sale marketable securities	—	—	—	74	—	74
Net loss	—	—	—	—	(6,481)	(6,481)
<b>Balances at September 30, 2024</b>	<b>16,850,350</b>	<b>\$ 2</b>	<b>\$ 516,006</b>	<b>\$ 39</b>	<b>\$ (501,903)</b>	<b>\$ 14,144</b>



	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2022</b>	<b>14,215,302</b>	<b>\$ 1</b>	<b>\$ 500,827</b>	<b>\$ (251)</b>	<b>\$ (444,493)</b>	<b>\$ 56,084</b>
Issuance of common stock, net of issuance costs, under at-the-market ("ATM") offering program	106,781	—	274	—	—	274
Vesting of restricted stock units	37,131	—	—	—	—	—
Stock-based compensation	—	—	2,175	—	—	2,175
Unrealized gain on available-for-sale marketable securities	—	—	—	101	—	101
Net loss	—	—	—	—	(5,279)	(5,279)
<b>Balances at March 31, 2023</b>	<b>14,359,214</b>	<b>\$ 1</b>	<b>\$ 503,276</b>	<b>\$ (150)</b>	<b>\$ (449,772)</b>	<b>\$ 53,355</b>
Issuance of common stock, net of issuance costs, under ATM offering program	168,000	—	518	—	—	518
Issuance of common stock under 2018 ESPP	41,497	—	91	—	—	91
Vesting of restricted stock units	26,766	—	—	—	—	—
Stock-based compensation	—	—	2,247	—	—	2,247
Unrealized gain on available-for-sale marketable securities	—	—	—	14	—	14
Net loss	—	—	—	—	(15,456)	(15,456)
<b>Balances at June 30, 2023</b>	<b>14,595,477</b>	<b>\$ 1</b>	<b>\$ 506,132</b>	<b>\$ (136)</b>	<b>\$ (465,228)</b>	<b>\$ 40,769</b>
Fees related to the ATM offering program	—	—	(48)	—	—	(48)
Vesting of restricted stock units	19,413	—	—	—	—	—
Stock-based compensation	—	—	1,705	—	—	1,705
Unrealized gain on available-for-sale marketable securities	—	—	—	81	—	81
Net loss	—	—	—	—	(14,782)	(14,782)
<b>Balances at September 30, 2023</b>	<b>14,614,890</b>	<b>\$ 1</b>	<b>\$ 507,789</b>	<b>\$ (55)</b>	<b>\$ (480,010)</b>	<b>\$ 27,725</b>

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Condensed Statements of Cash Flows**  
(In thousands)  
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
<b>Operating activities</b>		
Net loss	\$ (17,550)	\$ (35,520)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	664	951
Amortization of debt issuance costs	—	705
Debt extinguishment loss upon paydown of principal	—	491
Net accretion and amortization of premium and discounts on marketable securities	(638)	(1,199)
Gain on disposal of property and equipment	(23)	—
Stock-based compensation	3,165	6,127
Non-cash rent expense	(937)	(811)
Impairment of long-lived assets	—	5,602
(Gain) loss on warrant liability	(2,407)	(2,283)
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses and other current assets	2,178	(1,858)
Other long-term assets	(74)	52
Accounts payable	424	(642)
Accrued compensation	(137)	(793)
Accrued liabilities and other current liabilities	375	(335)
Net cash used in operating activities	<u>(14,960)</u>	<u>(29,513)</u>
<b>Investing activities</b>		
Purchase of marketable securities	(21,289)	(28,609)
Maturities of marketable securities	25,250	74,000
Purchase of property and equipment	—	(11)
Sale of property and equipment	26	1
Net cash provided by investing activities	<u>3,987</u>	<u>45,381</u>
<b>Financing activities</b>		
Payment of debt principal	—	(20,000)
Payment of debt issuance costs	—	(1,563)
Proceeds from issuance of common stock under ATM offering program, net of issuance costs	—	744
Proceeds from issuance of common stock under 2018 ESPP	68	91
Net cash provided by (used in) financing activities	<u>68</u>	<u>(20,728)</u>
Net decrease in cash, cash equivalents and restricted cash	(10,905)	(4,860)
Cash, cash equivalents and restricted cash at beginning of the period	20,699	13,632
Cash, cash equivalents and restricted cash at end of the period	<u>\$ 9,794</u>	<u>\$ 8,772</u>
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Cash paid for interest	<u>\$ —</u>	<u>\$ 1,969</u>
Cash and cash equivalents	\$ 8,898	\$ 7,876
Long-term restricted cash	896	896
Total cash, cash equivalents and restricted cash	<u>\$ 9,794</u>	<u>\$ 8,772</u>

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Notes to Condensed Financial Statements**  
**(Unaudited)**

**1. Organization**

***Description of Business***

Unity Biotechnology, Inc. (the “Company”) is a biotechnology company engaged in the research and development of therapeutics to slow, halt, or reverse diseases of aging. The Company devotes substantially all of its time and efforts to performing research and development and raising capital. The Company’s headquarters are located in South San Francisco, California. The Company was incorporated in the State of Delaware in 2009.

***Liquidity***

The accompanying condensed financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has incurred operating losses and has an accumulated deficit as a result of ongoing efforts to develop drug product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. The Company had an accumulated deficit of \$501.9 million and \$484.4 million as of September 30, 2024 and December 31, 2023, respectively. The Company had net losses of \$6.5 million and \$14.8 million for the three months ended September 30, 2024 and 2023, respectively, net losses of \$17.6 million and \$35.5 million for the nine months ended September 30, 2024 and 2023, respectively, and net cash used in operating activities of \$15.0 million and \$29.5 million for the nine months ended September 30, 2024 and 2023, respectively. To date, none of the Company’s drug product candidates have been approved for sale; therefore, the Company has not generated any product revenue. The Company anticipates operating losses and negative operating cash flows to continue for the foreseeable future. The Company has financed its operations primarily through private placements of preferred stock and promissory notes, public equity issuances and more recently, from its ATM Offering Programs, the sale of common stock and warrants under a Follow-On Offering and the Inducement Offer and will continue to be dependent upon equity and/or debt financing until the Company is able to generate positive cash flows from its operations.

The Company had cash, cash equivalents, and marketable securities of \$29.0 million as of September 30, 2024. The Company expects that its cash, cash equivalents, and marketable securities as of September 30, 2024 will not be sufficient to fund its current business plan including related operating expenditure requirements through at least 12 months from the date of issuance of these condensed financial statements are filed with the Securities and Exchange Commission (“SEC”). These conditions raise substantial doubt about the Company’s ability to continue as going concern. The Company plans to seek to address this condition by raising additional capital to finance its operations. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing. If sufficient funds on acceptable terms are not available when needed, the Company could be further required to significantly reduce its operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company’s ability to achieve its intended business objectives, or the Company may be forced to liquidate assets where possible, or to cease operations or file for bankruptcy protection. Therefore, it is not considered probable that the Company’s plans to raise additional capital nor reduce discretionary spending will alleviate the substantial doubt regarding its ability to continue as a going concern.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

These condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and the rules and regulations of the United States SEC for interim reporting.

Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted. Accordingly, the condensed financial statements should be read in

conjunction with the audited financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC.

### ***Condensed Financial Statements***

The accompanying financial information for the three and nine months ended September 30, 2024 and 2023 are unaudited. The condensed financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position as of September 30, 2024 and its results of operations for the three and nine months ended September 30, 2024 and 2023 and cash flows for the nine months ended September 30, 2024 and 2023. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other periods.

### ***Use of Estimates***

The condensed financial statements have been prepared in accordance with GAAP, which requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed financial statements and accompanying notes. The Company bases its estimates on historical experience and market-specific or other relevant assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's condensed balance sheets and the amount of expenses and income reported for each of the periods presented are affected by estimates and assumptions, which are used for, but are not limited to, determining the fair value of assets and liabilities, the fair value of right-of-use assets and lease liabilities, and stock-based compensation. Actual results could differ from such estimates or assumptions.

Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. As liability-classified financial instruments are initially and subsequently carried at fair value, the Company's financial results will reflect the volatility in these estimate and assumption changes. Changes in estimated fair value are recognized as a component of "Gain (loss) on warrant liability" in the Statements of Operations and Comprehensive Loss.

### ***Segments***

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources.

### ***Recently Issued Accounting Pronouncements Not Yet Adopted***

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The Company is currently in the process of evaluating the effects of this pronouncement on its related disclosures.

In December 2023, the Financial Accounting Standards Board (FASB) issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances the disclosures required for income taxes in the Company's annual financial statements. ASU 2023-09 is effective for the Company in its annual reporting for fiscal 2025 on a prospective basis. Early adoption and retrospective reporting are permitted. The Company does not plan to adopt this standard early. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

### 3. Fair Value Measurements

The carrying amounts of financial instruments such as cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable, accrued compensation, accrued and other current liabilities approximate the related fair values due to the short maturities of these instruments.

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

	September 30, 2024			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 7,144	\$ 7,144	\$ —	\$ —
Total cash equivalents	<u>7,144</u>	<u>7,144</u>	<u>—</u>	<u>—</u>
Short-term marketable securities:				
U.S. treasuries	14,633	—	14,633	—
U.S. government debt securities	5,506	—	5,506	—
Total short-term marketable securities	<u>20,139</u>	<u>—</u>	<u>20,139</u>	<u>—</u>
Restricted cash equivalents:				
Money market funds	896	896	—	—
Total restricted cash equivalents	<u>896</u>	<u>896</u>	<u>—</u>	<u>—</u>
Total assets subject to fair value measurements	<u>\$ 28,179</u>	<u>\$ 8,040</u>	<u>\$ 20,139</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrant Liability	\$ 3,506	\$ —	\$ —	\$ 3,506
Total liabilities subject to fair value measurements on a recurring basis	<u>\$ 3,506</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,506</u>
<b>December 31, 2023</b>				
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 12,864	\$ 12,864	\$ —	\$ —
U.S. treasuries	2,989	—	2,989	—
Total cash equivalents	<u>15,853</u>	<u>12,864</u>	<u>2,989</u>	<u>—</u>
Short-term marketable securities:				
U.S. treasuries	7,849	—	7,849	—
U.S. government debt securities	15,549	—	15,549	—
Total short-term marketable securities	<u>23,398</u>	<u>—</u>	<u>23,398</u>	<u>—</u>
Restricted cash equivalents:				
Money market funds	896	896	—	—
Total restricted cash equivalents	<u>896</u>	<u>896</u>	<u>—</u>	<u>—</u>
Total assets subject to fair value measurements	<u>\$ 40,147</u>	<u>\$ 13,760</u>	<u>\$ 26,387</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrant Liability	\$ 5,913	\$ —	\$ —	\$ 5,913
Total liabilities subject to fair value measurements on a recurring basis	<u>\$ 5,913</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,913</u>

The Company estimates the fair value of its money market funds, U.S. treasuries, and U.S. government debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

### August 2022 Warrants ("Existing Warrants")

The common stock warrants are classified as a liability on the Balance Sheets and are measured at fair value with the change in fair value recorded within "Gain (loss) on warrant liability" on the Statement of Operations and Comprehensive Loss. The estimated fair value of the outstanding common stock warrants was \$1.4 million and \$2.8 million as of September 30, 2024 and December 31, 2023, respectively.

The Company estimates the fair value of its warrant liability using a Monte Carlo simulation model based on significant inputs not observable in the market, which represents a Level 3 measurement. The Company used the following key assumptions within its valuation. In all scenarios, the Company also applied the likelihood of a fundamental transaction and the related impact on the Company's common stock price and volatility.

	September 30, 2024	
Common stock price	\$	1.47
Exercise price per share	\$	8.50
Estimated volatility		80.0%
Risk-free interest rate		3.59%
Remaining contractual term (in years)		2.89

### November 2023 Inducement Offer ("New Warrants")

In November 2023, the Company issued common stock warrants to purchase an aggregate of 2,143,000 shares of common stock at an exercise price of \$1.92 per warrant. Additionally, 128,580 common stock warrants were issued to the Placement Agent ("Placement Agent Warrants") at an exercise price of \$2.5563 per warrant. The New Warrants and Placement Agent Warrants are recorded as a liability on the Balance Sheet and are adjusted to estimated fair value at period end within "Gain (loss) on warrant liability" on the Statement of Operations and Comprehensive Loss. The estimated fair value of the New Warrants was \$2.1 million and \$3.1 million as of September 30, 2024 and December 31, 2023, respectively.

The Company estimates the fair value of its Level 3 warrant liabilities using a Monte Carlo simulation model. The Company used the following key assumptions within its valuation. In all scenarios, the Company also applied the likelihood of a fundamental transaction and the related impact on the Company's common stock price and volatility.

	September 30, 2024	
Common stock price	\$	1.47
Exercise price per share	\$	1.92 - 2.5563
Expected volatility		80.0%
Risk-free interest rate		3.58%
Remaining contractual term (in years)		4.12

The following is a roll forward of the fair value of Level 3 warrants for the three months ended September 30, 2024 (in thousands):

	Warrant Liability Fair Value	
Balance at June 30, 2024	\$	3,291
Change in fair value		215
Balance at September 30, 2024	\$	3,506

The following is a roll forward of the fair value of Level 3 warrants for the nine months ended September 30, 2024 (in thousands):

	Warrant Liability Fair Value	
Balance at December 31, 2023	\$	5,913
Change in fair value		(2,407)
Balance at September 30, 2024	\$	3,506

#### 4. Marketable Securities

Marketable securities, which are classified as available-for-sale, consisted of the following as of September 30, 2024 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
Money market funds	\$ 7,144	\$ —	\$ —	\$ 7,144
Total cash equivalents	7,144	—	—	7,144
Short-term marketable securities:				
U.S. treasuries	14,602	31	—	14,633
U.S. government debt securities	5,498	8	—	5,506
Total short-term marketable securities	20,100	39	—	20,139
Restricted cash equivalents:				
Money market funds	896	—	—	896
Total restricted cash equivalents	896	—	—	896
Total	\$ 28,140	\$ 39	\$ —	\$ 28,179

Marketable securities, which are classified as available-for-sale, consisted of the following as of December 31, 2023 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
Money market funds	\$ 12,864	\$ —	\$ —	\$ 12,864
U.S. treasuries	2,989	—	—	2,989
Total cash equivalents	15,853	—	—	15,853
Short-term marketable securities:				
U.S. treasuries	7,853	4	(8)	7,849
U.S. government debt securities	15,570	1	(22)	15,549
Total short-term marketable securities	23,423	5	(30)	23,398
Restricted Cash equivalents:				
Money market funds	896	—	—	896
Total restricted cash equivalents	896	—	—	896
Total	\$ 40,172	\$ 5	\$ (30)	\$ 40,147

At September 30, 2024, the remaining contractual maturities of available-for-sale securities were less than one year. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. As of September 30, 2024, the Company did not hold any individual securities in an unrealized loss position for 12 months or greater. The Company has the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery. No significant facts or circumstances have arisen to indicate that there has been any significant deterioration in the creditworthiness of the issuers of the securities held by the Company. The Company considered the current and expected future economic and market conditions and determined that the estimate of credit losses was not significantly impacted. Thus, there has been no change in estimate of expected credit loss during the three and nine months ended September 30, 2024 and no allowance for credit loss was recorded at September 30, 2024. The Company will continue to assess the current and expected future economic and market conditions as further development arises.

