UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2025

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 001-39386

ALX ONCOLOGY HOLDINGS INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-0642577**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
323 Allerton Avenue	
South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

650-466-7125

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ALXO	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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of October 31, 2025, the registrant had 54,218,001 shares of common stock outstanding, $0.001 par value per share.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and our ability to grow a sales team;
- the implementation of our strategic plans for our business and product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates for various diseases;
- our reliance on third parties to conduct preclinical research activities, and for the manufacture of our product candidates;
- the beneficial characteristics, mechanisms of action, safety profile, efficacy and therapeutic effects of our product candidates;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials, including collaborations and investigator sponsored trials, to demonstrate the safety and efficacy of our product candidates, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our continued reliance on third parties to conduct clinical trials of our product candidates, and for the manufacture of our product candidates;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights, including our technology platform and product candidates;
- our ability to retain the continued service of our key personnel, the impacts of any executive officer changes, and to identify, hire, and then retain additional qualified personnel;

- the impact of macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, duration of the U.S. federal government shutdown, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic;
- our plans for and prospects of our acquisitions and other business development activities, and our ability to successfully capitalize on these opportunities;
- changes in our financial and internal controls; and
- our anticipated use of our existing cash and cash equivalents, short-term and long-term investments, and the funds available from our term loan.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 23,442	$ 17,567
Short-term investments	37,184	110,190
Prepaid expenses and other current assets	5,890	6,595
Total current assets	66,516	134,352
Property and equipment, net	1,351	2,905
Long-term investments	5,838	3,524
Other assets	9,018	6,994
Total assets	$ 82,723	$ 147,775
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,583	$ 4,497
Payable and accrued liabilities due to related party	—	149
Term loan, current	4,348	435
Accrued expenses and other current liabilities	16,791	13,419
Total current liabilities	27,722	18,500
Term loan, non-current	5,764	9,469
Other non-current liabilities	4,437	6,188
Total liabilities	37,923	34,157
Commitments and contingencies (Note 12)		
Stockholders' equity		
Common stock, $0.001 par value; 1,000,000,000 shares authorized as of September 30, 2025 and December 31, 2024; 53,577,566 and 53,052,912 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	54	53
Additional paid-in capital	744,672	734,412
Accumulated other comprehensive income	43	275
Accumulated deficit	(699,969)	(621,122)
Total stockholders' equity	44,800	113,618
Total liabilities and stockholders' equity	$ 82,723	$ 147,775

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 17,441	$ 26,471	$ 59,351	$ 92,841
General and administrative	5,091	6,096	18,474	19,013
Impairment charge	—	—	3,175	—
Total operating expenses	22,532	32,567	81,000	111,854
Loss from operations	(22,532)	(32,567)	(81,000)	(111,854)
Interest income	802	2,303	3,391	7,488
Interest expense	(408)	(446)	(1,219)	(1,302)
Other income (expense), net	(6)	3	(19)	(19)
Net loss	$ (22,144)	$ (30,707)	$ (78,847)	$ (105,687)
Net loss per share, basic and diluted	$ (0.41)	$ (0.58)	$ (1.48)	$ (2.05)
Weighted-average shares of common stock used to compute net loss per share, basic and diluted	53,577,066	52,693,878	53,452,319	51,544,501

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Net loss	$ (22,144)	$ (30,707)	$ (78,847)	$ (105,687)
Other comprehensive gain (loss), net of tax:				
Unrealized gain (loss) on available-for-sale investments	7	636	(232)	307
Total comprehensive loss	$ (22,137)	$ (30,071)	$ (79,079)	$ (105,380)

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2024	53,052,912	$ 53	$ 734,412	$ 275	$ (621,122)	$ 113,618
Issuance of common stock under equity incentive plans	125,920	—	—	—	—	—
Issuance of common stock through ATM offering, net of commissions	205,313	—	372	—	—	372
Stock-based compensation	—	—	5,216	—	—	5,216
Unrealized loss on available-for-sale investments	—	—	—	(157)	—	(157)
Net loss	—	—	—	—	(30,754)	(30,754)
Balance as of March 31, 2025	53,384,145	53	740,000	118	(651,876)	88,295
Issuance of common stock under equity incentive plans	84,099	1	(1)	—	—	—
Issuance of common stock under employee stock purchase plan	38,533	—	15	—	—	15
Stock-based compensation	—	—	2,136	—	—	2,136
Unrealized loss on available-for-sale investments	—	—	—	(82)	—	(82)
Net loss	—	—	—	—	(25,949)	(25,949)
Balance as of June 30, 2025	53,506,777	$ 54	$ 742,150	$ 36	$ (677,825)	$ 64,415
Issuance of common stock under equity incentive plans	70,789	—	1	—	—	1
Stock-based compensation	—	—	2,521	—	—	2,521
Unrealized gain on available-for-sale investments	—	—	—	7	—	7
Net loss	—	—	—	—	(22,144)	(22,144)
Balance as of September 30, 2025	53,577,566	$ 54	$ 744,672	$ 43	$ (699,969)	$ 44,800

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	49,951,989	$ 50	$ 675,678	$ 256	$ (486,272)	$ 189,712
Issuance of common stock under equity incentive plans	113,385	—	237	—	—	237
Issuance of common stock through ATM offering, net of commissions of $0.1 million	211,819	—	3,024	—	—	3,024
Stock-based compensation	—	—	7,031	—	—	7,031
Unrealized loss on available-for-sale investments	—	—	—	(228)	—	(228)
Net loss	—	—	—	—	(35,581)	(35,581)
Balance as of March 31, 2024	50,277,193	50	685,970	28	(521,853)	164,195
Issuance of common stock under equity incentive plans	321,753	—	861	—	—	861
Issuance of common stock under employee stock purchase plan	59,712	—	306	—	—	306
Issuance of common stock through ATM offering, net of commissions and offering costs of $0.8 million	1,794,091	2	26,201	—	—	26,203
Stock-based compensation	—	—	7,252	—	—	7,252
Unrealized loss on available-for-sale investments	—	—	—	(101)	—	(101)
Net loss	—	—	—	—	(39,399)	(39,399)
Balance as of June 30, 2024	52,452,749	$ 52	$ 720,590	$ (73)	$ (561,252)	$ 159,317
Issuance of common stock under equity incentive plans	290,355	1	533	—	—	534
Issuance of common stock through ATM offering, net of commissions and offering costs	—	—	75	—	—	75
Stock-based compensation	—	—	6,952	—	—	6,952
Unrealized gain on available-for-sale investments	—	—	—	636	—	636
Net loss	—	—	—	—	(30,707)	(30,707)
Balance as of September 30, 2024	52,743,104	$ 53	$ 728,150	$ 563	$ (591,959)	$ 136,807

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2025	**2024**
Operating activities		
Net loss	$ (78,847)	$ (105,687)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,873	21,235
Depreciation and amortization	555	658
Non-cash lease costs	1,333	1,312
Net accretion of discounts on investments	(1,056)	(3,920)
Accretion of term loan discount and issuance costs	208	196
Impairment charge	3,175	—
Loss on disposal of fixed asset	—	10
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	705	(1,418)
Other assets	(5,693)	2,170
Accounts payable	2,090	(637)
Payable and accrued liabilities due to related party	(149)	(480)
Accrued expenses and other current liabilities	4,150	(1,730)
Other non-current liabilities	(1,506)	(1,575)
Net cash used in operating activities	(65,162)	(89,866)
Investing activities		
Purchase of investments	(45,619)	(102,962)
Maturities of investments	117,135	156,422
Purchase of property and equipment	(163)	(387)
Net cash provided by investing activities	71,353	53,073
Financing activities		
Proceeds from ATM offering, net of commissions	372	29,302
Proceeds from exercise of stock options under equity incentive plan	1	1,632
Proceeds from issuance of common stock under employee stock purchase plan	15	306
Principal payments on finance leases	(704)	(751)
Net cash (used in) provided by financing activities	(316)	30,489
Net increase (decrease) in cash, cash equivalents and restricted cash	5,875	(6,304)
Cash, cash equivalents and restricted cash at beginning of year	17,633	22,472
Cash, cash equivalents and restricted cash at end of period	$ 23,508	$ 16,168
Supplemental disclosure of non-cash investing and financing activities		
Purchase of property and equipment in accounts payable and accrued expenses	$ 1,011	$ 1,211
Right-of-use asset (modified) acquired under finance leases	$ (182)	$ 1,309
Reconciliation of cash and cash equivalents and restricted cash:		
Cash and cash equivalents	$ 23,442	$ 16,102
Restricted cash (included in other assets)	66	66
Total cash, cash equivalents and restricted cash	$ 23,508	$ 16,168

See accompanying notes to these condensed consolidated financial statements (unaudited).