#### 5. Commitments and Contingencies

##### Leases

In February 2019, the Company entered into a lease agreement for new office and laboratory space in South San Francisco, California. The term of the lease agreement commenced in May 2019. The lease has an initial term from occupancy of approximately ten years ending on December 31, 2029 with an option to extend the term for an additional eight years at then-market rental rates. The total base rent payment escalates annually based on a fixed percentage beginning from the 13<sup>th</sup> month of the lease agreement. The Company will also be responsible for the operating

expenses and real estate taxes allocated to the building and common areas. Pursuant to the lease agreement, the landlord provided the Company with a tenant improvement allowance of \$10.7 million, which was included in deferred rent and leasehold improvements on the balance sheet at December 31, 2019. In connection with the execution of the lease agreement, the Company delivered a letter of credit of approximately \$0.9 million to the landlord. The Company had a total operating lease liability of \$24.4 million as of September 30, 2024 and \$27.0 million as of December 31, 2023. Current operating lease liability was \$3.7 million as of September 30, 2024 and \$3.5 million as of December 31, 2023, which is included in "Accrued and other current liabilities" on the Balance Sheet.

The Company's operating leases include various covenants, indemnities, defaults, termination rights, security deposits and other provisions customary for lease transactions of this nature.

In June 2021, the Company entered into an agreement to sublease a portion of the first floor of the South San Francisco, California facility, consisting of approximately 23,000 square feet, to Freenome Holdings, Inc., which ended on July 31, 2024. The base sublease rent rate was \$6.25 per rental square foot per month and increased annually by 3.5% through expiration of the agreement. Additionally, the subtenant was required to pay approximately 37% of operating expenses and property management fees that the Company is required to pay under the lease for the South San Francisco, California facility. The Company incurred initial direct costs of \$0.2 million in sublease commissions related to entering into the agreements to sublease the South San Francisco, California facility. To account for the commissions, the Company capitalized the total commissions amount and will amortize the balance over the term of the sublease. Sublease income was \$0.2 million and \$0.6 million for the three months ended September 30, 2024 and 2023, respectively, and \$1.5 million and \$1.7 million for the nine months ended September 30, 2024 and 2023, respectively, which was offset against total rent expense.

In May 2022, the Company entered into an agreement to sublease a portion of the second floor of the South San Francisco, California facility, consisting of approximately 15,000 square feet, to Initial Therapeutics, Inc. ("Initial Therapeutics"). The original sublease term commenced on July 1, 2022 and continued through June 30, 2024 and further extended through June 30, 2026 upon execution of an amendment as defined below. The base sublease rent rate is \$7.80 per rental square foot per month and will increase by 3.5% annually through the expiration of the agreement. Additionally, the subtenant is required to pay approximately 24% of operating expenses and property management fees that the Company is required to pay under the lease for the South San Francisco, California facility. The Company incurred initial direct costs of \$0.1 million in sublease commissions related to entering into the agreements to sublease the South San Francisco, California facility. To account for the commissions, the Company capitalized the total commissions amount and will amortize the balance over the term of the sublease.

On September 15, 2023, the Company entered into an amendment with Initial Therapeutics to sublease the remainder of the second floor of the South San Francisco, California facility, consisting of an additional 17,000 square feet. The sublease term will commence on October 1, 2023 and extends the existing sublease agreement that commenced on July 1, 2022 through June 30, 2026. The additional space was subleased at a monthly rent rate of \$1.00 per square foot starting a month after Initial Therapeutics first took possession of the additional space through June 30, 2024. Starting July 1, 2024, the rent rate for the entirety of Initial Therapeutics' subleased space is \$6.02 per rental square foot per month and will increase 3.5% on December 1, 2024 and 2025. Additionally, Initial Therapeutics will be required to pay approximately 51% of operating expenses and property management fees that the Company is required to pay under the lease for the South San Francisco, California facility. The Company incurred initial direct costs of \$0.3 million in sublease commissions. Sublease income from Initial Therapeutics, Inc. was \$0.9 million and \$0.4 million for the three months ended September 30, 2024 and 2023, respectively, and \$2.5 million and \$1.2 million for the nine months ended September 30, 2024 and 2023, respectively, which was offset against total rent expense.

The following table summarizes the components of lease expense and sublease income, which are included in operating expenses in the Company's Statements of Operations and Comprehensive Loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost	\$ 913	\$ 930	\$ 2,777	\$ 2,790
Variable lease cost	272	203	746	546
Sublease income	(1,067)	(976)	(4,011)	(2,904)
Total lease (income) cost	\$ 118	\$ 157	\$ (488)	\$ 432



Variable lease payments include amounts relating to common area maintenance, real estate taxes and insurance and are recognized in the Statements of Operations and Comprehensive Loss as incurred.

The following table summarizes the maturities of lease liabilities as of September 30, 2024 (in thousands):

	<b>Amount</b>
2024 (remaining 3 months)	\$ 1,250
2025	5,123
2026	5,287
2027	5,457
2028	5,633
Thereafter	5,801
<b>Total future minimum lease payments</b>	<b>28,551</b>
Less: Amount representing interest	(4,121)
<b>Present value of future minimum lease payments</b>	<b>24,430</b>
Less: Current portion of operating lease liability	(3,732)
<b>Noncurrent portion of operating lease liability</b>	<b>\$ 20,698</b>

On September 15, 2023, the Company entered into a sub-sublease agreement with GT Biopharma, Inc. to sublease a portion of its first floor at 8000 Marina Boulevard, Brisbane, California, consisting of 4,500 square feet. The sub-sublease term commenced on October 6, 2023 and ended June 30, 2024. The space was subleased at a rent rate of \$2.00 per rent square feet.

### ***Indemnifications***

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with the Company's amended and restated certificate of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable the Company to recover a portion of any future amounts paid. The Company believes that the fair value of these potential indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

### **6. Equity Financing**

The Company has 10,000,000 shares of convertible preferred stock authorized for issuance, par value of \$0.0001 per share. As of September 30, 2024 and December 31, 2023, no shares of preferred stock were issued and outstanding.

The Company has 300,000,000 shares of common stock authorized for issuance, par value of \$0.0001 per share. Holders of the Company's common stock are entitled to one vote per share. As of September 30, 2024 and December 31, 2023, there were 16,850,350 and 16,784,969 shares, respectively, of common stock issued and outstanding.

### ***Follow-On Offering***

In August 2022, the Company closed an underwritten offering (the "Follow-On Offering") in which the Company issued and sold an aggregate of 6,428,571 of the Company's common stock together with warrants (the "Existing Warrants") to purchase up to 6,428,572 of the Company's common stock at an offering price of at an aggregate offering price of \$7.00 per unit. The Existing Warrants have an exercise price of \$8.50 per warrant. The gross proceeds to the Company were \$45.0 million before deducting underwriting discounts and commissions and other offering expenses. The net proceeds of the Follow-On Offering were approximately \$41.7 million.

The Existing Warrants are exercisable at any time after their original issuance and on or prior to the five-year anniversary of the original issuance date. A holder of Existing Warrants may not exercise the warrant if the holder,

together with its affiliates, would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. As of September 30, 2024, 2,143,000 warrants have been exercised.

The Company recorded the Existing Warrants as liabilities based upon the guidance of ASC 480 and ASC 815. The Company evaluated the Existing Warrants under ASC 815-40 and concluded that they do not meet the criteria to be classified in stockholders' equity. Specifically, the settlement value in a scenario of a fundamental transaction precluded the Existing Warrants from being indexed to the Company's own stock and Company believes that the scope exception related to the occurrence of a fundamental transaction in ASC 815-40 is not met. Since the Existing Warrants meet the definition of a derivative, they are recorded as liabilities and measured at fair value at initial recognition. Any subsequent changes in their respective fair values are recognized in the Statement of Operations and Comprehensive Loss at each reporting date.

At September 30, 2024 and December 31, 2023, the Company updated the estimated fair value of the outstanding Existing Warrants using a Monte-Carlo valuation model resulting in an estimated fair value of \$1.4 million and \$2.8 million (subsequent to the exercise of the Existing Warrants as described in the section below), respectively. The change in fair value for the three months ended September 30, 2024 and 2023 of \$0.1 million and \$0.3 million, respectively, and the nine months ended September 30, 2024 and 2023 of \$1.4 million and \$2.3 million, respectively, was recorded as "Gain (loss) on warrant liability" in the Statements of Operations and Comprehensive Loss.

### ***Inducement Offer***

On November 9, 2023, the Company entered into an inducement offer letter agreement (the "Inducement Offer") with certain holders (collectively, the "Holders") of the Company's Existing Warrants to purchase up to an aggregate of 2,143,000 shares of common stock. The Holders agreed to exercise for cash their Existing Warrants to purchase an aggregate of 2,143,000 shares of common stock at a reduced exercise price of \$2.045 per share in consideration of the Company's agreement to issue new unregistered common stock purchase warrants (the "New Warrants") to purchase up to an aggregate of 2,143,000 shares of the Company's common stock.

Each New Warrant will have an exercise price equal to \$1.92 per share. The New Warrants will be exercisable on or after the initial issue date until the five-year anniversary of such date. The exercise price and number of New Warrant Shares issuable upon exercise of the New Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, subsequent rights offerings, pro rata distributions, reorganizations, or similar events affecting the Company's common stock and the exercise price.

The Company engaged H.C. Wainwright & Co., LLC (the "Placement Agent") to act as its exclusive placement agent in connection with the transactions summarized above. The Company also issued to the Placement Agent or its designees warrants to purchase up to 128,580 shares of common stock. The Placement Agent Warrants have substantially the same terms as the New Warrants, except that the Placement Agent Warrants have an exercise price equal to \$2.5563 per share.

The Company recorded the New Warrants and Placement Agent Warrants (together "2023 Warrants") as liabilities based upon the guidance of ASC 480 and ASC 815. The Company evaluated the 2023 Warrants under ASC 815-40 and concluded that they do not meet the criteria to be classified in stockholders' equity. Specifically, the settlement value in a scenario of a fundamental transaction precludes the 2023 Warrants from being indexed to the Company's own stock and Company believes that the scope exception related to the occurrence of a fundamental transaction in ASC 815-40 is not met. Since the 2023 Warrants are recorded as liabilities on the Balance Sheet at fair value, any subsequent changes in their respective fair values are recognized in the Statement of Operations and Comprehensive Loss at each reporting date.

The Company received aggregate gross proceeds of \$4.4 million from the exercise of the Existing Warrants by the Holders (the "Exercise"), before deducting placement agent fees and other offering expenses payable by the Company.

At September 30, 2024 and December 31, 2023, the Company updated the estimated fair value of the outstanding New Warrants using a Monte-Carlo valuation model resulting in an estimated fair value of \$2.1 million and \$3.1 million, respectively. The change in fair value for the three months ended September 30, 2024 and 2023 of \$0.1 million and zero, respectively, and for the nine months ended September 30, 2024 and 2023 of \$1.0 million and zero,

respectively, was recorded as "Gain (loss) on warrant liability" in the Statements of Operations and Comprehensive Loss.

## 7. Stock-Based Compensation

### *Stock Options and Restricted Stock Units (RSUs) Activity*

A summary of the Company's stock option activity under the 2013 Equity Incentive Plan, 2018 Incentive Award Plan (the "2018 Plan"), and 2020 Employment Inducement Incentive Plan for the nine months ended September 30, 2024 is as follows:

	Number of Shares	Weighted- Average Exercise Price
Balances at December 31, 2023	1,913,345	\$ 14.23
Granted	791,834	\$ 1.62
Canceled	(325,970)	\$ 4.10
Balances at September 30, 2024	<u>2,379,209</u>	\$ 11.42

A summary of the Company's restricted stock units ("RSUs") activity for the nine months ended September 30, 2024 is as follows:

	Number of Shares	Weighted- Average Grant Date Fair Value
Unvested at December 31, 2023	41,225	\$ 30.18
Granted	422,725	\$ 1.66
Vested	(16,354)	\$ 27.59
Canceled	(62,066)	\$ 1.98
Unvested at September 30, 2024	<u>385,530</u>	\$ 3.56

### *Stock Based Compensation Expense*

The following table sets forth the total stock-based compensation expense for all options granted to employees and nonemployees and costs associated with the Company's 2018 Employee Stock Purchase Plan ("2018 ESPP") included in the Company's Statements of Operations and Comprehensive Loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 56	\$ 405	\$ 494	\$ 1,801
General and administrative	741	1,300	2,671	4,326
Total	<u>\$ 797</u>	<u>\$ 1,705</u>	<u>\$ 3,165</u>	<u>\$ 6,127</u>

## 8. Net Loss per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares outstanding for the period. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period if the effect is dilutive.

The calculation of diluted loss per share also requires the consideration of the effect of dilutive potential common shares outstanding during the period determined using the treasury-stock related to the warrants outstanding.

A reconciliation of the numerators and denominators used in computing net loss from continuing operations per share is as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Numerator:</b>				
Net loss	\$ (6,481)	\$ (14,782)	\$ (17,550)	\$ (35,520)
<b>Denominator:</b>				
Weighted-average number of shares outstanding—basic and diluted	16,849,283	14,598,218	16,816,706	14,446,672
Net loss per share—basic and diluted	\$ (0.38)	\$ (1.01)	\$ (1.04)	\$ (2.46)

Since the Company was in a net loss position for all periods presented, basic net loss per common share is the same as diluted net loss per common share as the inclusion of all potential common shares outstanding would have been anti-dilutive.

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Nine Months Ended September 30,	
	2024	2023
Options to purchase common stock	2,379,209	2,003,383
Outstanding warrants to purchase common stock	6,557,152	6,428,572
Early exercised common stock subject to future vesting	—	3,336
RSUs subject to future vesting	385,530	59,365
Shares subject to future vesting relating to the 2018 ESPP	26,693	30,462
Total	9,348,584	8,525,118

Up to 3,390 shares may be contingently issued, if certain performance conditions are met under the Company's in-licensing agreements.

## Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our condensed financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2023.*

### Overview

We are a biotechnology company engaged in researching and developing therapeutics to slow, halt, or reverse diseases of aging. Our initial focus is on creating senolytic medicines to selectively eliminate senescent cells and thereby treat diseases of aging, such as ophthalmologic diseases.