ALX ONCOLOGY HOLDINGS INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

(1) ORGANIZATION

Organization

ALX Oncology Holdings Inc., or the Company, was formed as a Delaware corporation on April 1, 2020, or Inception. The Company was formed for the purpose of completing the Company's initial public offering of its common stock and related transactions in order to carry on the business of ALX Oncology Limited. The Company is a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives.

ALX Oncology Holdings Inc. is incorporated in Delaware. ALX Oncology Limited, incorporated in Ireland, is a wholly-owned subsidiary of ALX Oncology Holdings Inc. ALX Oncology Inc., incorporated in Delaware, is a wholly-owned subsidiary of ALX Oncology Limited. All the companies, except for ALX Oncology Holdings Inc., are collectively known as the Subsidiaries.

As of September 30, 2025, the Company has devoted substantially all of its efforts to the formation and financing of the Company, as well as product development, and has not realized product revenues from its planned principal operations. The Company does not have manufacturing facilities and all manufacturing related activities are contracted out to third-party service providers.

Management expects to incur additional losses in the future to conduct product candidate research and development and to conduct pre-commercialization activities and recognizes that the Company will be required to raise additional capital to fully implement its business plan. The Company intends to raise such capital through the sale of additional equity, debt financings and/or strategic alliances with third parties. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms acceptable to the Company. If the Company is unsuccessful in its efforts to raise additional financing, the Company could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate some of its development programs or its future commercialization efforts, out-license intellectual property rights to its product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all. The Company believes that the existing capital resources will be sufficient to fund the projected operating requirements for at least the next twelve months after the date the condensed consolidated financial statements are issued.

(2) SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, and applicable rules and regulations of the Securities and Exchange Commission, or SEC, regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 6, 2025.

The condensed consolidated balance sheet as of September 30, 2025 included herein was derived from the audited financial statements as of that date, but does not include all disclosures including notes required by U.S. GAAP.

The accompanying condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year ending December 31, 2025.

Principles of Consolidation

All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates, including, but not limited to, those related to the estimated useful lives and impairment of long-lived assets, clinical and contract manufacturing accruals, fair value of assets and liabilities, fair value of investments, and stock-based compensation. The Company evaluates its estimates and assumptions on an ongoing basis based on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances and adjusts those estimates and assumptions when facts and circumstances change. Actual results could differ from those estimates.

Significant Accounting Policies

There have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures* (ASU 2023-09). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement Reporting - Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03). ASU 2024-03 requires disaggregated disclosure of certain costs and expenses, including purchases of inventory, employee compensation, depreciation and amortization, within relevant income statement captions. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The guidance is applied on a prospective basis with the option for retrospective application. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

(3) SEGMENT REPORTING

The Company manages its operations as a single operating segment. The Company's chief operating decision maker (CODM) uses consolidated, single-segment financial information for the purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

The CODM assesses performance and decides how to allocate resources based on the Company's consolidated net loss, including key components of research and development costs and general and administrative costs. These measures are used to monitor budget versus actual results and to evaluate the performance of the segment.

The CODM reviews cash, cash equivalents and investments as a measure of segment assets. As of September 30, 2025 and December 31, 2024, the Company's cash, cash equivalents and investments were $66.5 million and $131.3 million, respectively.

The following table presents the significant segment expenses for the three months and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development expenses:				
Clinical and development costs	$ 9,911	$ 12,463	$ 32,282	$ 50,370
Preclinical costs	183	2,037	2,039	5,190
Personnel and related costs	2,710	5,865	13,855	17,438
Stock-based compensation expense	1,104	4,648	4,949	14,556
Other research costs	3,533	1,458	6,226	5,287
Total research and development expenses	17,441	26,471	59,351	92,841
General and administrative expenses:				
Personnel and related costs	1,678	1,644	6,379	5,061
Stock-based compensation expense	1,417	2,304	4,924	6,679
Other general and administrative costs	1,996	2,148	7,171	7,273
Total general and administrative expenses	5,091	6,096	18,474	19,013
Impairment charge:				
Impairment of long-lived assets	—	—	3,175	—
Total impairment charge	—	—	3,175	—
Loss from operations	(22,532)	(32,567)	(81,000)	(111,854)
Interest income	802	2,303	3,391	7,488
Interest expense	(408)	(446)	(1,219)	(1,302)
Other income (expense), net	(6)	3	(19)	(19)
Net loss	$ (22,144)	$ (30,707)	$ (78,847)	$ (105,687)

(4) FAIR VALUE OF FINANCIAL INSTRUMENTS

The fair value of the Company's financial assets and liabilities are determined in accordance with the fair value hierarchy established in ASC 820, Fair Value Measurements and Disclosures.

The following table presents the Company's investments, which consist of cash equivalents and investments classified as available-for-sale investments, that are measured at fair value on a recurring basis by level within the fair value hierarchy as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents					
Money market funds	Level 1	$ 19,986	$ —	$ —	$ 19,986
U.S. government agency securities	Level 2	1,986	—	—	1,986
Short-term investments					
U.S. Treasury securities	Level 1	12,906	10	—	12,916
Corporate debt securities	Level 2	20,282	30	—	20,312
Commercial paper	Level 2	3,954	2	—	3,956
Long-term investments					
Corporate debt securities	Level 2	5,837	2	(1)	5,838
Total		$ 64,951	$ 44	$ (1)	$ 64,994

	December 31, 2024				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents					
Money market funds	Level 1	$ 15,468	$ —	$ —	$ 15,468
Short-term investments					
U.S. Treasury securities	Level 1	52,167	148	—	52,315
U.S. government agency securities	Level 2	3,101	6	—	3,107
Corporate debt securities	Level 2	52,657	122	—	52,779
Commercial paper	Level 2	1,988	1	—	1,989
Long-term investments					
Corporate debt securities	Level 2	3,526	1	(3)	3,524
Total		$ 128,907	$ 278	$ (3)	$ 129,182

The fair value of cash equivalents and available-for-sale investments by classification included in the condensed consolidated balance sheets was as follows as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025	December 31, 2024
Cash equivalents	$ 21,972	$ 15,468
Short-term investments	37,184	110,190
Long-term investments	5,838	3,524
Total	$ 64,994	$ 129,182

Cash and cash equivalents in the above table excludes bank account cash of $1.5 million and $2.1 million as of September 30, 2025 and December 31, 2024, respectively.

The fair value of cash equivalents and available-for-sale investments by contractual maturity was as follows as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025	December 31, 2024
Maturing in one year or less	$ 59,156	$ 125,658
Maturing after one year through five years	5,838	3,524
Total	$ 64,994	$ 129,182

The primary objective of the Company's investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

There were no transfers of financial instruments between the fair value measurement levels during the three months and nine months ended September 30, 2025 and 2024 and there were no financial instruments classified as Level 3 as of September 30, 2025 and December 31, 2024.

As of September 30, 2025 and December 31, 2024, accrued interest receivable related to the Company's investments of $0.4 million and $0.9 million was included in prepaid expenses and other current assets on the condensed consolidated balance sheet.

As of September 30, 2025, the unrealized losses for available-for-sale investments were non-credit related and the Company does not intend to sell the investments that were in an unrealized loss position, nor does it foresee or project that it will be required to sell those investments before recovery of their amortized costs basis, which may be maturity. As of September 30, 2025 and 2024, no allowance for credit losses for the Company's investments was recorded. As of September 30, 2025 and December 31, 2024, no securities were in a continuous net unrealized loss position for more than 12 months. As of September 30, 2025 and 2024, the Company has not recognized any impairment losses on available-for-sale investments.

(5) BALANCE SHEET COMPONENTS

Prepaid Expenses and Other Current Assets

The following table presents the components of prepaid expenses and other current assets as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025	December 31, 2024
Prepaid clinical expenses	$ 3,834	$ 3,757
Prepaid expenses	892	1,343
Prepaid insurance	766	576
Interest and investment receivables	398	892
Other current assets	—	27
Total prepaid expenses and other current assets	$ 5,890	$ 6,595

Property and Equipment, Net

The following table presents the components of property and equipment, net as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025	December 31, 2024
Laboratory equipment	$ 1,844	$ 1,835
Leasehold improvements	709	2,509
Computer hardware and software	461	473
Furniture and fixtures	165	165
Property and equipment, gross	3,179	4,982
Less: accumulated depreciation	(1,828)	(2,077)
Property and equipment, net	$ 1,351	$ 2,905

Depreciation was $0.2 million for the three months ended September 30, 2025 and 2024 and $0.6 million and $0.7 million for the nine months ended September 30, 2025 and 2024, respectively.

Other Assets

The following table presents the components of other assets as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025	December 31, 2024
Long-term prepaid clinical expenses	$ 5,603	$ —
Finance lease right-of-use assets	1,752	2,704
Operating lease right-of-use assets	1,306	4,023
Other assets	220	200
Long-term prepaid contract manufacturing costs	137	67
Total other assets	$ 9,018	$ 6,994

Impairment of Long-Lived Assets

The Company has determined it operates in a single operating segment and has one reportable segment. The Company reviews for indicators of impairment on a quarterly basis, including changes in how its property is being used.

In May 2025, the Company made a decision to sublease its leased property in Palo Alto. The Company is actively marketing the leased building for sublease. In connection with the preparation of these condensed consolidated financial statements, the Company determined that the change in how this building is being used could indicate impairment. The Company identified this to-be-sublet property as a separate asset group for purposes of long-lived asset impairment assessment. The Company concluded that the carrying value of this to-be-sublet property asset group was not recoverable and the estimated fair value of this asset group was below its carrying value. The lower fair value of this asset group was mainly due to the lower estimated sublease income compared to the lease payments in accordance with the initial operating lease agreement and higher discount rate. The Company applied a discounted cash flow method to estimate fair value of its right-of-use asset and leasehold improvements. Based on this analysis, the Company concluded the fair value of the right-of-use asset and leasehold improvements of $1.5 million was lower than its net book value of $4.7 million. The Company recognized a pre-tax long-lived asset impairment charge of $3.2 million on the right-of-use asset and leasehold improvements. For the three months and nine months ended September 30, 2025, the Company has recognized impairment of zero and $3.2 million, respectively, on the right-of-use asset and leasehold improvements.

The determination of the fair value of the Company's asset group related to the to-be-sublet property that is currently being marketed for sublease purposes represents a Level 3 nonrecurring fair value measurement. Calculating the fair value of the asset involves significant estimates and assumptions. These estimates and assumptions include, among other things, expected sublease rental income of $2.5 million and risk-adjusted annual discount rate of 10%.

Accrued Expenses and Other Current Liabilities

The following table presents the components of accrued expenses and other current liabilities as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025	December 31, 2024
Accrued clinical and nonclinical study costs	$ 10,184	$ 3,858
Accrued compensation and related expenses	2,787	5,306
Other current liabilities	2,457	2,573
Accrued contract manufacturing	1,161	1,479
Accrued property and equipment	202	203
Total accrued expenses and other current liabilities	$ 16,791	$ 13,419

(6) LEASES

The Company has non-cancelable operating leases for its offices located in the U.S. As of September 30, 2025, these leases expire on various dates between 2026 and 2030. Certain lease agreements include one or more options to renew, with renewal terms that can extend the lease up to two years after expiration. The Company has the right to exercise or forego the lease renewal options. The lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The following table presents the maturities and balance sheet information of the Company's operating lease liabilities as of September 30, 2025 (in thousands, except lease term and discount rate):

	September 30, 2025	
	Operating Leases	Finance Leases
2025	$ 329	$ 264
2026	1,187	1,056
2027	912	616
2028	939	—
2029	967	—
Thereafter	163	—
Total lease payments	4,497	1,936
Less: imputed interest	(789)	(149)
Total lease liabilities	$ 3,708	$ 1,787
Lease liabilities: current [(i)]	$ 990	$ 940
Lease liabilities: non-current [(ii)]	2,718	847
Total lease liabilities	$ 3,708	$ 1,787
Weighted average remaining lease term (in years)	4.0	1.8
Weighted average discount rate	9.3%	8.5%

(i) Current lease liabilities are presented within accrued expenses and other current liabilities on the condensed consolidated balance sheets.

(ii) Non-current lease liabilities are presented within other non-current liabilities on the condensed consolidated balance sheets.

The following table presents the components of lease costs for the three months and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating lease cost	$ 234	$ 311	$ 812	$ 933
Variable lease cost and other, net [(i)]	134	131	381	429
Short-term lease cost	—	3	—	14
Finance lease cost:				
Amortization of right-of-use assets	247	254	770	700
Interest	49	63	154	160
Total lease costs	$ 664	$ 762	$ 2,117	$ 2,236

(i) The variable lease cost and other, net is comprised primarily of common area maintenance charges for the operating lease, which are dependent on usage. These costs are classified as operating lease expense due to the election to not separate lease and non-lease components. These costs were not included within the measurement of the Company's operating lease right-of-use assets and operating lease liabilities.

The following table presents the supplemental cash flow disclosures for cash paid for leases for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 976	$ 948
Operating cash flows from finance leases	$ 160	$ 169
Financing cash flows from finance leases	$ 704	$ 751
Right-of-use asset (modified) acquired under leases		
Finance leases	$ (182)	$ 1,309

(7) TERM LOAN

Oxford Finance and Silicon Valley Bank Loan

In October 2022, the Company entered into a loan and security agreement, as amended, the Loan Agreement, with Oxford Finance LLC, Oxford Finance Credit Fund II LP, and Silicon Valley Bank, or SVB, collectively the Lenders, for a secured term loan facility of up to $100.0 million. Pursuant to the Loan Agreement, the Company drew an initial loan of $10.0 million. Under the original terms of the Loan Agreement, the Company had the right to draw an additional $40.0 million through the end of December 2023. In December 2023, the original terms of the Loan Agreement were amended to extend the draw deadline to June 2024. The original terms of the Loan Agreement provided for an additional $50.0 million over three tranches, with $12.5 million available in each of two tranches based upon the achievement of milestones related to the development of evorpacept and one preclinical product candidate, and $25.0 million at the Lenders' sole discretion. The Company decided not to draw down on any portion of the $40.0 million available under the Loan Agreement by the deadline of June 30, 2024 and did not achieve all of the requirements needed to gain access to each of the two tranches available upon the achievement of pre-determined development milestones by the deadline of December 31, 2024. As a result, only the $25.0 million tranche available at the Lenders' sole discretion was available as of September 30, 2025.