In July 2020, we filed an Investigational New Drug application, or IND, to commence a Phase 1, first-in-human, open-label, single-ascending dose study of UBX1325 (foselutoclax) in patients with advanced diabetic macular edema, or DME, and neovascular age-related macular degeneration, or nAMD. Our goal with UBX1325 is to transformationally improve outcomes for patients with DME. In October 2020, the Phase 1, first-in-human, clinical study of UBX1325 commenced. That study, an open-label, single ascending dose clinical trial, evaluated doses from 0.5 – 10 µg administered as a single intra-vitreous injection in up to 8 patients with DME and 11 patients with nAMD all of whom had been off all anti-VEGF treatment due to lack of benefit for at least 6 months. The results of this study demonstrated acceptable safety and tolerability without any dose-limiting toxicities; no evidence of intraocular inflammation; and mean improvement in Best Corrected Visual Acuity (BCVA) of up to 9.5 ETDRS letters in those patients with DME receiving higher doses (5 and 10 µg) and a mean improvement in BCVA of 3.2 ETDRS letters in evaluable patients with nAMD at all doses, both at 24 weeks after treatment with UBX1325.

In May 2021, we initiated our Phase 2 BEHOLD study of UBX1325 in patients with DME and dosed our first patient in June 2021. This study was a multi-center, randomized, double-masked, sham-controlled study designed to evaluate the safety, tolerability, efficacy and durability of a single 10 µg dose of UBX1325 (foselutoclax) in patients with DME evaluated through 24 weeks. Patients had the option of rolling over to a 48-week long term extension and a majority of patients who completed their 24-week visits opted to remain in the study. A total of 65 patients were enrolled, randomized evenly between UBX1325 and sham-injected patients. These patients were being actively treated with anti-VEGF for at least 6 months prior to being randomized into the BEHOLD study (mean of 4.03 injections in the 6 months preceding randomization), and had persistent visual acuity deficits (requirement of 73 ETDRS letters or worse, equal to Snellen equivalent of approximately 20/40 or worse, where the mean of 61.4 letters at baseline was observed) and residual retinal fluid (requirement of  $\geq 300$  µm of central subfield thickness on optical coherence tomography, where the mean of approximately 439.6 µm at baseline was observed). At the time of randomization, patients were taken off of their anti-VEGF treatment, and instead treated with UBX1325 or a sham procedure. Endpoints explored in the study included safety and tolerability, changes in BCVA, CST, presence of SRF/IRF, proportion of patients requiring rescue treatment, and durability of effects.

In August 2022, we announced positive 12- and 18-week data in our Phase 2 BEHOLD study, including that a single injection of UBX1325 led to a progressive, statistically significant, and clinically meaningful improvement in mean best-corrected visual acuity compared to sham treatment. At Week 18, the mean change from baseline of BCVA for UBX1325-treated subjects was an increase of 6.1 ETDRS letters that represented a difference of +5.0 ETDRS letters compared to sham-treated subjects ( $p=0.0368$ ). In addition, patients treated with UBX1325 maintained central subfield thickness (CST) (+3.2 microns) compared to sham-treated patients who had progressive worsening (increase) in CST through 18 weeks (+53.5 microns) ( $p=0.0719$ ).

In November 2022, we announced positive 24-week data in our BEHOLD study, showing that a single injection of UBX1325 led to a statistically significant and clinically meaningful improvement in BCVA of +6.2 ETDRS letters from baseline and +7.6 ETDRS letters compared to sham treatment ( $p=0.0084$ ). Inclusive of rescue data, patients treated with UBX1325 had a mean improvement in BCVA of +6.4 ETDRS letters from baseline and +5.2 ETDRS letters compared to sham ( $p=0.0068$ ). At 24 weeks, patients treated with UBX1325 had a mean change in CST of -5.4 microns from baseline compared to a worsening (increase) of +34.6 microns in sham-treated patients ( $p=0.1244$ ). The proportion of rescue-free patients at 24 weeks was greater on UBX1325 (59.4%) as compared to sham (37.5%) with fewer total rescues and longer time-to-rescue in UBX1325-treated patients as compared to sham. UBX1325

demonstrated a favorable safety and tolerability profile with no cases of intraocular inflammation, retinal artery occlusion, endophthalmitis, or vasculitis. Patients were followed through 48 weeks post-treatment in a long-term follow-up.

In April 2023, we announced positive 48-week data from this long-term follow-up in our BEHOLD study in 50 patients who participated in the 48-week extension study, showing that a single injection of UBX1325 led to a statistically significant and clinically meaningful improvement in vision lasting for the duration of the study (48 weeks), marked by a gain of +6.2 ETDRS letters from baseline, representing a difference of +5.6 ETDRS letters compared to sham-treated patients ( $p=0.1198$ ). In addition, patients treated with UBX1325 maintained stable CST ( $-13.7 \mu\text{m}$ ) compared to worsening in sham-treated patients ( $+24.2 \mu\text{m}$ ) that did not lead to a statistical significant difference ( $p=0.2289$ ). Approximately 53% of UBX1325-treated patients did not require any additional injections through 48 weeks, compared to only 22% of patients in the sham arm. Retinal structure, as measured by central subfield thickness (CST), was maintained in UBX1325-treated patients throughout the duration of the study. UBX1325 continued to show a favorable safety and tolerability profile with no evidence of intraocular inflammation.

In December 2023, we announced that the first patients have been dosed in our Phase 2b ASPIRE study, designed to evaluate UBX1325 (foselutoclax) head-to-head against aflibercept in previously treated patients with active DME who are not achieving optimal benefit from standard of care. In August 2024, we completed enrollment of patients into the ASPIRE study in DME, which is a multi-center, randomized, double-masked, active-controlled study designed to evaluate the safety and efficacy of UBX1325 in comparison to aflibercept. Patients are randomized 1:1 to receive either 10  $\mu\text{g}$  UBX1325, or 2 mg of aflibercept control injections every eight weeks for six months. We exceeded enrollment of approximately 50 participants with DME who have residual visual acuity deficits and excess fluid in the retina despite having received at least three anti-VEGF injections in the preceding six months. All participants will receive three monthly doses of 2 mg aflibercept as a “run-in” prior to randomization. The primary efficacy endpoint will be mean change from baseline in BCVA to week 24. Secondary endpoints will include change in BCVA over time, and CST change from baseline to week 24, proportion of participants who do not require rescue, and percentage of participants with one or more treatment-emergent ocular adverse events during the course of the study.

In April 2024, we announced that the ongoing Phase 2b ASPIRE study of UBX1325 has been extended from 24 to 36 weeks to assess safety, efficacy, and potentially greater durability compared to aflibercept. There will be no scheduled treatments in either arm between 24 and 36 weeks to allow direct comparison of durability of effect between the two treatment arms. We completed enrollment in August 2024 and expect to disclose topline results from the ASPIRE study in two data readouts: 24-week primary endpoint data in the first quarter of 2025, and 36-week long-term extension data in the second quarter of 2025.

From August through September 2024, we had a Type C interaction with the U.S. Food and Drug Administration, or FDA, regarding the development of UBX1325 (foselutoclax) for DME. The objectives of this meeting were to obtain FDA input regarding the design of the pivotal trial and endpoint for regulatory approval. Based on the interaction, we expect the pivotal study would need to be a non-inferiority trial comparing UBX1325 to an approved anti-VEGF agent. The primary endpoint is expected to be an assessment of change in baseline in best-corrected visual acuity (BCVA), as assessed by the ETDRS scale with a non-inferiority margin of 4 letters.

On age-related macular degeneration (AMD), in March 2022, we enrolled our first patient in the Phase 2 ENVISION study. This study was a prospective, multicenter, randomized, double-masked, active-controlled study to assess the safety, tolerability, and evidence of activity of a repeat intravitreal injection of UBX1325 (foselutoclax) in patients with neovascular AMD. In September 2022, the study completed enrollment of patients with nAMD who have had at least two intravitreal injections of anti-VEGF therapy in the preceding six months and who still have active choroidal neovascularization and residual sub- or intra-retinal fluid. Patients were to have received their last anti-VEGF treatment approximately 4-8 weeks prior to screening, and all patients were followed for approximately 24 weeks after dosing with either UBX1325 or aflibercept.

In March 2023, we announced 16-week and 24-week data in Part A of our ENVISION study, in which UBX1325 monotherapy did not achieve non-inferiority through 24 weeks due, in part, to an unexpected 3.5 letter gain at week two in the anti-VEGF control arm. UBX1325 maintained visual acuity in patients with ongoing active disease through 24 weeks with less than one letter mean decrease from baseline ( $-0.8$  ETDRS letters at 24 weeks compared to  $+3.1$  ETDRS letters in the aflibercept control arm). Of UBX1325-treated patients, 52% did not require anti-VEGF treatment through 24 weeks. UBX1325 demonstrated a favorable safety and tolerability profile with no cases of intraocular inflammation, retinal artery occlusion, endophthalmitis, or vasculitis.

In September 2023, we announced 48-week data in Part B of our ENVISION study, in which UBX1325 demonstrated a favorable safety and tolerability profile in the combination and monotherapy arms with no cases of significant intraocular inflammation, retinal artery occlusion or endophthalmitis. Patients switched from every 8-week aflibercept to a combination of aflibercept and UBX1325 at week 24 maintained vision gains achieved with aflibercept alone through week 48. Patients in a pre-specified subgroup with poor visual acuity at baseline ( $\leq 60$  ETDRS letters) gained 3.2 ETDRS letters on combination treatment between weeks 24 and 48. In the UBX1325 monotherapy arm, patients maintained visual acuity for the duration of the study, with a mean change of +0.1 ETDRS letters at the 24-week time point and a mean change of -1.5 ETDRS letters at 48 weeks. 40% of UBX1325-treated patients did not need anti-VEGF rescue through 48 weeks and 64% of the patients achieved an anti-VEGF treatment-free period of over 24-weeks. The median time to first anti-VEGF rescue was 32 weeks.

In February 2022, and again on May 4, 2023, we announced restructuring efforts to align resources to focus on our ongoing clinical programs and deliver on key development milestones. These actions to prioritize our ophthalmology programs, optimize resource allocation, extend our runway, and implement cost saving measures were designed to enable us to achieve multiple key clinical data readouts for UBX1325. As part of the May 2023 restructuring actions, we reduced our headcount by a total of nine employees, or approximately 29%, effective as of May 31, 2023, with three employees who departed as of June 30, 2023.

On November 9, 2023, we entered into an Inducement Offer with certain holders, or Holders of existing warrants, or Existing Warrants, to purchase up to an aggregate of 2,143,000 shares of common stock, which warrants were issued to the Holders on August 22, 2022, having an exercise price of \$8.50 per share. The Holders agreed to exercise for cash their Existing Warrants to purchase an aggregate of 2,143,000 shares of common stock at a reduced exercise price of \$2.045 per share, or the Exercise, in consideration of our agreement to issue new warrants, or the New Warrants to purchase up to an aggregate of 2,143,000 shares of common stock, or the New Warrant Shares. Each New Warrant has an exercise price equal to \$1.92 per share. We received aggregate gross proceeds of approximately \$4.4 million from the Exercise, before deducting \$0.6 million in placement agent fees and other offering expenses payable by us. We also issued to the placement agent, H.C. Wainwright & Co., LLC, warrants to purchase up to 128,580 shares of common stock with an exercise price equal to \$2.5563 per share. We expect to use the net proceeds from the Inducement Offer for working capital, operating expenses to include clinical trial progression, and general corporate purposes. The resale of the New Warrant Shares and the shares underlying the warrants issued to the placement agent was registered on a Registration Statement on Form S-3 initially filed on December 6, 2023 pursuant to the terms of the Inducement Offer.

Since the commencement of our operations, we have invested a significant portion of our efforts and financial resources in research and development activities, and we have incurred net losses each year since inception. Our net losses were \$6.5 million and \$14.8 million for the three months ended September 30, 2024 and 2023, respectively, and \$17.6 million and \$35.5 million for the nine months ended September 30, 2024 and 2023, respectively. We do not have any products approved for sale, and we have never generated any product revenue. As of September 30, 2024, we had an accumulated deficit of \$501.9 million, and we do not expect positive cash flows from operations in the foreseeable future.

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. Based on our current operating plans, we expect our existing capital resources will fund our planned operating expenses into the third quarter of 2025, which will be used to advance UBX1325. Since our capital resources will fund operations less than 12 months from the date of this Quarterly Report on Form 10-Q, we concluded that these conditions raise substantial doubt about our ability to continue as a going concern. We will need to raise additional capital; however, adequate funding may not be available to us on acceptable terms, or at all, particularly in light of the current economic uncertainty, high interest rates, rising inflation, and the potential for local and/or global economic recession. We expect to continue to look for opportunities to secure such financing in the near future, in addition to using our existing 2022 ATM Offering Programs (as defined below). If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs.

We expect to continue to incur net operating losses for at least the next several years as we continue our research and development efforts, advance our drug candidates through preclinical and clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We do not expect to generate revenue from any

drug candidates that we develop until we obtain regulatory approval for one or more of such drug candidates and commercialize our products or enter into collaborative agreements with third parties.

We rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our drug candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, many of whom are single-source suppliers, for our preclinical and clinical trial materials, as well as the commercial supply of our products. In addition, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, we will incur significant expenses to develop a marketing and sales organization and commercial infrastructure in advance of generating any product sales.

## **Components of Our Results of Operations**

### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for the development of our drug candidates, which include:

- personnel-related expenses, including salaries, benefits, severance, and stock-based compensation for personnel contributing to research and development activities;
- laboratory expenses including supplies and services;
- clinical trial expenses;
- expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, research and development service providers, academic research institutions, and consultants;
- expenses related to license and sponsored research agreements; and
- facilities and other allocated expenses, including expenses for rent and facilities maintenance, and depreciation and amortization.

We expect our research and development expenses to increase as we advance our drug candidates into and through preclinical and clinical trials and pursue regulatory approval of our drug candidates. The process of conducting the clinical trials required to obtain regulatory approval is costly and time-consuming. Clinical trials generally become larger and more costly to conduct as they advance into later stages, and we are required to make estimates for expense accruals related to clinical trial expenses. The actual probability of success for our drug candidates may be affected by a variety of factors including: the safety and efficacy of our drug candidates, early clinical data, investment in our clinical program, the ability of collaborators, if any, to successfully develop any drug candidates we license to them, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our drug candidates. Program costs that are direct external expenses are tracked on a program-by-program basis once they enter clinical studies. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our drug candidates.

### ***General and Administrative Expenses***

Our general and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, audit and accounting services, and depreciation and amortization expense related to property and equipment. Personnel costs consist of salaries, benefits, severance, and stock-based compensation. We expect to continue to incur additional expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities, and other administrative and professional services.

### ***Interest Income***

Interest income is primarily related to interest earned on our marketable securities.



### ***Interest Expense***

Interest expense relates to interest on the Loan Agreement entered into on August 3, 2020 which was subsequently extinguished on September 6, 2023.

### ***Gain or Loss on Warrant Liability***

Gain or loss is primarily related to the non-cash changes in the estimated fair value of the warrants associated with the Follow-On Offering of our common stock in August 2022 and the Inducement Offer in November 2023.