The proceeds of the loans may be used by the Company for working capital and to fund its general business requirements.

Additional information regarding our indebtedness is included in our notes to our consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, which was filed with the SEC on March 6, 2025.

During the three months ended September 30, 2025 and 2024, interest expense incurred in connection with the Loan Agreement was $0.3 million and $0.3 million, respectively. During the nine months ended September 30, 2025 and 2024, interest expense incurred in connection with the Loan Agreement was $1.0 million and $0.9 million, respectively.

As of September 30, 2025, the Company was in compliance with all financial reporting covenants under the Loan Agreement.

As of September 30, 2025, the future maturities under the Loan Agreement are as follows (in thousands):

	September 30, 2025
2025	$ 435
2026	5,217
2027	4,948
2028	—
2029	—
Total future maturities	10,600
Less: current portion of term loan	(4,348)
Total term loan, net of current portion	6,252
Less: unamortized debt issuance costs	(384)
Less: unaccreted final payment costs	(104)
Term loan, non-current, net	$ 5,764

(8) STOCKHOLDERS' EQUITY

On July 21, 2020, the Company's amended and restated certificate of incorporation became effective, authorizing 1,000,000,000 shares of common stock, $0.001 par value per share, and 100,000,000 shares of undesignated preferred stock, $0.001 par value per share. As of September 30, 2025 and December 31, 2024, the Company had 53,577,566 and 53,052,912 shares of common stock outstanding, respectively, and no shares of undesignated preferred stock outstanding, respectively.

Common stock reserved for future issuance as of September 30, 2025 consists of the following:

	September 30, 2025
Stock options issued and outstanding	11,647,294
RSUs issued and outstanding	266,529
PSUs issued and outstanding	60,750
Stock options authorized for future issuance	3,794,298
Employee Stock Purchase Plan shares authorized for future issuance	1,466,247
Pre-funded warrants issued and outstanding	1,250,000
Total	18,485,118

At-the-Market Equity Offering

In December 2021, the Company entered into a sales agreement (as amended, Sales Agreement) with Cantor Fitzgerald & Co. and Credit Suisse Securities (USA) LLC (Credit Suisse), under which it may offer and sell shares of the Company's common stock, having aggregate gross proceeds of up to $150.0 million, from time to time through them as the Company's sales agents in its at-the-market (ATM) equity offering program. In August 2023, the Company entered into an amendment to the Sales Agreement to include UBS Securities LLC as an additional sales agent and to remove Credit Suisse as a sales agent. As of September 30, 2025, the Company had issued approximately 2,404,855 shares of common stock pursuant to the Sales Agreement for net proceeds of $30.0 million. The Company may terminate this ATM program at any time, pursuant to its terms.

Pre-Funded Warrants

In October 2023, the Company completed an underwritten follow-on public offering (the October 2023 Offering) pursuant to a shelf registration statement, which provides for aggregate offerings of up to $450.0 million of the Company's securities. As part of the October 2023 underwritten public offering, the Company issued pre-funded warrants to certain investors to purchase 1,250,000 shares of common stock in an underwritten public offering at a public offering price of $6.379 per pre-funded warrant. Each pre-funded warrant entitles the holder to purchase one share of common stock at an exercise price of $0.001 per share.

As of September 30, 2025 and December 31, 2024, respectively, no shares underlying the pre-funded warrants had been exercised. All of the outstanding pre-funded warrants are included in the weighted-average number of shares of common stock used to calculate basic net loss per share attributable to common stockholders (see Note 11 "Net Loss Per Share").

(9) STOCK-BASED COMPENSATION

Equity Incentive Plans

Amended and Restated 2020 Equity Incentive Plan

The Company's Amended and Restated 2020 Equity Incentive Plan, or the 2020 Plan, serves as the successor to the Company's 2020 Equity Incentive Plan and provides for the granting of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance shares.

On January 1, 2025, the number of shares available under the 2020 Plan was increased by 2,122,116 shares.

2025 Inducement Equity Incentive Plan

In January 2025, the Company adopted the 2025 Inducement Equity Incentive Plan, or the 2025 Plan. The 2025 Plan provides for the granting of equity-based awards, including non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance shares. A total of 1,500,000 shares were reserved under the 2025 Plan.

Performance-Based Restricted Stock Units

In February 2024, the Company granted 365,000 performance-based restricted stock units, or PSUs, to certain employees under the 2020 Plan. The PSUs are subject to both performance-based and service-based vesting conditions with a fair value based on the closing price of the underlying common stock on the date of grant. Each PSU is split into two tranches with each tranche having performance goals based on the achievement of pre-determined clinical milestones that result in the shares attributable to such tranche being eligible for vesting, subject to the service-based vesting condition. The service-based vesting condition is satisfied on the one-year anniversary of the performance achievement date for each tranche and is subject to the employee's continuous service through such vesting date. Upon vesting, each PSU will automatically convert into one share of the Company's common stock. If the performance condition for a tranche is not met by March 31, 2025, the shares attributable to such tranche will be forfeited.

The Company determined that the performance conditions for one tranche of PSUs was achieved by the March 31, 2025 deadline. As a result, compensation expense of a nominal amount and $0.8 million has been recognized related to this tranche of PSUs as of and for the three months and nine months ended September 30, 2025, respectively. The performance conditions for the other tranche of PSUs was not achieved as of March 31, 2025, and therefore, these awards were forfeited. As of September 30, 2025, there were 60,750 PSUs outstanding and unvested.

Employee Stock Purchase Plan

Under the Company's 2020 Employee Stock Purchase Plan, or the ESPP, eligible employees are entitled to purchase shares of common stock with accumulated payroll deductions.

Stock-based Compensation Expenses

Total stock-based compensation expense recognized in the condensed consolidated statements of operations was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 1,104	$ 4,648	$ 4,949	$ 14,556
General and administrative	1,417	2,304	4,924	6,679
Total	$ 2,521	$ 6,952	$ 9,873	$ 21,235

(10) RELATED-PARTY TRANSACTIONS

The Company has several related-party agreements with Tallac Therapeutics, Inc., or Tallac. The details of these agreements are described in our notes to our consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, which was filed with the SEC on March 6, 2025. During the three months and nine months ended September 30, 2025, there were no material changes to these agreements.

Tallac Service Agreement

During the three months and nine months ended September 30, 2024, the Company recorded a nominal amount as research and development, or R&D, costs in relation to the research and development services agreement with Tallac, or the Tallac Services Agreement. Per contractual terms, the Tallac Services Agreement terminated on July 1, 2024.

Tallac Collaboration Agreement

During the three months ended September 30, 2025 and 2024, the Company recorded zero and $0.1 million, respectively, as R&D costs in relation to the collaboration agreement with Tallac, or the Tallac Collaboration Agreement. During the nine months ended September 30, 2025 and 2024, the Company recorded $0.1 million and $0.7 million, respectively, as R&D costs in relation to the Tallac Collaboration Agreement.

As of September 30, 2025 and December 31, 2024, the Company had accrued expenses of zero and $0.1 million, respectively, related to the Tallac Collaboration Agreement, which was presented within the payable and accrued liabilities due to related party on the condensed consolidated balance sheets.

(11) NET LOSS PER SHARE

The following table sets forth the computation of the basic and diluted net loss per share for the three months and nine months ended September 30, 2025 and 2024 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss	$ (22,144)	$ (30,707)	$ (78,847)	$ (105,687)
Denominator:				
Weighted-average shares of common stock outstanding, basic and diluted	53,577,066	52,693,878	53,452,319	51,544,501
Net loss per share, basic and diluted	$ (0.41)	$ (0.58)	$ (1.48)	$ (2.05)

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

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share for the three months and nine months ended September 30, 2025 and 2024 because including them would have been anti-dilutive:

	Three Months and Nine Months Ended September 30,	
	2025	2024
Stock options issued and outstanding	11,647,294	10,089,807
RSUs issued and outstanding	266,529	1,026,238
PSUs issued and outstanding	60,750	357,500
Employee Stock Purchase Plan estimated shares issuable	5,930	17,520
Total	11,980,503	11,491,065

(12) COMMITMENTS AND CONTINGENCIES

Guarantees and Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of September 30, 2025.