### ***Other Expense, Net***

Other expense, net includes property and other taxes and foreign exchange losses from payments to international vendor, and sale of laboratory equipment. In 2023, Other expense, net included, in addition to the items above, the debt extinguishment loss associated with the unamortized debt discount.

## **Results of Operations**

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

The following table sets forth the significant components of our results of operations (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
<b>Summary of Operations Data:</b>						
<b>Operating expenses:</b>						
Research and development	\$ 2,787	\$ 4,632	\$ (1,845)	\$ 9,971	\$ 16,828	\$ (6,857)
General and administrative	3,815	4,347	(532)	11,209	14,560	(3,351)
Impairment of long-lived assets	—	5,602	(5,602)	—	5,602	(5,602)
Total operating expenses	6,602	14,581	(7,979)	21,180	36,990	(15,810)
Loss from operations	(6,602)	(14,581)	7,979	(21,180)	(36,990)	15,810
Interest income	396	689	(293)	1,424	2,349	(925)
Interest expense	—	(566)	566	—	(2,451)	2,451
Gain (loss) on warrant liability	(215)	253	(468)	2,407	2,283	124
Other expense, net	(60)	(577)	517	(201)	(711)	510
Net loss	<u>\$ (6,481)</u>	<u>\$ (14,782)</u>	<u>\$ 8,301</u>	<u>\$ (17,550)</u>	<u>\$ (35,520)</u>	<u>\$ 17,970</u>

### ***Research and Development***

Research and development expenses decreased by \$1.8 million, to \$2.8 million for the three months ended September 30, 2024 from \$4.6 million for the three months ended September 30, 2023. The decrease was primarily due to decreases of \$0.9 million in personnel costs due to our reduced headcount related to our reduction in force, \$0.8 million in direct research and development expenses mainly due to the completion of the Phase 2 BEHOLD study of UBX1325 in patients with DME and the Phase 2 ENVISION study of UBX1325 in patients with AMD, and \$0.1 million in operating costs due to reduced fixed assets depreciation and reduced office space.

Research and development expenses decreased by \$6.8 million, to \$10.0 million for the nine months ended September 30, 2024 from \$16.8 million for the nine months ended September 30, 2023. The decrease was primarily due to decreases of \$3.0 million in direct research and development expenses mainly due to the completion of the Phase 2 BEHOLD study of UBX1325 in patients with DME and the Phase 2 ENVISION study of UBX1325 in patients with AMD compared to the single Phase 2 ASPIRE study of UBX1325, \$3.0 million in personnel costs due to our reduced headcount related to our reduction in force, and \$0.8 million in operating costs due to reduced fixed assets depreciation and reduced office space.

### ***General and Administrative***

General and administrative expenses decreased by \$0.5 million, to \$3.8 million for the three months ended September 30, 2024 from \$4.3 million for the three months ended September 30, 2023. The decrease was primarily due to decreases of \$0.5 million in personnel-related expenses due to reduced headcount and the reduction in bonus and severance amounts paid as compared to 2023 and \$0.1 million in operating costs mainly from the continuation of sublease income generated from the East Grand property, partially offset by an increase of \$0.1 million in professional fees and accounting service fees.

General and administrative expenses decreased by \$3.4 million, to \$11.2 million for the nine months ended September 30, 2024 from \$14.6 million for the nine months ended September 30, 2023. The decrease was primarily due to decreases of \$2.2 million in personnel-related expenses due to reduced headcount and the reduction bonus and severance amounts paid as compared to 2023, \$0.6 million in operating costs mainly from the continuation of sublease income generated from the East Grand property, and \$0.6 million in professional fees and accounting service fees.

### ***Interest Income***

Our interest income was \$0.4 million for the three months ended September 30, 2024, as compared to \$0.7 million for the three months ended September 30, 2023, while interest income was \$1.4 million for the nine months ended September 30, 2024, as compared to \$2.3 million for the nine months ended September 30, 2023. The decrease is primarily attributable to decreased cash on hand generating interest income.

### ***Interest Expense***

Our interest expense was zero for each of the three and nine months ended September 30, 2024, and \$0.6 million and \$2.5 million for the three and nine months ended September 30, 2023, respectively, related to the Loan Agreement which was extinguished on September 6, 2023.

### ***Gain (Loss) on Warrant Liability***

Our unrealized loss was \$0.2 million and unrealized gain was \$0.3 million for the three months ended September 30, 2024 and 2023, respectively. Our unrealized gain was \$2.4 million and \$2.3 million for the nine months ended September 30, 2024 and 2023, respectively. Gain (loss) is attributable to the subsequent non-cash changes in the estimated fair value of the warrants associated with the Follow-On Offering of our common stock in August 2022 and the Inducement Offering in November 2023.

### ***Other Expense, net***

Other expense, net, was \$0.1 million and \$0.2 million for each of the three and nine months ended September 30, 2024, respectively, and was primarily due to expenses for property and other taxes. Other expense, net, was \$0.6 million and \$0.7 million for the three and nine months ended September 30, 2023, respectively, and was primarily due to the extinguishment loss from unamortized debt discount, and expenses for property and other taxes partially offset by gains on sale of laboratory equipment in either period.

## **Liquidity, Capital Resources and Capital Requirements**

### ***Sources of Liquidity***

We have incurred net losses each year since inception. We do not have any products approved for sale and have never generated any revenue from product sales. Historically, we have incurred operating losses as a result of ongoing efforts to develop our drug candidates, including conducting ongoing research and development, preclinical studies and providing general and administrative support for these operations. Our net losses were \$6.5 million and \$14.8 million for the three months ended September 30, 2024 and 2023, respectively, and \$17.6 million and \$35.5 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$501.9 million, and we do not expect positive cash flows from operations in the foreseeable future. Our future viability is dependent on our ability to raise additional capital to finance our operations. Although we have been successful in raising capital in the past, there is no assurance that we will be successful in obtaining such additional financing. If sufficient funds on acceptable terms are not available when needed, we could be further required to

significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact our ability to achieve our intended business objectives, or we may be forced to liquidate assets where possible, cease operations or file for bankruptcy protection.

Based on our current operating plans, we expect our existing capital resources will fund our planned operating expenses into the third quarter of 2025, which will be used to advance UBX1325. Since our capital resources will fund operations less than 12 months from the date of this Quarterly Report on Form 10-Q, we concluded that these conditions raise substantial doubt about our ability to continue as a going concern. We expect to incur operating losses and negative operating cash flows over at least the next several years as we continue our research and development activities, advance our drug candidate through preclinical and clinical testing and move into later and more costly stages of drug development, hire personnel and prepare for regulatory submissions and the commercialization of our drug candidates.

As a result, we will need to raise additional capital to finance its operations. Adequate funding may not be available to us on acceptable terms, or at all, particularly in light of the economic uncertainty, and potential for local and/or global economic recession. Further, if banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents, and marketable securities may be threatened, which could have a material adverse effect on our business and financial condition.

Further, based on our public float, as of the date of the filing of this Quarterly Report on Form 10-Q, we are only permitted to utilize a shelf registration statement, including the registration statements under which our ATM Offering Programs are operated, subject to Instruction I.B.6 to Form S-3, which is referred to as the "baby shelf" rule. For so long as our public float is less than \$75.0 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact our ability to achieve our intended business objectives because without substantial additional capital, we may not be able to complete pivotal trials necessary to advance our product development and our programs.

We have historically financed our operations primarily through private placements of preferred stock and promissory notes, as well as public equity issuances, such as our initial public offering, and more recently through proceeds from our Loan Agreement, our prior and existing at-the-market offering programs, the Equity Purchase Agreement, and the sale of common stock and warrants in the Follow-On Offering and the Inducement Offer (each as defined above) and we will continue to be dependent upon equity and/or debt financing to operate our business until we are able to generate positive cash flows from our operations.

In August 2020, we entered into a Loan and Security Agreement, as amended, restated, supplemented or otherwise modified, the "Hercules Loan Agreement") with Hercules Capital, Inc., or Hercules, as administrative agent and collateral agent for the lenders, and certain banks and other financial institutions or entities from time to time parties thereto, for an aggregate principal amount of up to \$80.0 million secured term loan facility, or the Hercules Facility, subject to certain terms and conditions. \$25.0 million was advanced to us on the date of execution of the Hercules Loan Agreement. In August 2022, we met certain clinical and capital raising milestones, which extended the interest only period to March 2023. On January 25, 2023, we entered into a second amendment to the Hercules Loan Agreement whereas the amortization date was extended from March 1, 2023 to April 1, 2023. As such, we continued to make interest only payments up to the amended amortization date and were required to repay the principal balance and interest in equal monthly installments through August 1, 2024. In December 2021, we entered into an amendment to the Hercules Loan Agreement under the terms of which, Hercules (including any of its assignees) had the option for a period of six (6) months to convert up to \$5.0 million of the outstanding principal under the existing loan into shares of our common stock. Under this amendment, the required cash reserve amount would be reduced by the principal amount of the converted loan to not less than \$10 million. As of December 31, 2022, we had issued 435,497 shares of our common stock reducing our outstanding loan principal balance by \$5.0 million and reducing the required cash reserve to \$10 million. In addition, the interest-only period could extend an additional three months to June 1, 2023 if specific milestones related to our clinical trials and raising additional capital by April 1, 2023 were met;

however, we did not meet all these criteria such that the amortization date remained April 1, 2023. There were no material adverse events in connection with the Hercules Loan Agreement.

In September 2023, we and Hercules entered into a payoff letter for a voluntary prepayment with respect to the Hercules Loan Agreement, or the Payoff Letter. Pursuant to the Payoff Letter, we paid a total of \$15.0 million to Hercules, representing the outstanding principal, accrued and unpaid interest, fees, costs and expenses due to Hercules under the Hercules Facility and the Hercules Loan Agreement and related loan documents, in repayment of our outstanding obligations under the Hercules Facility and the Hercules Loan Agreement and related loan documents, and thereby terminated the Hercules Loan Agreement and the Hercules Facility and related loan documents.

In March 2022, we filed the March 2022 Shelf Registration Statement and entered into the March 2022 Sales Agreement, as amended, with Cowen as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$25.0 million pursuant to the March 2022 Shelf Registration Statement as an “at-the-market” offering under the Securities Act. Cowen is entitled to up to 3.0% of the gross proceeds of any shares of common stock sold under the March 2022 Sales Agreement. During the nine months ended September 30, 2024, there were no shares of our common stock sold pursuant to the March 2022 Sales Agreement.

On August 22, 2022, we closed an underwritten offering, or the Follow-On Offering, in which we issued and sold an aggregate of 6,428,571 shares of common stock together with warrants, or the Warrants, to purchase an up to aggregate of 6,428,572 shares of common stock at an offering price of \$7.00 per unit. The Warrants have an exercise price of \$8.50 per share underlying the Warrant. The gross proceeds to us were approximately \$45 million.

On November 9, 2023, we entered into an Inducement Offer with certain Holders of Existing Warrants to purchase up to an aggregate of 2,143,000 shares of common stock, which warrants were issued to the Holders on August 22, 2022, having an exercise price of \$8.50 per share. The Holders agreed to exercise for cash their Existing Warrants to purchase an aggregate of 2,143,000 shares of common stock at a reduced exercise price of \$2.045 per share in consideration of our agreement to issue New Warrants to purchase up to an aggregate of 2,143,000 shares of New Warrant Shares. Each New Warrant has an exercise price equal to \$1.92 per share. We received aggregate gross proceeds of approximately \$4.4 million from the Exercise, before deducting placement agent fees and other offering expenses payable by us. We also issued to the placement agent, H.C. Wainwright & Co., LLC, warrants to purchase up to 128,580 shares of common stock with an exercise price equal to \$2.5563 per share. We expect to use the net proceeds from the Inducement Offer for working capital, operating expenses to include clinical trial progression, and general corporate purposes. The New Warrant Shares were registered on a Registration Statement on Form S-3 filed on December 6, 2023 pursuant to the terms of the Inducement Offer.

In October 2022, we filed the October 2022 Shelf Registration Statement and also entered into the October 2022 Sales Agreement with Cowen as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$50.0 million pursuant to the October 2022 Shelf Registration Statement as an “at-the-market” offering under the Securities Act. Cowen is entitled to up to 3.0% of the gross proceeds of any shares of common stock sold under the October 2022 Sales Agreement. There were no shares sold under the October 2022 ATM Offering Program during the nine months ended September 30, 2024.

In September 2021, we entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC (the Equity Purchase Agreement). During the term of the Equity Purchase Agreement, we initiated the purchase of 0.5 million shares of our common stock amounting to \$9.2 million in gross proceeds. The Equity Purchase Agreement expired according to its terms in September 2024.

### ***Future Funding Requirements***

To date we have not generated any product revenue. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our drug candidates, and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Moreover, since becoming a public company, we continue to incur additional ongoing costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from the commercialization of our drug candidates or from collaborative agreements with third parties, if ever, we expect to finance our future cash needs through various means. We do not have any committed external source of funds. Additional capital may be raised through the sale of our equity securities through our ATM Offering Programs or otherwise, incurring debt, entering into licensing or collaboration agreements with partners, receiving research contributions, grants or other sources of financing to fund our operations. There can be no assurance that sufficient funds will be available to us on attractive terms or at all. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to drug candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development, and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the results of our ongoing clinical trials of UBX1325 (foselutoclax);
- our ability to reduce our operating expenses;
- the scope, progress, results and costs of researching and developing our drug candidates, and conducting preclinical studies and clinical studies;
- potential delays in or an increase in costs associated with our ongoing or planned preclinical studies or clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our current drug candidates or any future drug candidates;
- the number and characteristics of any additional drug candidates we develop or acquire;
- the timing and amount of any milestone payments we are required to make pursuant to our license agreements;
- the cost of manufacturing our current drug candidates or any future drug candidates and any products we successfully commercialize;
- the cost of commercialization activities if our current drug candidates or any future drug candidates are approved for sale, including marketing, sales and distribution costs;
- 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;
- any product liability or other lawsuits related to our products;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- our ability to utilize our ATM Offering Programs and raise additional capital;
- whether or not we can maintain compliance with the continued listing requirements of Nasdaq; and
- the timing, receipt and amount of sales of any future approved products, if any.

## Cash Flows

The following table sets forth a summary of the primary sources and uses of cash, cash equivalents and restricted cash for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Cash used in operating activities	\$ (14,960)	\$ (29,513)
Cash provided by investing activities	3,987	45,381
Cash provided by (used in) financing activities	68	(20,728)
Net decrease in cash, cash equivalents and restricted cash	\$ (10,905)	\$ (4,860)

### *Operating Activities*

Cash used in operating activities of \$15.0 million for the nine months ended September 30, 2024 consisted primarily of a net loss of \$17.6 million, adjusted for changes in net operating assets and liabilities of \$2.8 million. Our non-cash charges consisted primarily of \$3.2 million in stock-based compensation and \$0.7 million in depreciation and amortization, partially offset by a \$2.4 million unrealized gain on the warrant liability, \$0.9 million in non-cash rent expense, and \$0.6 million in premium and discounts on marketable securities. The net change in our operating assets and liabilities consisted primarily of decreases of \$2.2 million in prepaid expenses, an increase of \$0.4 million in accrued and other current liabilities, and \$0.4 million in accounts payable, partially offset by an increase of \$0.1 million in other long-term assets and a decrease of \$0.1 million in accrued compensation.