Contingencies

From time to time, the Company may be a party to various claims in the normal course of business. Legal fees and other costs associated with such actions will be expensed as incurred. The Company will assess, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates will be recorded when and if it is determined that a loss related matter is both probable and reasonably estimable. As of September 30, 2025, the Company had no pending or threatened litigation.

License Agreements

In 2021, the Company entered into a stock purchase agreement with ScalmiBio, Inc., or ScalmiBio. The details of this agreement including the ongoing milestone and royalty payments to the former stockholders of ScalmiBio are described in our notes to our consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, which was filed with the SEC on March 6, 2025. During the three months and nine months ended September 30, 2025, there were no material changes to this agreement.

During the three months ended September 30, 2025 and 2024, the Company recorded costs of $2.5 million and zero, respectively, for payments relating to milestone achievements to the former stockholders of ScalmiBio. During the nine months ended September 30, 2025 and 2024, the Company recorded costs of $2.5 million and $1.0 million, respectively, for payments relating to milestone achievements to the former stockholders of ScalmiBio.

Other Contractual Obligations and Other Commitments

The Company has other contractual obligations and other commitments from manufacturing and service contracts, which are presented as follows as of September 30, 2025 (in thousands):

	September 30, 2025				
	Total	2025 (remaining three months)	2026-2027	2028-2029	Thereafter
Manufacturing and service contracts	$ 2,097	$ 1,000	$ 1,097	$ —	$ —
Total	$ 2,097	$ 1,000	$ 1,097	$ —	$ —

In November 2015, the Company entered into a Master Service Agreement, or the MSA, with KBI Biopharma, Inc. relating to formulation development, process development and current good manufacturing practices, or cGMP, manufacturing of evorpacept for use in clinical trials on a project basis. The MSA had an initial term of three years with successive one-year renewal periods, which was extended an additional eight years until November 2026, is cancellable upon notice and is non-exclusive. Statements of work under the MSA commit the Company to certain future purchase obligations of approximately $0.5 million. In addition, the Company has commitments with five other pharmaceutical contract manufacturers and suppliers, including certain future purchase obligations of approximately $1.6 million. These amounts are based on non-cancellable commitments and forecasts that include estimates of future market demand, quantity discounts and manufacturing efficiencies that may impact timing of purchases.

The Company enters into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of the Company's service providers, up to the date of cancellation.

(13) SUBSEQUENT EVENTS

In preparing the consolidated financial statements as of September 30, 2025, the Company evaluated subsequent events for recognition and measurement purposes through the filing date of this Quarterly Report on Form 10-Q. The Company concluded that no events or transactions have occurred that require disclosure in the accompanying condensed consolidated financial statements.

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

You should read the following discussion of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives. Our clinical pipeline includes two clinical-stage product candidates, the CD47 blocker evorpacept and an epidermal growth factor receptor (EGFR)-targeted antibody drug candidate (ADC) ALX2004. Our lead product, evorpacept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built. Evorpacept is currently being evaluated in combination with trastuzumab and chemotherapy in patients with metastatic HER2-positive breast cancer in the Phase 2 ASPEN-Breast clinical trial and is also being studied in clinical trials with other targeted anti-cancer antibodies. Cancer cells leverage CD47, a cell surface protein, as a "don't eat me" signal to evade macrophage phagocytosis. We are developing evorpacept to be a next-generation checkpoint inhibitor designed to have a high affinity for CD47 and to avoid the limitations caused by hematologic toxicities inherent in other CD47 blocking approaches. Our second pipeline candidate, ALX2004, is a novel EGFR-targeted antibody-drug conjugate with a differentiated mechanism of action entered into a Phase 1 clinical trial in August 2025.

Evorpacept is a next-generation CD47 blocking therapeutic that we believe has significantly enhanced properties compared to competing CD47 blocking approaches. Evorpacept is a fusion protein that combines a high-affinity CD47 binding domain with a proprietary inactivated Fc domain. The CD47 binding domain of evorpacept is an affinity enhanced extracellular domain of SIRPα, a protein found on myeloid cells such as macrophages, that is the natural receptor to CD47. We have engineered the Fc domain of evorpacept so that it does not provide a pro-phagocytic signal while still maintaining an antibody-like half-life for the molecule. We believe our inactive Fc approach improves tolerability when compared to other CD47 blocking approaches that have an Fc domain that engages activating receptors on macrophages, causing phagocytosis and death of healthy cells in addition to cancer cells.

Evorpacept's design has several additional advantages that we believe will make it broadly applicable to treating a number of oncology indications. Due to the inactive Fc, evorpacept is specifically designed for use in combination with other anti-cancer agents that provide a positive immune-stimulating signal. We believe evorpacept has a favorable tolerability profile that may enable higher dosing levels, increased tumor penetration, and greater combination potential with other leading anti-cancer agents.

We are focused on evorpacept development with the standard-of-care agents that provide a stimulatory signal to the innate immune system. We are combining evorpacept with anti-cancer targeted antibodies with an active Fc domain, where evorpacept enables the Fc-mediated antibody dependent phagocytosis that is impaired by the expression of CD47 on cancer cells.

Data from the randomized ASPEN-06 Phase 2 clinical trial supports the clinical validation of this mechanism of action. ASPEN-06 evaluates the contribution of evorpacept to HERCEPTIN® (trastuzumab) plus standard of care (CYRAMZA® (ramucirumab) + paclitaxel) (Evo-TRP), versus trastuzumab, ramucirumab, and paclitaxel (TRP) in second line or later human epidermal growth factor receptor 2 (HER2)-positive gastric/gastroesophageal junction (GEJ) cancer, where all patients had received an anti-HER2 agent in prior lines of therapy. The full data set was previously presented. Results from a pre-planned exploratory analysis will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting:

- In a pre-planned exploratory analysis of the ASPEN-06 clinical trial in gastric cancer, CD47 overexpression was identified as a key predictive biomarker for response and durable benefit in patients with retained HER2 expression. Retained HER2 expression is defined as patients who are HER-2 positive on a tumor biopsy after receiving a HER2-targeted treatment or by HER2 amplification by circulating tumor DNA (ctDNA). The data will be highlighted as part of a poster presentation at the SITC Annual Meeting on November 8th.
  - In patients with retained HER2-positive and CD47-high gastric cancer (n=43), Evo-TRP had a 65.0% objective response rate (ORR) versus 26.1% ORR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer (n=47), Evo-TRP had a 37.5% ORR compared to 26.1% ORR for TRP.
  - The duration of response (DOR) was three times longer in the Evo-TRP arm relative to TRP in these patients. Evo-TRP had a median DOR (mDOR) of 25.5 months versus 8.4 months mDOR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer, had an mDOR of 11.2 months for Evo-TRP compared to 12 months for TRP. Progression free survival (PFS) and overall survival (OS) data were evaluated in these patients. Treatment with Evo-TRP resulted in a PFS of 18.4 months versus 7.0 months for TRP, hazard ratio (HR) of 0.39. Treatment with Evo-TRP resulted in an OS of 17 months versus 9.9 months for TRP, HR of 0.63.

Evorpacept has been combined in clinical trials with multiple anti-cancer antibodies in addition to trastuzumab. Our earlier ASPEN-01 Phase 1 positive data in combination with rituximab in non-Hodgkin lymphoma (NHL) and the recent clinical data of our investigator-sponsored trial (IST) collaborator from the ongoing Phase 1/2 IST of evorpacept in combination with rituximab and lenalidomide patients with relapsed refractory B-cell NHL (R/R B-NHL) provide additional support for the clinical validation of this mechanism of action and support exploring combinations of evorpacept with other anti-cancer antibodies.