Cash used in operating activities of \$29.5 million for the nine months ended September 30, 2023 consisted primarily of a net loss of \$35.5 million, adjusted for net non-cash charges of \$9.6 million and changes in net operating assets and liabilities of \$3.6 million. Our non-cash charges consisted primarily of \$6.1 million in stock-based compensation, \$5.6 million in impairment of long-lived assets, \$1.0 million in depreciation and amortization, \$0.7 million in amortization of debt issuance costs and \$0.5 million in debt extinguishment loss, partially offset by a \$2.3 million unrealized gain on the warrant liability, \$1.2 million in premium and discounts on marketable securities and \$0.8 million in non-cash rent expense. The net change in our operating assets and liabilities consisted primarily of increases of \$1.9 million in prepaid expenses and other current assets, and decreases of \$0.8 million in accrued compensation, \$0.6 million in accounts payable and \$0.3 million in accrued liabilities and other current liabilities.

### *Investing Activities*

Cash provided by investing activities of \$4.0 million for the nine months ended September 30, 2024 was related to the maturities of marketable securities of \$25.3 million, partially offset by the purchases of marketable securities of \$21.3 million.

Cash provided by investing activities of \$45.4 million for the nine months ended September 30, 2023 was related to the maturities of marketable securities of \$74.0 million, partially offset by purchases of marketable securities of \$28.6 million.

### *Financing Activities*

Cash provided by financing activities of \$0.1 million for the nine months ended September 30, 2024 was related to the \$0.1 million proceeds from issuance of common stock under the 2018 ESPP.

Cash used in financing activities of \$20.7 million for the nine months ended September 30, 2023 was primarily related to the \$20.0 million principal repayment of our long-term debt and \$1.6 million of term loan issuance costs, partially offset by \$0.8 million proceeds, net of issuance costs, from the sale of common stock through our March 2022 ATM Offering Program and \$0.1 million proceeds from issuance of common stock under the 2018 ESPP.

### **Contractual Obligations and Other Commitments**

Our contractual obligations and commitments relate primarily to our operating leases and non-cancelable purchase obligations under agreements with various research and development organizations and suppliers in the ordinary course of business. See Note 5, "Commitments and Contingencies" to our unaudited condensed financial statements for further information.

We are party to various license agreements pursuant to which we have in-licensed rights to various technologies, including patents, research “know-how” and proprietary research tools, for the discovery, research, development and commercialization of drug candidates to treat age-related diseases. The license agreements obligate us to make certain milestone payments related to specified clinical development and sales milestone events, as well as tiered royalties in the low-single digits based on sales of licensed products.

### **Indemnification**

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our certificate of incorporation and bylaws, we have potential indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

### **Critical Accounting Policies and Estimates**

There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2024 as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

### **Recent Accounting Pronouncements**

See Note 2 to our unaudited condensed financial statements, “Summary of Significant Accounting Policies,” for information.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

#### ***Cash, Cash Equivalents, and Marketable Securities***

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate sensitivities. We had cash, cash equivalents, and marketable securities of \$29.0 million as of September 30, 2024, which consist of bank deposits, money market funds, and marketable securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our chief executive and financial officers, evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on this evaluation, and as a result of the material weakness described below, our chief executive officer and chief financial officer concluded that, as of September 30, 2024, our disclosure controls and procedures were not effective at a reasonable assurance level.

As described in the Company's Annual Report filed with the SEC on April 15, 2024, management had identified a material weakness in the design and operating effectiveness of the Company's review procedures related to complex security transactions. The reviewer had insufficient technical resources supporting the assessment of the complex securities accounting model and review procedures were not performed at a level of precision to prevent or detect a material misstatement on a timely basis in the normal course of the review. Based on this assessment, management believes that our internal control over financial reporting was not effective as of December 31, 2023.

#### **Remediation Measures**

We have identified and begun to implement steps, as further described below, designed to remediate the above material weakness. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

To remediate this material weakness, we are in the process of expanding and improving our review process for complex security transactions and related accounting standards. We plan to improve this process by specifically incorporating the review of the accounting conclusions for each significant relevant contractual term, by using a robust accounting literature tool, and engaging third-party subject matter experts with relevant experience to determine the appropriate accounting for complex security transactions.

While the foregoing measures are intended to effectively remediate the material weakness described in this Item 4, it is possible that additional remediation steps will be necessary. As such, as we continue to evaluate and implement our plan to remediate the material weakness, our management may decide to take additional measures to address the material weakness or modify the remediation steps described above. Until this material weakness is remediated, we



plan to continue to perform additional analyses and other procedures to help ensure that our financial statements are prepared in accordance with GAAP.

**Changes in Internal Control over Financial Reporting**

Other than as discussed above, management determined that, as of September 30, 2024, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

We are, and from time to time may be, party to litigation and subject to claims incident to the ordinary course of business. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect our future results of operations, cash flows, or financial condition. We are not presently party to any legal proceedings that in the opinion of management, if determined to adversely affect us, may individually or taken together have a material adverse effect on our business, results of operations, cash flows, or financial condition.

### Item 1A. Risk Factors

#### Risks Related to Our Limited Operating History, Financial Condition, and Capital Requirements

***We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, make it difficult to assess our future viability.***

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not yet sought approval for commercial sale of any products and therefore have no products approved for commercial sale and have not generated any product revenue and have incurred losses in each year since our inception in March 2009. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry.

We have had significant operating losses since our inception. Our net loss for the three months ended September 30, 2024 and 2023 was approximately \$6.5 million and \$14.8 million, respectively, and \$17.6 million and \$35.5 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$501.9 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our drug candidates, conduct clinical studies and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***Our financial condition raises substantial doubt as to our ability to continue as a going concern.***

Based on our current operating plans, we expect our existing capital resources will fund our planned operating expenses into the third quarter of 2025, which will be used to advance UBX1325 (foselutoclax). Since our capital resources will fund operations less than 12 months from the date of this Quarterly Report on Form 10-Q, we concluded that these conditions raise substantial doubt about our ability to continue as a going concern. We expect to continue to incur net operating losses for at least the next several years as we continue our research and development efforts, advance our drug candidates through preclinical and clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We do not expect to generate revenue from any drug candidates that we develop until we obtain regulatory approval for one or more of such drug candidates and commercialize our products or enter into collaborative agreements with third parties.

Additionally, in recent fiscal periods, these and similar conditions have raised substantial doubt about our ability to continue as a going concern. For example, our independent registered public accounting firm included in its audit opinion for the year ended December 31, 2022 an explanatory paragraph that there was substantial doubt as to our ability to continue as a going concern. The reaction of investors to the inclusion of a going concern statement by our auditors may materially adversely affect our share price and our ability to raise new capital or enter into partnerships. While our financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, we will

need to raise additional funds. There is no assurance that funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. Failure to raise additional financing may adversely impact our ability to achieve our intended business objectives because without substantial additional capital, we may not be able to complete pivotal trials necessary to advance our product development and our programs. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

***We will require substantial additional financing to achieve our goals, and a failure to obtain this capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.***

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. Preclinical studies and clinical studies for our drug candidates and additional research and development activities to discover and develop new drug candidates will require substantial funds to complete. As of September 30, 2024, we had capital resources consisting of cash, cash equivalents, and marketable securities of \$29.0 million. We believe that we will continue to expend substantial resources for the foreseeable future in connection with our programs, including the clinical development of UBX1325, and the development of any other drug candidates we may choose to pursue. These expenditures will include costs associated with conducting preclinical studies and clinical studies, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current drug candidates or any future drug candidates.

In February 2022, and again on May 4, 2023, we announced restructuring efforts to align resources to focus on our ongoing clinical programs and deliver on key development milestones. These actions to prioritize our ophthalmology programs, optimize resource allocation, extend our runway, and implement cost saving measures were designed to enable us to achieve multiple key clinical data readouts for UBX1325. As part of the May 2023 restructuring actions, we reduced our headcount by a total of nine employees, or approximately 29%, effective as of May 31, 2023, with three employees who departed as of June 30, 2023.

Based on our current operating plans, we expect our existing capital resources will fund our planned operating expenses into the third quarter of 2025, which will be used to advance UBX1325. Since our capital resources will fund operations less than 12 months from the date of this Quarterly Report on Form 10-Q, we concluded that these conditions raise substantial doubt about our ability to continue as a going concern.

We will need substantial additional capital to operate our business and continue our development activities and without substantial additional capital, we may not be able to complete pivotal trials necessary to advance our product development and our programs. If funding is only available on less desirable terms or not available at all for companies in the life sciences industry or if we are unable to access our cash deposits held at financial institutions due any liquidity concerns at such financial institutions, our business and operations would be adversely affected.

To date, we have primarily financed our operations through the sale of equity securities. For example, in March 2022, we filed a Registration Statement on Form S-3 covering the offering of up to \$125.0 million of common stock, preferred stock, debt securities, warrants and units, which was declared effective by the SEC in May 2022, or the March 2022 Shelf Registration Statement. In March 2022, we also entered into a sales agreement, or the March 2022 Sales Agreement, with Cowen and Company, LLC, or Cowen, as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$25.0 million pursuant to the March 2022 Shelf Registration Statement as an “at-the-market” offering under the Securities Act, or the March 2022 ATM Offering Program. Further, in October 2022, we filed a Registration Statement on Form S-3 covering the offering of up to \$250.0 million of common stock, preferred stock, debt securities, warrants and units, or the October 2022 Shelf Registration Statement and, together with the March 2022 Shelf Registration Statement, the shelf registration statements. In October 2022, we also entered into a sales agreement with Cowen as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$50.0 million pursuant to the October 2022 Shelf Registration Statement as an “at-the-market” offering under the Securities Act, or the October 2022 ATM Offering Program, and, together with the March 2022 ATM Offering Program, the ATM Offering Programs.

We will be required to seek additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. Such financing may result in dilution to stockholders and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. For example, financial markets have been negatively affected by high interest rates, rising inflation, and the potential for local and/or global economic recession. Such impacts may be exacerbated by unforeseen events or public health emergencies. Adequate funding may not be available to us on acceptable terms, or at all, particularly in light of these conditions. 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.

We currently have shelf registration statements effective and existing ATM Offering Programs, however, our ability to raise capital under these registration statements and through these ATM Offering Programs may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Based on our public float, as of the date of the filing of this Annual Report on Form 10-K, we are only permitted to utilize a shelf registration statement, including the registration statements under which our ATM Offering Programs are operated, subject to Instruction I.B.6 to Form S-3, which is referred to as the “baby shelf” rule. For so long as our public float is less than \$75.0 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

Our future capital requirements depend on many factors, including:

- the results of our ongoing clinical trials of UBX1325 (foselutoclax);
- our ability to reduce our operating expenses;
- the scope, progress, results and costs of researching and developing our drug candidates, and conducting preclinical studies and clinical studies;
- potential delays in or an increase in costs associated with our ongoing or planned preclinical studies or clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our current drug candidates or any future drug candidates;
- the number and characteristics of any additional drug candidates we develop or acquire;
- the timing and amount of any milestone payments we are required to make pursuant to our license agreements;
- the cost of manufacturing our current drug candidates or any future drug candidates and any products we successfully commercialize;
- the cost of commercialization activities if our current drug candidates or any future drug candidates are approved for sale, including marketing, sales and distribution costs;
- 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;
- any product liability or other lawsuits related to our products;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio;

- our ability to utilize our ATM Offering Programs and raise additional capital;
- whether we can maintain compliance with the continued listing requirements of Nasdaq; and
- the timing, receipt and amount of sales of any future approved products, if any.

Additional and sufficient funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis and if we do not manage discretionary spending, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for our current drug candidates or any future drug candidate;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our current drug candidates or any future drug candidate, or reduce our flexibility in developing or maintaining our sales and marketing strategy; or
- liquidate assets where possible, cease operations or file for bankruptcy protection.

We also could choose or be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or drug candidates that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until our drug candidates are clinically tested, approved for commercialization and successfully marketed.

***We may not be able to maintain compliance with the continued listing requirements of Nasdaq, and, if so, we would be subject to delisting.***

Our common stock is currently listed for trading on the Nasdaq Global Select Market under the symbol “UBX”. The continued listing of our common stock on Nasdaq is subject to our compliance with a number of listing standards. On June 3, 2022, we received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC indicating that for the last 30 consecutive business days, the closing bid price of our common stock was below \$1.00 per share, which is the minimum required closing bid price for continued listing on the Nasdaq Global Select Market pursuant to Listing Rule 5450(a)(1). We had 180 calendar days, or until November 30, 2022, to regain compliance. To regain compliance, the closing bid price of our common stock needed to be at least \$1.00 per share for a minimum of ten consecutive business days. On October 19, 2022, we effected a 1-for-10 reverse stock split of our common stock seeking to regain compliance with Nasdaq Global Select Market's continued listing standards. From October 20, 2022 to November 2, 2022 (10 consecutive business days), the closing bid price of our common stock exceeded \$1.00 per share. Accordingly, on November 3, 2022, we received a notice from Nasdaq indicating that we have regained compliance with Listing Rule 5450(a)(1) as of such date.

Although we currently comply with the minimum bid requirement following the reverse stock split, our bid price could fall below \$1.00 per share again in the future, in which event we would receive another deficiency notice from Nasdaq advising us that we have 180 days to regain compliance by maintaining a minimum bid price of at least \$1.00 for a minimum of ten consecutive business days. Under certain circumstances, Nasdaq could require that the minimum bid price exceed \$1.00 for more than ten consecutive days before determining that a company complies. If we fail to satisfy the Nasdaq's continued listing requirements, we may transfer to the OTC Bulletin Board. Having our common stock trade on the OTC Bulletin Board could adversely affect the liquidity of our common stock. Any such transfer could make it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further and adversely impact the ability of stockholders to sell our common stock. We may also face other material adverse consequences in such event such as negative publicity, a decreased

ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, any of which may contribute to a further decline in our stock price.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.***

Our quarterly and annual operating results may fluctuate significantly, making it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing, cost and level of investment in research, development and, if approved, commercialization activities relating to our drug candidates, which may change from time to time;
- the timing and status of enrollment for our clinical studies;
- the cost of manufacturing our drug candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures we may incur to acquire, develop or commercialize additional drug candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical studies for our drug candidates or competing drug candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our drug candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our drug candidates, if approved, and potential future drugs that compete with our products;
- the level of demand for our products, if approved, which may vary significantly over time; and
- potential disruption caused by unforeseen events and public health emergencies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

#### **Risks Related to Our Business and Product Development**

***Our core therapeutic approach to slow, halt, or reverse diseases of aging is based on our understanding of cellular senescence. Utilizing senolytic molecules to treat diseases of aging is a novel therapeutic approach, which exposes us to unforeseen risks and makes it difficult to predict the time and cost of drug development and potential for regulatory approval.***

Our foundational science and lead drug candidate are based on senescence biology. We believe that we can develop drug candidates capable of eliminating or modulating accumulated senescent cells, when administered locally. In our development efforts we intend to explore senolytic medicines that use multiple modalities. However, our approach to treating diseases of aging is novel and the scientific research that forms the basis of our efforts to develop senolytic medicines is ongoing. We have only recently begun testing our senolytic molecules in humans and the majority of our

current data supporting our hypothesis regarding senescence biology is limited to pre-clinical animal models and in vitro cell lines, the results of which may not translate into humans. We currently have no conclusive evidence in humans, that the accumulation or modulation of senescent cells is the underlying cause of tissue damage and dysfunction associated with many diseases of aging. For example, in August 2020, we announced the 12-week results from our Phase 2 study of UBX0101 in patients with moderate-to-severe painful OA of the knee. There was no statistically significant difference between any arm of UBX0101 and placebo at the 12-week primary endpoint for change from baseline in WOMAC-A, an established measurement of pain in OA. Given these results, we decided not to progress UBX0101 into pivotal studies and have narrowed our near-term focus mainly to our ongoing ophthalmologic disease programs.

Our current program, UBX1325 (foselutoclax), is a BCL-xL inhibitor, and is intended to target senescent cells in the eye. While cellular senescence is a naturally occurring biological process, the administration of senolytic medicines to eliminate or cause the elimination or modulation of accumulated senescent cells in humans has not been widely tested and may potentially harm healthy tissue or result in unforeseen safety events or fail to achieve the intended therapeutic purpose entirely. We may also ultimately discover that our senolytic molecules do not possess certain properties required for therapeutic effectiveness, or that even if found to be effective in one type of tissue, that such molecules will be effective in other tissues. In addition, given the novel nature of this therapeutic approach, designing preclinical and clinical studies to demonstrate the effect of senolytic medicines is complex and exposes us to unforeseen risks. In addition, the scientific evidence to support the feasibility of developing systemic senolytic medicines is based primarily on preclinical data and not human clinical trials. We may spend substantial funds attempting to develop these drug candidates and never succeed in doing so.

No regulatory authority has granted approval for a senolytic medicine. As such, we believe the U.S. Food and Drug Administration, or the FDA, has limited experience with senescence, which may increase the complexity, uncertainty and length of the clinical development and regulatory approval process for our drug candidates. We may never receive approval to market and commercialize any drug candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be required to perform additional or unanticipated clinical studies to obtain approval or be subject to post-marketing testing requirements to maintain marketing authorization. If our other senolytic molecules prove to be ineffective, unsafe or commercially unviable, our entire senolytic platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our business is currently dependent on the successful development of UBX1325, which is in early stages of clinical development.***

We have no products approved for sale and all of our drug candidates are in early stages of development. We have one product candidate, UBX1325, in clinical development and are focused on advancing our ophthalmology program. In particular, in October 2020, we initiated a Phase 1 clinical study of UBX1325 in patients with DME or nAMD for whom anti-VEGF therapy was no longer considered beneficial, and in July, October, and November 2021, we announced positive data up to 24 weeks from this Phase 1 study. We initiated a Phase 2 proof-of-concept clinical study of UBX1325 in DME (BEHOLD) in May 2021, dosed the first patient in June 2021 and announced positive 24-week safety and efficacy data in November 2022, and announced positive 48-week safety and efficacy data in April 2023. In April 2022 we also dosed our first patient in our Phase 2 proof-of-concept study in nAMD (ENVISION), and we shared 16- and 24-week data in March 2023, and 48-week data in September 2023. We completed enrollment in our head-to-head Phase 2b (ASPIRE) study to explore the efficacy of UBX1325 in patients with DME compared to the current standard of care, aflibercept. We expect to disclose topline results from the ASPIRE study in two data readouts: 24-week primary endpoint data in the first quarter of 2025, and 36-week long-term extension data in the second quarter of 2025. We expect to disclose topline results from the ASPIRE study in two data readouts: 24-week primary endpoint data in the first quarter of 2025, and 36-week long-term extension data in the second quarter of 2025.

In February 2022, and again on May 4, 2023, we announced restructuring efforts to align resources to focus on our ongoing clinical programs and deliver on key development milestones. These actions to prioritize our ophthalmology programs, optimize resource allocation, extend our runway, and implement cost saving measures were designed to enable us to achieve multiple key clinical data readouts for UBX1325. As a result, our business, including our ability to finance our company and generate any revenue in the future, is currently dependent on the successful development of UBX1325. If UBX1325 does not demonstrate clinical benefit, we may be required to significantly delay or abandon

its development. In the event UBX1325 is not successful in clinical development, we have limited resources and capital with which to develop additional drug candidates and we may be forced to sell or liquidate our business.

The clinical and commercial success of UBX1325, and any other future drug candidates, will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND-enabling studies and successfully submit an IND or comparable applications in foreign jurisdictions;
- timely completion of our preclinical studies and clinical studies, which may be significantly slower, or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors, some of whom could be adversely impacted by unforeseen events such as pandemics and public health emergencies;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical studies or other studies beyond those planned to support the approval and commercialization of our drug candidates or any future drug candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our drug candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy, and acceptable risk-to-benefit profile of our current drug candidates or any future drug candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our drug candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our current drug candidates or any future drug candidates or approved products, if any;
- the willingness of physicians, professional societies, operators of clinics, hospitals, and patients to recommend, utilize, or adopt any of our future drug candidates to treat diseases of aging;
- the ability of third parties with whom we contract to manufacture adequate clinical study and commercial supplies of our current drug candidates or any future drug candidates, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our drug candidates or any future drug candidates in the United States, and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors, and patients of the benefits, safety, and efficacy of our drug candidates or any future drug candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our drug candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our drug candidates or any future drug candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges, or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or be unable to obtain regulatory approvals or commercialize our drug candidates. Even if regulatory approvals are obtained, we may



never achieve success in commercializing any of our drug candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our drug candidates or any future drug candidates to continue our business or achieve profitability.

***Other than UBX1325, all of our other programs are preclinical and face significant development risk.***

Other than UBX1325, all of our other programs are in preclinical and early research stage. In addition, we have limited resources for which to develop any products other than UBX1325. Given the early stage nature of these programs, each of the drug candidates and programs faces substantial development risk. UBX1325 is the only current drug candidate that we have administered to humans, and as such, we face significant translational risk with our earlier stage drug candidates. We may also be required by the FDA or similar foreign regulatory agencies to conduct additional preclinical studies beyond those planned to support the commencement of additional clinical trials. Accordingly, there can be no assurance that we are able to bring any of our preclinical product candidates or development programs into the clinic or otherwise successfully develop them.

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical study process. Success in preclinical studies and early clinical studies does not ensure that later clinical studies will be successful. A number of companies in the biotechnology, and pharmaceutical industries have suffered significant setbacks in clinical studies, even after positive results in earlier preclinical studies or clinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. The results of our preclinical animal studies or studies in ex vivo human tissues may not be predictive of the results of outcomes in human clinical studies. For example, our senolytic molecules may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways.

Drug candidates in later stages of clinical studies may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical studies. Notwithstanding any promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if we are able to initiate and complete clinical studies, the results may not be sufficient to obtain regulatory approval for our drug candidates.

We cannot be certain that studies or trials for our drug candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. Future pandemics or public health emergencies could cause or exacerbate these factors. For example, for our Phase 2 studies for UBX1325 and future studies, clinical sites may be unable to recruit and retain investigators and study staff, screen and enroll patients, patients may be unable to adhere to the study visit schedule, and the completion of the study could be delayed. Clinical studies can be prolonged, delayed or terminated for a variety of reasons, including:

- the FDA or comparable foreign regulatory authorities disagreeing with or requiring changes to the design or implementation of our clinical studies;
- delays in obtaining regulatory approval to commence or continue a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each trial site;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- encountering difficulties in gathering the range of biological data from patients needed to fully assess the impact of our drug candidates;
- clinical sites deviating from trial protocol or dropping out of a trial;

- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical study sites; or
- obtaining sufficient product supply of drug candidate for use in preclinical studies or clinical studies from third-party suppliers some of whom could be adversely impacted by unforeseen events such as pandemics and public health emergencies.

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

- clinical studies of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to modify clinical study design, conduct additional clinical studies or abandon drug development programs, including all of our senolytic programs;
- the number of patients required for clinical studies of our drug candidates may be larger than we anticipate, enrollment in these clinical studies may be slower than we anticipate, or participants may drop out of these clinical studies at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical studies of our drug candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical studies of our drug candidates for various reasons, including noncompliance with regulatory requirements, a finding that our drug candidates have undesirable side effects or other unexpected characteristics, a finding that the participants are being exposed to unacceptable health risks, or due to unforeseen events such as pandemics and public health emergencies;
- the cost of clinical studies of our drug candidates may be greater than we anticipate;
- the quality of our drug candidates or other materials necessary to conduct preclinical studies or clinical studies of our drug candidates may be inadequate;
- regulators may revise the requirements for approving our drug candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical studies in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical studies or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical studies of our drug candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive, or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our drug candidates or fail to obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the treatment removed from the market after obtaining marketing approval.

We could also encounter delays if a clinical study is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA

or other regulatory authorities. Such authorities may suspend or terminate a clinical study due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols, inspection of the clinical study operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study.

Further, conducting clinical studies in foreign countries, as we may do for certain of our drug candidates, presents additional risks that may delay completion of our clinical studies. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries, including those caused by unforeseen events such as pandemics and public health emergencies similar to the COVID-19 pandemic.

Moreover, in January 2024, the U.S. House of Representatives introduced the BIOSECURE Act (H.R. 7085) and the Senate advance a substantially similar bill (S.3558), which legislation, if passed and enacted into law, would have the potential to restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies “of concern” without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do business with companies in China, and it is possible some of our contractual counterparties could be impacted by this legislation.

Principal investigators for our clinical studies may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future drug candidates.

If we experience termination or delays in the completion of any preclinical study or clinical study of our drug candidates, the commercial prospects of our drug candidates may be harmed, and our ability to generate revenues from any of these drug candidates will be delayed or unrealized. In addition, any delays in completing our clinical studies may increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. If one or more of our drug candidates or our senescence technology generally prove to be ineffective, unsafe or commercially unviable, our platform and pipeline would have significantly diminished value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects and we may be forced to sell or liquidate our business.

***If we encounter difficulties enrolling patients in our clinical studies, our clinical development activities could be delayed or otherwise adversely affected.***

The timely completion of clinical studies in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical studies for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial’s primary endpoints;
- the proximity of patients to trial sites;
- patients’ fear of visiting or traveling to trial sites due to pandemics and public health emergencies;
- the design of the trial;
- our ability to recruit clinical study investigators with the appropriate competencies and experience;

- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient consents.

In addition, our clinical studies may compete with other clinical studies for drug candidates that are in the same therapeutic areas as our drug candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical studies at the same clinical study sites that some of our competitors use, which will reduce the number of patients who are available for our clinical studies in such clinical study site.

Further, the administration of senolytic medicines designed to eliminate or cause the elimination of senescent cells and thereby modulate their associated SASP may result in unforeseen events, including by harming healthy tissues. As a result, it is possible that safety concerns could negatively affect patient enrollment among the patient populations that we intend to treat, including among those in indications with a low risk of mortality. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical studies, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is 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 preliminary 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 or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data is available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may conduct are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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 or product, our ability to make certain claims about our products, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent products***

*from being developed, approved, or commercialized in a timely manner or at all, which may adversely affect our business.*

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of other government agencies 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, including a prolonged government shutdown, may cause significant regulatory delays and, therefore, delay our efforts to seek approvals and adversely affect our business, financial condition, results of operations, or cash flows. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

*Our drug candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.*

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Other than our clinical studies of UBX0101 and UBX1325 (foslutoclax), senolytic medicines designed to eliminate or cause the elimination of senescent cells have never been tested in humans. As a result, although UBX1325 has been well tolerated in our Phase 1 and Phase 2 clinical studies with no adversities that would prevent advancement into later stage clinical trials as of the date of this Annual Report on Form 10-K, UBX1325 could reveal a high and unacceptable severity and prevalence of side effects, and it is possible that patients enrolled in such clinical studies could respond in unexpected ways. For instance, in preclinical in vivo animal and ex vivo human tissue studies, our senolytic molecules have exhibited clearance of senescent cells; however, the elimination of accumulated senescent cells may result in unforeseen events, including harming healthy cells or tissues. In addition, the entry by cells into a senescent state is a natural biological process that we believe may have protective effects, such as halting the proliferation of damaged cells. The treatment of tissues with senolytic molecules could interfere with such protective processes.

If unacceptable side effects arise in the development of our drug candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical studies, or the FDA or comparable foreign regulatory authorities could order us to cease clinical studies or deny approval of our drug candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our drug candidates to understand the side effect profiles for our clinical studies and upon any commercialization of any of our drug candidates. Inadequate training in recognizing or managing the potential side effects of our drug candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, even if we successfully advance any of our drug candidates into and through clinical studies, such trials will likely only include a limited number of subjects and limited duration of exposure to our drug candidates. As a result, we cannot be assured that adverse effects of our drug candidates will not be uncovered when a significantly larger number of patients are exposed to the drug candidate. Further, clinical studies may not be sufficient to determine the effect and safety consequences of taking our drug candidates over a multi-year period. There can be no assurance that it will demonstrate a similarly favorable safety profile in subsequent clinical trials.

If any of our drug candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our drug candidates or our senescence approach generally prove to be unsafe, our entire platform and pipeline could be affected, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We may not be successful in our efforts to continue to create a pipeline of drug candidates or to develop commercially successful products. If we fail to successfully identify and develop additional drug candidates, our commercial opportunity may be limited.***

We are committed to developing senolytic medicines that slow, halt, or reverse diseases of aging, and we are currently advancing multiple senolytic molecules to address a variety of diseases of aging, including ophthalmologic disorders. As senolytic medicines are not limited to intervention by a single mode of action or molecular target, we believe that we can modulate a number of biologic pathways in order to trigger the beneficial elimination of senescent cells. However, our core therapeutic approach is based on our belief that senescent cells drive diseases of aging, and that hypothesis has not yet been proven. In addition, we do not know if we will be able to develop medicines that selectively eliminate senescent cells or whether the elimination of such senescent cells will mitigate the effects of or effectively treat any diseases.