Our second product candidate is ALX2004, a novel EGFR-targeted ADC. ALX2004 was created from our proprietary linker-payload platform and fully designed and developed in-house by our scientists. ALX2004 comprises a matuzumab-derived affinity-selected EGFR antibody backbone engineered for optimal activity as an antibody drug conjugate (ADC), a proprietary topoisomerase I inhibitor payload with enhanced bystander effect, and a linker with enhanced stability. EGFR is clinically validated as a therapeutic target with several U.S. Food and Drug Administration (FDA)-approved targeted antibodies and small molecules. However, there are currently no approved EGFR-targeted ADCs and early-generation attempts to develop EGFR-targeted ADCs were limited by drug design, on-target off-tumor toxicities and toxicity of older generation payloads.

We are engaged in the following clinical programs, collaborations, and investigator-sponsored trials:

Evorpacept

Combination with the HER2-targeted antibody trastuzumab

- ASPEN-Breast - Breast Cancer
  - In March 2025, we announced intent to initiate a randomized Phase 2 clinical trial evaluating evorpacept in combination with trastuzumab and chemotherapy for the treatment of patients with HER2-positive metastatic breast cancer after prior treatment with fam-trastuzumab deruxtecan-nxki.
  - In August 2025, we announced that based on the magnitude of benefit in patients with high CD47 expression in HER2-positive gastric cancer, the ASPEN-Breast study in HER2-positive breast cancer evaluating evorpacept in combination with trastuzumab and chemotherapy has been amended to a single-arm design in all previously treated HER2 positive patients and will be evaluated by CD47 expression.
- ASPEN-06 - Gastric/GEJ Cancer
  - In January 2020, the FDA granted Fast Track designation for evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-overexpressing advanced gastric or GEJ adenocarcinoma with disease progression on or after prior trastuzumab and fluoropyrimidine or platinum containing chemotherapy.
  - In January 2022, the FDA's Office of Orphan Products Development granted Orphan Drug Designation (ODD) to evorpacept for the treatment of patients with gastric/GEJ cancer.
  - In March 2022, we announced the dosing of the first patient in the multi-center, international ASPEN-06 trial, a randomized Phase 2/3 trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of second- and third-line advanced HER2-overexpressing gastric/GEJ cancer, where all patients had received an anti-HER2 agent in prior lines of therapy.
  - In June 2023, the European Commission granted ODD to evorpacept for the treatment of patients with gastric/GEJ cancer.
  - In October 2023, we announced positive prespecified interim Phase 2 clinical data from our ASPEN-06 clinical trial. This prespecified interim analysis reported results from 54 randomized patients with second and third line gastric/GEJ cancer, including patients previously treated with fam-trastuzumab deruxtecan-nxki and checkpoint inhibitors. A confirmed ORR of 52% was demonstrated for the Evo-TRP treatment arm compared to 22% for the TRP control arm. An mDOR was not reached for the Evo-TRP treatment arm compared to 7.4 months for the control group. The safety profile of evorpacept was consistent with previous clinical trials and was well-tolerated.
  - In July 2024, we announced the topline data from our ASPEN-06 Phase 2 clinical trial. This topline data reported results from 127 randomized patients with second and third line gastric/GEJ cancer and was generally well-balanced across arms based on prespecified stratification factors including line of therapy, prior ENHERTU use, Asia region, tumor location (GC or GEJ), HER2 expression level, and having HER2-positive disease based upon a tissue biopsy after anti-HER2 treatment. A confirmed ORR of 40.3% was demonstrated for the Evo-TRP treatment arm compared to 26.6% for the TRP control arm. The mDOR was 15.7 months for the Evo-TRP treatment arm and 7.6 months for the TRP control arm in the full trial population. In patients with fresh HER2-positive biopsies (n=48), Evo-TRP demonstrated an ORR of 54.8% compared to 23.1% for the TRP control.

- In January 2025, we presented updated results from the ASPEN-06 Phase 2 clinical trial in an oral presentation at the 2025 American Society of Clinical Oncology Gastrointestinal Cancers Symposium. A confirmed ORR of 41.3% was demonstrated for the Evo-TRP treatment arm compared to 26.6% for the TRP control arm in the intent-to-treat patient population. In patients with confirmed HER2-positive expression as determined by either fresh biopsy or ctDNA HER2-positivity (n=96), the addition of evorpacept to TRP resulted in a 48.9% ORR, an mDOR of 15.7 months and median progression free survival (mPFS) of 7.5 months, compared to a 24.5% ORR, an mDOR of 9.1 months and mPFS of 6.7 months in the TRP control group, with a PFS HR of 0.64.
- In April 2025, we received guidance from the FDA that the ASPEN-06 Phase 2 trial data evaluating Evo-TRP was not eligible for submission for accelerated approval given the availability of ENHERTU. A Phase 3 versus ENHERTU trial would be needed to pursue a regulatory approval of evorpacept in the second-line setting for HER2-positive gastric and GEJ. Given our disciplined focus and the allocation of our resources, we will not pursue a U.S. registrational path with a Phase 3 trial in gastric cancer and will consider exploring development partnerships to advance this program in gastric cancer.
- In August 2025, we announced topline results from pre-planned exploratory analysis of the ASPEN-06 trial in gastric cancer, where CD47 overexpression was identified as a key predictive biomarker for response and durable benefit.
- In November 2025, we will present a pre-planned exploratory analysis of the ASPEN-06 clinical trial in gastric cancer in which CD47 overexpression was identified as a key predictive biomarker for response and durable benefit in patients with retained HER2 expression.
    - In patients with retained HER2-positive and CD47-high gastric cancer (n=43), Evo-TRP had a 65.0% ORR versus 26.1% ORR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer (n=47), Evo-TRP had a 37.5% ORR compared to 26.1% ORR for TRP.
    - The DOR was three times longer in the Evo-TRP arm relative to TRP in these patients. Evo-TRP had an mDOR of 25.5 months versus 8.4 months mDOR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer, had an mDOR of 11.2 months for Evo-TRP compared to 12 months for TRP. PFS and OS data were evaluated in these patients. Treatment with Evo-TRP resulted in a PFS of 18.4 months versus 7.0 months for TRP, HR of 0.39. Treatment with Evo-TRP resulted in an OS of 17 months versus 9.9 months for TRP, HR of 0.63.

Combination with the EGFR-targeted antibody cetuximab

- ASPEN-CRC - Colorectal Cancer (CRC)
    - In March 2025, we announced intent to initiate a Phase 1b study evaluating evorpacept in combination with the EGFR-targeted antibody cetuximab and FOLFIRI for the treatment of patients with second-line metastatic CRC.
    - In August 2025, we streamlined evorpacept development program to focus our resources on the ASPEN-Breast trial and paused the ASPEN-CRC study announced earlier in March 2025.

Collaborations and Investigator-Sponsored Trials (ISTs)

Combination with the HER2-targeted bispecific, zanidatamab, and HER2-targeted ADC, fam-trastuzumab deruxtecan-nxki

- Jazz Pharmaceuticals plc - Breast Cancer
    - Our collaborator, Jazz Pharmaceuticals plc (Jazz), is sponsoring and managing an ongoing Phase 1 trial of zanidatamab, a HER2-targeted anti-cancer antibody, for the treatment of advanced HER2-expressing breast cancer and other solid tumors in combination with evorpacept (Zanidatamab Trial). We announced the dosing of the first patient in this trial in October 2021.
    - Our initial collaborator for the Zanidatamab Trial was Zymeworks Inc. (Zymeworks), however in a series of transactions commencing in October 2022, Jazz assumed responsibility from Zymeworks for the development and commercialization of zanidatamab in the United States, Europe, Japan and certain other territories, including responsibility for the Zanidatamab Trial.

- In December 2024, Phase 1b/2 data were presented in a poster presentation at the 2024 San Antonio Breast Cancer Symposium (SABCS). The SABCS poster presentation data-cut reported on efficacy findings from all three of the part-two trial cohorts: Cohort 1 (n=21) consisted of patients with HER2-positive breast cancer who had received prior ENHERTU and also a median of six prior systemic therapies in the metastatic setting. Patients were enrolled based on local assessment of tumor samples or central assessment. Of the 21 patients enrolled in Cohort 1, nine were found to be HER2-positive based on central assessment. Cohort 2 (n=15) consisted of patients with HER2-low breast cancer who had received a median of five prior systemic therapies. Cohort 3 (n=8) consisted of patients with other HER2-expressing cancers. Patients in Cohort 1 who were HER2-positive by central assessment (n=9) showed the greatest anti-tumor activity with a confirmed ORR of 55.6% and an mPFS of 7.4 months. Overall, patients in Cohort 1 (n=21) had a confirmed ORR and mPFS of 33.3% and 3.6 months, respectively. Patients in Cohort 2 had a confirmed ORR and mPFS of 20.0% and 1.9 months, respectively. As of the August 2024 data cutoff, median follow-up was 9.6 months, with six patients still on treatment. The mDOR was not reached for Cohort 1 patients (range: 3.6-25.9 months) and was 5.5 months for Cohort 2 patients (range: 3.6-11.0 months), with responses ongoing, including the longest observed response, in each cohort. The combination therapy was well tolerated with a manageable safety profile that was consistent with prior experience of each agent.

- Quantum Leap Healthcare Collaborative - I-SPY Trial - Breast Cancer
  - Our collaborator, Quantum Leap Healthcare Collaborative (Quantum Leap), is sponsoring and managing an ongoing Phase 1 trial (I-SPY) to evaluate evorpacept in combination with fam-trastuzumab deruxtecan-nxki for the treatment of patients with unresectable or metastatic HER2-positive and HER2-low breast cancer. We announced the dosing of the first patient in March 2023.

Combination with the CD20-targeted antibody rituximab

- MD Anderson Cancer Center - Non-Hodgkin Lymphoma
  - In 2021, an IST of evorpacept was initiated in combination with rituximab and lenalidomide (R^2) for the treatment of patients with indolent and aggressive NHL, sponsored by MD Anderson Cancer Center in Texas. We announced the dosing of the first patient in September 2021.
  - In April 2024, MD Anderson Cancer Center reported clinical data from the ongoing Phase 1/2 IST of evorpacept in combination with R2 in patients with R/R B-NHL. The new data were presented in an oral presentation at the 2024 American Association for Cancer Research (AACR) Annual Meeting. The Phase 1 part of the clinical trial enrolled a total of 20 patients with indolent (n=18) and aggressive (n=2) R/R B-NHL where all patients had received prior rituximab and 72% had received prior chemoimmunotherapy. Patients received evorpacept 30 mg/kg every two weeks (Q2W) (n=3) or 60 mg/kg every four weeks (Q4W) (n=17) in combination with standard R2 treatment. The regimen was well tolerated, and there were no dose-limiting toxicities. Patients with indolent R/R B-NHL (n=18) had a best ORR of 94% and a complete response rate of 83%. The mDOR was not reached.
  - In April 2025, final data for the Phase 1 portion of the MD Anderson Cancer Center IST was presented at the 2025 AACR Annual Meeting. In the total population (n=20), after a median follow-up of 28 months (95% CI, 18-28 months) the two-year PFS rate was 69% and two-year OS rate was 84%. The Phase 2 portion of the clinical trial in patients with previously untreated indolent NHL is ongoing and has completed enrollment.

Combination with the CD38-targeted antibody isatuximab-irfc

- Sanofi - Multiple Myeloma
  - In April 2023, we announced a collaboration with Sanofi who will sponsor and manage a Phase 1/2 trial of SARCLISA® (isatuximab-irfc), an anti-cancer antibody, and dexamethasone in combination with evorpacept for the treatment of patients with relapsed or refractory multiple myeloma. We announced the dosing of the first patient in September 2024.
  - In July 2025, Sanofi and ALX Oncology announced the dose escalation portion of the cohort testing evorpacept with isatuximab-irfc and dexamethasone within the randomized phase 1/2 UMBRELLA study in patients with previously treated multiple myeloma is complete.
  - In August 2025, we announced that Sanofi began the dose optimization portion of the study.

Combination with PD-1/PD-L1 immune checkpoint inhibitor

Dendritic cells are also inhibited by the interaction of SIRPα with CD47. Activated dendritic cells present neoantigens to T-cells that, once activated, will kill cancer cells when the PD-1/PD-L1 inhibitory interaction is blocked by T-cell checkpoint inhibitors such as pembrolizumab.

- University of Pittsburgh - Ovarian Cancer
  - In 2023, a Phase 2 IST of evorpacept was initiated in combination with liposomal doxorubicin and pembrolizumab in patients with recurrent platinum-resistant ovarian cancer, sponsored by the University of Pittsburgh in Pennsylvania. We announced the dosing of the first patient in May 2023.
- University of California San Diego - Oropharyngeal Cancer
  - In April 2024, a Phase 2 IST of evorpacept was initiated in combination with neoadjuvant radiation and pembrolizumab in patients with previously untreated and early-stage locally advanced, resectable, human papillomavirus-mediated oropharyngeal cancer, sponsored by the University of California San Diego.

ALX2004

- ALX2004 is a novel EGFR-targeted ADC that was created from our proprietary linker-payload platform and fully designed and developed in-house by our scientists. ALX2004 comprises a matuzumab-derived affinity-selected EGFR antibody backbone engineered for optimal activity as an ADC, a proprietary topoisomerase I inhibitor payload with enhanced bystander effect, and a linker with enhanced stability.
- In March 2025, we filed an IND application for our first ADC program, ALX2004 and in April 2025, the FDA cleared the IND to evaluate ALX2004 in a Phase 1 clinical trial for patients with epidermal growth factor receptor expressing solid tumors.
- In August 2025, we announced the dosing of the first patient in the first-in-human, open-label multi-center Phase 1 clinical trial of ALX2004 for the treatment of advanced or metastatic select EGFR-expressing solid tumors.

Since our founding, we have devoted substantially all of our resources to developing evorpacept, identifying and advancing preclinical programs, including the initiation and advancement of clinical trials of ALX2004, scaling up manufacturing, conducting clinical trials and providing general and administrative support for these operations. We have no products approved for marketing and we have never received any revenue from drug product sales.

From inception through September 30, 2025, we have raised an aggregate of $643.5 million to fund our operations, of which $175.1 million were net proceeds from sales of our convertible preferred stock, $5.8 million were net proceeds from borrowings under a term loan, $169.5 million were net proceeds from our initial public offering, $194.9 million were net proceeds from our follow-on offering in December 2020, $9.3 million were net proceeds from borrowings under the Loan Agreement (as defined below), $58.9 million were net proceeds from our follow-on offering in October 2023, and $30.0 million were net proceeds from our at-the-market (ATM) offering. For more information on the funding of our operations since inception, see section titled "—Liquidity and Capital Resources; Plan of Operations—Funding Requirements" included elsewhere in this Quarterly Report on Form 10-Q.

We have incurred net losses in each year since inception. Our net losses were $22.1 million and $30.7 million for the three months ended September 30, 2025 and 2024, respectively, and $78.8 million and $105.7 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $700.0 million. Substantially all of our operating losses are a result of expenses incurred in connection with our research and development programs, primarily evorpacept, and from general and administrative expenses associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance evorpacept through multiple clinical trials in multiple indications;
- pursue regulatory approval of evorpacept in solid tumors and hematological malignancies;
- advance ALX2004 through a first-in-human trial;
- continue preclinical and clinical development efforts;
- obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- manufacture supplies for our preclinical studies and clinical trials; and
- continue to add operational, financial and management information systems to support ongoing operations as a public company.