In addition, identifying, developing, obtaining regulatory approval and commercializing drug candidates for the treatment of diseases of aging will require substantial additional funding and is prone to the risks of failure inherent in drug development. Research programs to identify drug candidates also require substantial technical, financial and human resources, regardless of whether or not any drug candidates are ultimately identified, and even if our preclinical research programs initially show promise in identifying potential drug candidates, they may fail to yield drug candidates for clinical development.

While we have a number of drug discovery programs targeting senescent cells, we do not know whether these will be successful, or whether we will be able to identify novel senolytic mechanisms to continue to build our pipeline. We also cannot provide any assurance that we will be able to successfully identify or acquire additional drug candidates, advance any of these additional drug candidates through the development process, successfully commercialize any such additional drug candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional drug candidates. If we are unable to successfully identify, acquire, develop and commercialize additional drug candidates, our commercial opportunities may be limited.

***We may be unable to obtain regulatory approval for our drug candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our drug candidates and adversely impact our potential to generate revenue, our business and our results of operations.***

To gain approval to market our drug candidates, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety and efficacy of the drug candidate for the intended indication applied for in the applicable regulatory filing. For our senolytic medicines, we must also demonstrate that eliminating or causing the elimination of senescent cells and modulating relevant associated SASP factors will lead to the improvement of well-defined and measurable endpoints.

We have not previously submitted an NDA, or biologics license application, or BLA, to the FDA, or similar approval filings to comparable foreign regulatory authorities. An NDA, BLA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the drug candidate is safe and effective, or that a biological drug candidate is safe, pure and potent for each desired indication. The NDA, BLA or

other relevant regulatory submission must also include significant information regarding the chemistry, manufacturing and controls for the product.

The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our drug candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our drug candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that any of our drug candidates is safe and effective for the requested indication;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical studies;
- our inability to demonstrate that the clinical and other benefits of any of our drug candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical studies;
- the FDA's or the applicable foreign regulatory agency's failure to approve the formulation, labeling or specifications of our current or future drug candidates, including UBX1325;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers upon which we rely; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner that renders our clinical data insufficient for approval.

Of the large number of biopharmaceutical and pharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval from the FDA or applicable foreign agencies for any of our drug candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical studies which may be required after approval. The FDA or the applicable foreign regulatory agency also may approve our current drug candidates for limited indications or narrower patient populations than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve our drug candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such drug candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our drug candidates and would materially adversely impact our business and prospects.

***Even if our current drug candidates or any future drug candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.***

Even if one or more of our drug candidates receive FDA or other regulatory approvals, the commercial success of any of our current or future drug candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our drug candidates may not be commercially successful for a variety of reasons, including: competitive factors, pricing or physician preference, reimbursement by insurers, and the degree and rate of physician and patient adoption of our current or future drug candidates. If approved, the commercial success of our drug candidates will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;

- the availability of coverage and adequate reimbursement from managed care plans, insurers and other healthcare payors for any of our drug candidates that may be approved;
- acceptance by physicians, operators of clinics, and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our drug candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, or public bias against “anti-aging” companies;
- patient satisfaction with the results and administration of our drug candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our drug candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payers, physicians and patients;
- the willingness of patients to pay for certain of our products, if approved;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our products;
- the willingness of physicians, operators of clinics and patients to utilize or adopt our products as a solution;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future drug candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our drug candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

***We rely on third-party suppliers to manufacture supplies of our drug candidates and we intend to continue to rely on third parties to produce such preclinical and clinical supplies as well as commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

We do not have the infrastructure or capability internally to manufacture supplies of our drug candidates or the materials necessary to produce our drug candidates for use in the conduct of our clinical studies, and we lack the internal resources and the capability to manufacture any of our drug candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our drug candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of our drug candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our drug candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates.



We currently intend to supply all of our drug candidates in all territories for our planned clinical development programs. We currently rely on third parties at key stages in our supply chain. For instance, the supply chains for our current drug candidates involve several manufacturers that specialize in specific operations of the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing and drug product manufacturing. As a result, the supply chain for the manufacturing of our drug candidates is complicated and we expect the logistical challenges associated with our supply chain to grow more complex as our drug candidates progress through the clinical trial process. Some of these third parties have in the past and may in the future also be adversely impacted by unforeseen events and public health emergencies. For example, one of the manufacturers in our supply chain for UBX0101 experienced a two-week shutdown in April 2020 due to a COVID-19 related incident. While this incident did not impact our supply of UBX0101 for clinical studies being conducted in April 2020, there can be no assurance that our supply chain for any of our candidates and clinical trials will not be disrupted in the future due to such incidents.

We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. Further, we have not yet engaged any manufacturers for the commercial supply of our current drug candidates. Although we intend to enter into such agreements prior to commercial launch of any of our drug candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. We generally do not begin a preclinical study and we do not intend to initiate any clinical studies unless we believe we have access to a sufficient supply of a drug candidate to complete such study or trial. In addition, any significant delay in, or quality control problems with respect to, the supply of a drug candidate, or the raw material components thereof, for an ongoing study or trial could considerably delay completion of our preclinical studies or future clinical studies, product testing and potential regulatory approval of our drug candidates.

Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial supply of our drug candidates, we will have no other means of producing our current drug candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues.

Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our drug candidates on a timely basis.

Further, to manufacture our current drug candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers would likely need to increase manufacturing capacity and, in some cases, we would need to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our drug candidates on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the commercial launch of our current drug candidates or any future drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such drug candidates, if approved.

***If we fail to attract and retain key personnel, we may be unable to successfully develop our current drug candidates or any future drug candidates, conduct our clinical studies and commercialize our current or any future drug candidates.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and employees. In February 2022, and again on May 4, 2023, we announced restructuring actions to advance corporate strategy and focus on key ophthalmology programs and, as of May 2023, the UBX1325 program in DME in particular. As a result of the restructuring and other factors, additional unplanned loss of personnel may occur despite our efforts to retain management and employees. Additionally, continued disruption caused by the transition or by the loss of

ongoing services of any other members of our management or employees could delay or prevent the successful development of our ongoing programs, initiation or completion of our planned clinical studies or the commercialization of our current drug candidates or any future drug candidates. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry, and we may not be able to adequately address attrition, including unplanned, attrition, and as a result, the timely completion of our clinical trials could be jeopardized. Further, our ability to attract and retain highly qualified management and employees relies in part on our ability to offer competitive compensation and equity packages to such key personnel. We use restricted stock units, or RSUs, and stock options as a key component of compensation for key employees in order to align employee interests with the interests of our stockholder, provide competitive compensation packages, and encourage employee retention. Our stock price volatility or lack of positive performance may cause periods of time during which option exercise prices might be less than the sale price of our common stock or the value of RSUs might be less competitive, which may lessen the retentive attributes of these awards. We are also limited as to the number of equity awards that we may grant under our stock plans, and we are unsure how effective different stock-based awards with different vesting schedules will be to retain key employees. As a result, we may have to incur increased compensation costs, change our equity compensation strategy, or find it difficult to attract, retain and motivate employees.

***We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.***

We rely on third-party suppliers for the raw materials required for the production of our drug candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, and quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our drug candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our drug candidates, including limiting supplies necessary for clinical studies and regulatory approvals, which would have a material adverse effect on our business.

We rely on third parties in the conduct of critical portions of our preclinical studies and intend to rely on third parties in the conduct of critical portions of our future clinical studies. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our drug candidates. Some of these third parties may also be adversely impacted by unforeseen events and public health emergencies.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical studies. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical studies, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical studies. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical studies on our drug candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical studies play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical studies, we remain responsible for ensuring that each of our GLP preclinical studies and clinical studies is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, potentially including our competitors, for whom they may also be conducting clinical studies or other drug development activities that could harm our competitive position. If the third parties conducting our preclinical studies or our clinical studies do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical studies may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable drug candidate, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

***We face significant competition in an environment of rapid technological and scientific change, and our drug candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete.***

The biotechnology and pharmaceutical industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical study expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for drug candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, certain of our drug candidates, if approved, may compete with other products that treat diseases of aging, including over the counter, or OTC, treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

We are aware of other companies seeking to develop treatments to prevent or treat diseases of aging through various biological pathways. Within our lead senolytic program in ophthalmology diseases, our drug candidates would compete against current therapies from a wide range of companies and technologies, including current standard of care treatments such as anti-VEGF antibodies (bevacizumab, ranibizumab, aflibercept, brolocizumab), bispecific antibodies (faricimab), intravitreal steroid (dexamethasone), high-dose Eylea, complement inhibitors (e.g., pegcetacoplan) for the geographic atrophy form of AMD, and pan-retinal photocoagulation by laser. There are also potentially disease-modifying therapeutics being developed by several pharmaceutical and biotechnology companies, including Roche/Genentech and Regeneron.

Further, we believe that potential competitors may be able to develop senolytic medicines utilizing well-established molecules and pathways, which could enable the development of competitive drug candidates utilizing the same cellular senescence biological theories.

Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles. Furthermore, currently approved products could be discovered to have application for treatment of diseases of aging generally, which could give such products significant regulatory and market timing advantages over any of our drug candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our drug candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Newly developed systemic or non-systemic treatments that replace existing therapies that currently are only utilized in patients suffering from severe disease may also have lessened side effects or reduced prices compared to current therapies, which make them more attractive for patients

suffering from mild to moderate disease. Even if a generic or OTC product is less effective than our drug candidates, it may be more quickly adopted by physicians and patients than our competing drug candidates based upon cost or convenience.

***The successful commercialization of our drug candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our drug candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our drug candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug candidates. Assuming we obtain coverage for our drug candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our drug candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our drug candidates as substitutable and only offer to reimburse patients for the cost of the less expensive product. Even if we show improved efficacy or improved convenience of administration with our drug candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our drug candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our drug candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our drug candidates and may not be able to obtain a satisfactory financial return on our investment in the development of drug candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our drug candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our drug candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our drug candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our drug candidates. Accordingly, in markets outside the United States, the reimbursement for our drug

candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our drug candidates. We expect to experience pricing pressures in connection with the sale of our drug candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

***We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our drug candidates effectively in the U.S. and foreign jurisdictions, if approved, or generate product revenue.***

We currently do not have a marketing or sales organization. In order to commercialize our drug candidates in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our drug candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such drug candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our drug candidates. If we are not successful in commercializing our drug candidates or any future drug candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future drug candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, and a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates.

Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future drug candidates;
- injury to our reputation;
- withdrawal of clinical study participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and

- the inability to commercialize our current or any future drug candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future drug candidates we develop. We currently carry product liability insurance covering our clinical studies. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our drug candidates, we intend to expand our insurance coverage to include the sale of such drug candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

***Our existing collaborations as well as additional collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our drug candidates.***

We utilize external collaborations and currently maintain several active early-stage research and discovery focused collaborations. In the future, we may seek additional collaboration arrangements for the commercialization, or potentially for the development, of certain of our drug candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. To the extent that we decide to enter into additional collaboration agreements in the future, we may face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts to prudently manage our existing collaborations or to enter new ones should we chose to do so. The terms of new collaborations, or other arrangements that we may establish may not be favorable to us.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators and partners. Collaborations are subject to numerous risks, which may include risks that:

- collaborators and partners have significant discretion in determining the efforts and resources that they will apply to collaborations, and they may not devote the level of effort or resources we expect;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a drug candidate, repeat or conduct new clinical studies or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates;
- a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future drug candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated, resulting in a need for additional capital to pursue further development or commercialization of the applicable current or future drug candidates;
- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings; and
- collaborators may be adversely impacted by unforeseen events and public health emergencies.

### **Risks Related to Intellectual Property**

***Our senolytic medicine platform and any future products that we commercialize could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our products.***

Our commercial success depends on our ability to develop, manufacture and market our senolytic medicines and future drug candidates and use our proprietary technology without infringing the patents and other proprietary rights of third parties. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. We operate in an industry with extensive intellectual property litigation. As the biopharmaceutical and pharmaceutical industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated.

Whether merited or not, we may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including patents held by our competitors or by non-practicing entities. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties.

Litigation may make it necessary to defend ourselves by determining the scope, enforceability, and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether claims that we are infringing patents or other intellectual property rights have merit, the claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our products and features while we develop non-infringing substitutes, or may result in significant settlement costs. For example, litigation can involve substantial damages for infringement (and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees), and the court could prohibit us from selling or licensing our products unless the third-party licenses rights to us, which it is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible at all or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use, or sale.

In addition, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on whether the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the U.S. Patent and Trademark Office, to determine priority of invention in the United States. The costs of patent and other proceedings could be substantial, and it is possible that such efforts would be unsuccessful if it is determined

that the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Although we are not currently subject to any claims from third parties asserting infringement of their intellectual property rights, in the future, we may receive claims from third parties asserting infringement of their intellectual property rights. Future litigation may be necessary to establish our intellectual property rights or to defend ourselves by determining the scope, enforceability and validity of third-party intellectual property rights. There can be no assurance with respect to the outcome of any current or future litigation brought by or against us, and the outcome of any such litigation could have a material adverse impact on our business, operating results and financial condition. Litigation is inherently unpredictable, and outcomes are uncertain. Further, as the costs and outcomes of these types of claims and proceedings can vary significantly, it is difficult to estimate potential losses that may occur. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

***If we are unable to obtain, maintain and enforce intellectual property protection directed to our senolytic medicine platform and any future technologies that we develop, others may be able to make, use, or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.***

As of September 30, 2024, we own, co-own, or have an exclusive license in certain fields of use to more than 170 patents and pending applications in the United States and foreign jurisdictions. This portfolio includes 34 issued and allowed U.S. patents and applications and 68 granted and allowed foreign patents and applications, respectively. A composition of matter patent filing claiming the specific chemical structure of UBX1325 was issued in the U.S. on April 20, 2021, which will extend our loss of exclusivity on this molecule to 2039, not including any patent term adjustment or patent term extensions to which it may be entitled.

We have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our products in every country or territory in which we may sell our products. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they will issue in a form that will be advantageous to us. The U.S. Patent and Trademark Office (USPTO), international patent offices or judicial bodies may deny, or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with protection for our commercial products. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of our legal actions against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual property may be challenged, invalidated or circumvented, may not provide specific protection and/or may not prove to be enforceable in actions against specific alleged infringers.

The market for biopharmaceuticals, pharmaceuticals, and treatments for diseases of aging is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and products for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights in connection therewith. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our



technology and/or infringe our intellectual property to unfairly and illegally compete with our products. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use, or sell products that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market.

We use a combination of patents, trademarks, know-how, confidentiality procedures, and contractual provisions to protect our proprietary technology. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our currently pending or any future patent applications, and our issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us.

If we or one of our current or future collaborators were to initiate legal proceedings against a third party to enforce a patent covering one of our current drug candidates or future drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace.

Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or nonenablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make products that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our proposed commercial technologies or the future products that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have dominating, blocking, or other patents relevant to our technology of which we are not aware. There may be prior public disclosures or art that could be deemed to invalidate one or more of our patent claims. Further, we may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many international jurisdictions, policy regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and international legislative bodies. Those changes may materially affect our patents, our ability to obtain patents or the patents and patent applications of our licensors. Patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the

prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business and financial condition.

In addition, we have a number of international patents and patent applications and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. The laws of some international jurisdictions may not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in obtaining, protecting, and defending such rights in international jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in international jurisdictions, our business prospects could be substantially harmed.

Varying filing dates in international countries may also permit intervening third parties to allege priority to certain technology.

Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates, and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen the patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing (including any patent term extension or adjustment filing), whether intentional or unintentional, may also result in the loss of patent rights important to our business. Certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect confidential information and proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our drug candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. We may in the future rely on trade secret protection, which would be subject to the risks identified above with respect to confidential information.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products, and may in the future seek to enforce our patents or other rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product or service features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, such as (but not limited to) interferences, derivation proceedings, reexamination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions or other patent proceedings. We may need to initiate infringement claims or litigation.

Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court or other judicial body may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be

able to devote significantly more resources to intellectual property litigation and may have significantly broader patent portfolios to assert against us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending, and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings (such as litigation) costs.

***Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.***

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

We may not be able to protect our proprietary information and technology adequately. Although we use reasonable efforts to protect our proprietary information, technology, and know-how, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our proprietary information, technology or know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect proprietary information, technology, and know-how. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our proprietary information, technology, and know-how. These agreements may be breached, and we may not have adequate remedies for any breach. Moreover, others may independently develop similar or equivalent proprietary information, and third parties may otherwise gain access to our proprietary knowledge.

#### **Risks Related to Government Regulation**

***Even if we obtain regulatory approval for a drug candidate, our products will remain subject to regulatory scrutiny.***

If our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

***If any of our small molecule drug candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an ANDA, seeking approval of a generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be

given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our small molecule drug candidates, such as UBX1325, are approved, competitors could file ANDAs for generic versions of our small molecule drug products or 505(b)(2) NDAs that reference our small molecule drug products. If there are patents listed for our small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

***Any biologic, or large molecule, drug candidates for which we intend to seek approval may face competition sooner than anticipated.***

If we are successful in achieving regulatory approval to commercialize any biologic drug candidate faster than our competitors, such drug candidates may face competition from biosimilar products. In the United States, large molecule drug candidates are regulated by the FDA as biologic products subject to approval under the biologics license application, or BLA, pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical studies. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

If competitors are able to obtain marketing approval for biosimilars referencing our large molecule drug candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our drug candidates may have received approval.

***Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and may affect the prices we may set.***

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and ACA, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board, which, once empaneled, will have the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law unless overruled by a supermajority vote of Congress; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, there may be other efforts to challenge, repeal or replace the ACA that may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional action is taken by Congress. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Individual states in the United States have also become 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare 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 healthcare programs. This could reduce the ultimate demand for our drug candidates or put pressure on our product pricing. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our drug candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to commercialize our drug candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our drug candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

***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 and regulations. 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 drug candidates, if approved.

Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers starting in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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 civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant 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.

***U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our suppliers or our customers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.

### **Risks Related to Ownership of Our Common Stock**

***Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.***

The trading price of our common stock has been and may continue to be highly volatile and may be subject to wide fluctuations in response to various factors, some of which are beyond our control.



These factors include those discussed in this “Risk Factors” section of this report and others such as:

- results from, and any delays in, commencing, conducting or completing our clinical studies for our current drug candidates, or any other future clinical development programs;
- announcements by academic or other third parties challenging the fundamental premises underlying our approach to treating diseases of aging and/or drug development;
- announcements of regulatory approval or disapproval of our current or any future drug candidates;
- failure or discontinuation of any of our research and development programs;
- announcements relating to future licensing, collaboration, or development agreements;
- our ability to maintain compliance with Nasdaq listing standards;
- delays in the commercialization of our current or any future drug candidates;
- public misperception regarding the use of our therapies, or public bias of against “anti-aging” companies;
- acquisitions and sales of new products, technologies, or businesses;
- manufacturing and supply issues related to our drug candidates for clinical studies or future drug candidates for commercialization;
- quarterly variations in our results of operations or those of our future competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions, or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- any major changes in our board of directors or management;
- new legislation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our drug candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors; and
- general economic conditions in the United States and abroad, including high interest rates, rising inflation, the government closure of Silicon Valley Bank and liquidity concerns at other financial institutions, and the potential for local and/or global economic recession.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical, and biotechnology stocks in particular, have experienced extreme volatility as a result of the economic uncertainty and increased interest rates, inflation, the government closure of Silicon Valley Bank and liquidity concerns at other financial institutions that may be unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

On October 19, 2022, we effected a 1-for-10 reverse stock split of our common stock seeking to regain compliance with Nasdaq Global Select Market's continued listing standards. As a result of the reverse stock split, the split-adjusted per share market price of our common stock increased and, from October 20, 2022 to November 2, 2022 (10 consecutive business days), the closing bid price of our common stock exceeded \$1.00 per share. Accordingly, on November 3, 2022, we received a notice from Nasdaq indicating that we have regained compliance with Listing Rule 5450(a)(1) as of such date. See the risk factor titled “*We may not be able to maintain compliance with the continued*”

*listing requirements of Nasdaq and, if so, we would be subject to delisting.”* for additional information about our ability to maintain compliance with the continued listing requirements of Nasdaq. Although we currently comply with the minimum bid requirement following the reverse stock split, we cannot assure you that we will be able to maintain compliance with the continued listing requirements of Nasdaq and any delisting would adversely affect our stock price and the liquidity of our common stock.

***An active, liquid and orderly market for our common stock may not be maintained.***

Although our common stock is listed on the Nasdaq Global Select Market, an active trading market for our common stock may never be sustained on the Nasdaq Global Select Market or any other exchange in the future. On October 19, 2022, we effected a 1-for-10 reverse stock split of our common stock seeking to bring us into compliance with the minimum required closing bid price for continued listing on the Nasdaq Global Select Market and to regain compliance with Nasdaq Global Select Market's continued listing standards. While we have regained compliance, we cannot assure that we will continue to meet the minimum required closing bid price for continued listing on the Nasdaq Global Select Market in the future or that we will be able to maintain our listing on the Nasdaq Global Select Market or any other exchange. See the risk factor titled *“We may not be able to maintain compliance with the continued listing requirements of Nasdaq and, if so, we would be subject to delisting.”* for additional information about our ability to maintain compliance with the continued listing requirements of Nasdaq. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. In the event any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If our public float stays below \$75.0 million, the risk that analysts cease to cover our stock may increase.

***If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.***

We have and may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. For example, we may issue additional shares from time to time pursuant to our shelf registration statements and ATM Offering Programs. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. However, for so long as our public float is less than \$75.0 million, under our shelf registration statements, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules.

Sales of substantial amounts of shares of our common stock or other securities by our stockholders, by us under our shelf registration statements or the ATM Offering Programs or through any other means could also lower the market price of our common stock and impair our ability to raise capital through the sale of equity or equity-related securities.

***We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our results of operations and financial condition. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, evaluating the effectiveness of our internal controls and disclosing any changes or material weaknesses identified through such evaluation. A material weakness is a deficiency, or a combination of deficiencies, in internal control

over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In March 2024, we determined that we incorrectly classified certain warrants that were issued to investors in connection with a Follow-On offering of our common stock in August 2022. Our management subsequently concluded that a material weakness existed and our internal control over financial reporting was not effective as of August 2022. The material weakness was due to the inadequate design and implementation of controls to evaluate the accounting for warrant classification between liability and equity.

As a result, we determined that there were material errors in the financial statements that required a restatement of the December 31, 2022 financial statements and for our Forms 10-Q for the quarterly periods ended September 30, 2022, March 31, 2023, June 30, 2023 and September 30, 2023. Those restatements are included in the Annual Report on Form 10-K for the year ended December 31, 2023. This was due to the inadequate design and implementation of controls to evaluate the accounting for warrant classification between liability and equity.

Management is implementing enhanced internal controls to remediate the material weakness. Specifically, we are in the process of expanding and improving our review process for complex security transactions and related accounting standards. We plan to improve this process by specifically incorporating the review of the accounting conclusions for each significant relevant contractual term, by using a robust accounting literature tool, and engaging third-party subject matter experts with relevant experience to determine the appropriate accounting for complex security transactions. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. If we are not able to comply with the requirements of the Sarbanes-Oxley Act or if we are unable to maintain effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements or guarantee that information required to be disclosed by us in the reports that we file with the SEC, is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Any failure of our internal control over financial reporting or disclosure controls and procedures could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, expose us to sanctions or investigations by the SEC or other regulatory authorities, or impact our results of operations.

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

We have incurred substantial losses during our history and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, until such unused losses expire, if ever. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we achieve profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

***Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer or the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

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

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

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

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

- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

***We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.***

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

## **General Risk Factors**

***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. Furthermore, the market for products with the potential to treat diseases of aging, particularly those affecting large populations in a wide range of geographic locations, may be particularly vulnerable to unfavorable economic conditions. A global financial crisis or a global or regional political disruption, including most recently as a result of the COVID-19 pandemic, have caused and could continue to cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our current drug candidates or any future drug candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Weakened or declining economic conditions could be caused by a number of factors, including high interest rates, rising inflation, the government closure of Silicon Valley Bank and liquidity concerns at other financial institutions, and the potential for local and/or global economic recession. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

***We or the third parties upon whom we depend may be adversely affected by earthquakes, other natural disasters or unforeseen pandemics and public health emergencies, such as the COVID-19 pandemic, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. Although we carry earthquake insurance, it is limited in scope. Earthquakes, wildfires or other 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 our enterprise financial systems or manufacturing resource planning and enterprise quality systems, 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 currently are limited and are unlikely to prove adequate 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, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

***Significant disruptions of information technology systems or deficiencies in our cybersecurity could materially adversely affect our business, results of operations and financial condition.***

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information.

Our information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to attack, interruption and damage from computer viruses, malware (e.g. ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyberattacks or cyber-intrusion, including by computer hackers, “phishing” attacks, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. We may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees that work or may work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Moreover, if a security breach affects our systems, or those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

***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; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. 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 studies, the creation of fraudulent data in our preclinical studies or clinical studies, 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, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, individual 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.

***Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and drug candidates and other hazardous compounds. We and any third-party manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate

coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical studies or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition.

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

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

Filing, prosecuting and defending patents on drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can 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 United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Actual or perceived failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.***

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal information, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or any service providers', contractors' or future collaborators' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing processing of personal information could result in



negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA’s criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA’s requirements for disclosure of individually identifiable health information.

In addition, certain state laws govern the privacy and security of personal information, including health-related information. For example, the California Consumer Privacy Act, or the CCPA went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood, and risks associated with data breach litigation. Further, the California Privacy Rights Act, or the CPRA generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers, including our CRO, and contractors must comply. For example, the European Union General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes strict requirements for processing the personal information of subjects within the European Economic Area, or EEA, including clinical trial data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the EEA. On July 16, 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme, and imposed further restrictions on use of the standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, beginning January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in United Kingdom national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

***We incur increased costs as a result of operating as a public company, and our management devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.***

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel have devoted and will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. Once we are considered an "accelerated filer" or "larger accelerated filer" under SEC rules, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

During the course of our review of our internal controls we may identify deficiencies in our internal controls that we must remediate. If we identify a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm to our business.

***We have recorded, and may be required to record in the future, significant charges if our long-lived assets become impaired.***

We test long-lived assets for impairment if changes in circumstances or the occurrence of events suggest impairment exists. Any significant change in market conditions, including a sustained decline in our stock price, that indicate a reduction in carrying value may give rise to impairment in the period that indicators are present. For example, as a result of the sustained decline in our stock price and related market capitalization and a general decline in equity values in the biotechnology industry, we performed an impairment assessment of long-lived assets in connection with the preparation of the financial statements required to be included in our Annual Report on Form 10-K for the year ended December 31, 2023. Based on this assessment, we recognized a non-cash long-lived asset impairment charge of \$5.6 million during the year ended December 31, 2023.

It is possible that changes in circumstances, many of which are outside of our control, or in the numerous variables associated with the assumptions and estimates used in assessing the appropriate valuation of our long-lived assets, could in the future result in an impairment to our long-lived assets, requiring us to record impairment charges, which would adversely affect our business, financial condition and results of operations.

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

a) Sales of Unregistered Securities

There were no sales of unregistered securities during the three months ended September 30, 2024.

b) Repurchase of Shares or of Company Equity Securities

None.

**Item 3. Default Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

During the three months ended September 30, 2024, no director or officer of the Company adopted, terminated, or modified a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>Incorporated by Reference Date</b>	<b>Number</b>	<b>Filed Herewith</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Unity Biotechnology, Inc.</a>	8-K	5/7/2018	3.1	
3.2	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation of Unity Biotechnology, Inc.</a>	8-K	10/19/2022	3.1	
3.3	<a href="#">Amended and Restated Bylaws of Unity Biotechnology, Inc.</a>	10-K	4/15/2024	3.3	
4.1	Reference is made to exhibits <a href="#">3.1</a> through <a href="#">3.3</a> .				
4.2	<a href="#">Form of Common Stock Certificate.</a>	10-Q	11/8/2022	4.2	
4.3	<a href="#">Form of Warrant.</a>	8-K	8/22/2022	4.1	
4.4	<a href="#">Form of New Warrant.</a>	8-K	11/13/2023	4.1	
31.1	<a href="#">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.</a>				X
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
32.1*	<a href="#">Certification by the Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Document				X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, has been formatted in Inline XBRL.				X

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\* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Unity Biotechnology, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**SIGNATURES**

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

Unity Biotechnology, Inc.

Date: November 4, 2024

By:           /s/ Anirvan Ghosh

Anirvan Ghosh, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 4, 2024

By:           /s/ Lynne Sullivan

Lynne Sullivan  
Chief Financial Officer  
(Principal Financial and Accounting Officer)



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

I, Lynne Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Unity Biotechnology, 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.

Date: November 4, 2024

By: \_\_\_\_\_ /s/ Lynne Sullivan

**Lynne Sullivan**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

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

In connection with the Quarterly Report of Unity Biotechnology, Inc. (the “Company”) on Form 10-Q for the period ending September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Anirvan Ghosh, Chief Executive Officer of the Company, and Lynne Sullivan, Chief Financial Officer of the Company, do each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 4, 2024

By: \_\_\_\_\_  
*/s/ Anirvan Ghosh*  
**Anirvan Ghosh, Ph.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

Date: November 4, 2024

By: \_\_\_\_\_  
*/s/ Lynne Sullivan*  
**Lynne Sullivan**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

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