Nasdaq Minimum Bid Price Compliance

On April 23, 2025, we received a written notice (Notice), from the Listing Qualifications Staff (Staff) of The Nasdaq Stock Market LLC (Nasdaq) notifying us that we had not been in compliance with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market set forth in Nasdaq Listing Rule 5450(a)(1) for a period of 30 consecutive business days. The Notice had no immediate effect on the listing of our common stock on the Nasdaq Global Select Market, subject to our compliance with the other listing requirements of Nasdaq. In September 2025, we received written confirmation from the Staff of Nasdaq that we had regained compliance with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market, as the closing bid price of our common stock had been at $1.00 per share or greater for ten consecutive business days.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, evorpacept, and the initiation and advancement of ALX2004, which include:

- expenses incurred in connection with preclinical and clinical development, including expenses incurred under collaboration agreements and under agreements with contract research organizations, or CROs;
- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expenses for employees engaged in research and development functions;
- expenses related to production of clinical materials, including fees paid to contract manufacturing organizations, or CMOs;
- laboratory, vendor expenses and third-party drugs related to the execution of preclinical studies and clinical trials; and
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

We expense research and development costs as incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered or as services are performed. We record accruals for estimated costs of research, preclinical studies, clinical trials and manufacturing development, which are a significant component of research and development expenses. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

Our research and development expenses consist primarily of costs associated with the development of our lead product candidate, evorpacept, and the initiation and advancement of clinical trials of ALX2004, and include external costs, such as fees paid to consultants, central laboratories, contractors, collaborators, CMOs and CROs in connection with our preclinical and clinical development activities.

Almost all of our research and development expenses to date have been related to the clinical development of our lead product candidate, evorpacept, and the initiation and advancement of clinical trials of ALX2004. We expect to incur significant research and development expenses in the foreseeable future as we continue to invest in research and development activities related to progress on our existing product candidates. As our product candidates advance into later stages of development, we begin to conduct larger clinical trials. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, 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 any of our product candidates.

The successful development of our current and future product candidates is highly uncertain. This is due to numerous risks and uncertainties, including the following:

- successful completion of preclinical studies and clinical trials;
- delays in regulators or institutional review boards authorizing us or our investigators to commence our clinical trials;
- our ability to negotiate agreements with clinical trial sites or CROs;
- the number and location of clinical sites included in the trials;
- raising additional funds necessary to complete clinical development of our product candidates;

- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- contracting with third-party manufacturers for clinical supplies of our product candidates;
- protecting and enforcing our rights in our intellectual property portfolio, including, if necessary, litigation; and
- maintaining a continued acceptable safety profile of the products following approval.

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

Research and development activities are essential to our business model. There are numerous factors associated with the successful commercialization of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact the success, cost or timing of our clinical development programs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, business development expenses, facilities expenses, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit, accounting and tax-related services, and directors and officers liability insurance premiums. Personnel and related costs consist of salaries, benefits and stock-based compensation expenses. Facilities costs consist of rent and maintenance of facilities.

We anticipate that our general and administrative expenses will decrease as a result of the completed reduction in workforce. Other factors that may affect general administrative expenses include inflationary pressures, higher costs of consulting, legal, tax and regulatory-related services associated with maintaining compliance with stock exchange listing and Securities and Exchange Commission (SEC) requirements, audit and investor relations costs, director and officer insurance premiums and other costs associated with being a public company.

Impairment Charge

Impairment charge consists of impairment of long-lived assets.

Interest Income

Our interest income consists primarily of interest income on cash, cash equivalents and investments.

Interest Expense

Our interest expense consists primarily of interest expense on the term loan, amortization of deferred debt issuance costs, and interest related to finance leases.

Other Income (Expense), Net

Our other income (expense), net consists primarily of realized foreign currency transaction gains and losses.

Results of Operations and Net Loss

The following table summarizes our results of operations for the three months and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2025	2024	$	%	2025	2024	$	%
Operating expenses:								
Research and development	$ 17,441	$ 26,471	$ (9,030)	-34%	$ 59,351	$ 92,841	$ (33,490)	-36%
General and administrative	5,091	6,096	(1,005)	-16%	18,474	19,013	(539)	-3%
Impairment charge	—	—	—	0%	3,175	—	3,175	100%
Total operating expenses	22,532	32,567	(10,035)	-31%	81,000	111,854	(30,854)	-28%
Loss from operations	(22,532)	(32,567)	10,035	-31%	(81,000)	(111,854)	30,854	-28%
Interest income	802	2,303	(1,501)	-65%	3,391	7,488	(4,097)	-55%
Interest expense	(408)	(446)	38	-9%	(1,219)	(1,302)	83	-6%
Other income (expense), net	(6)	3	(9)	-300%	(19)	(19)	—	0%
Net loss	$ (22,144)	$ (30,707)	$ 8,563	-28%	$ (78,847)	$ (105,687)	$ 26,840	-25%

Research and Development Expenses

The following table summarizes our research and development (R&D) expenses incurred for the three months and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2025	2024	$	%	2025	2024	$	%
Clinical and development costs	$ 9,911	$ 12,463	$ (2,552)	-20%	$ 32,282	$ 50,370	$ (18,088)	-36%
Preclinical costs	183	2,037	(1,854)	-91%	2,039	5,190	(3,151)	-61%
Personnel and related costs	2,710	5,865	(3,155)	-54%	13,855	17,438	(3,583)	-21%
Stock-based compensation expense	1,104	4,648	(3,544)	-76%	4,949	14,556	(9,607)	-66%
Other research costs	3,533	1,458	2,075	142%	6,226	5,287	939	18%
Total research and development expenses	$ 17,441	$ 26,471	$ (9,030)	-34%	$ 59,351	$ 92,841	$ (33,490)	-36%

R&D expenses decreased by $9.0 million during the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The decrease was primarily attributable to a decrease of $2.6 million in clinical and development costs primarily due to manufacturing of clinical trial materials, the majority of which was completed in early 2024, to support active clinical trials for our lead product candidate, evorpacept, a decrease of $3.5 million in stock-based compensation expense due to terminations from the reduction in workforce as well as modification from the December 2024 option exchange, a decrease of $3.2 million in personnel and related costs primarily driven by the reduction in workforce in Q1 2025, and a decrease of $1.9 million in preclinical costs due to pipeline prioritization strategy. These decreases were offset by an increase of $2.1 million in other research costs due to a $2.5 million development milestone met related to ScalmiBio.

R&D expenses decreased by $33.5 million during the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The decrease was primarily attributable to a decrease of $18.1 million in clinical and development costs primarily due to manufacturing of clinical trial materials, the majority of which was completed in early 2024, to support active clinical trials for our lead product candidate, evorpacept, a decrease of $9.6 million in stock-based compensation expense due to terminations from the reduction in workforce as well as modification from the December 2024 option exchange, a decrease of $3.2 million in preclinical costs due to pipeline prioritization strategy, and a decrease of $3.6 million in personnel and related costs primarily driven by the reduction in workforce in Q1 2025. These decreases were offset by an increase of $0.9 million in other research costs due to an increase of $1.5 million in development milestone met related to ScalmiBio compared to the prior period offset by decreases in facility and IT costs allocated to R&D from a decrease in headcount as a result of the reduction in workforce.

General and Administrative Expenses

The following table summarizes our general and administrative (G&A) expenses incurred for the three months and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2025	2024	$	%	2025	2024	$	%
Personnel and related costs	$ 1,678	$ 1,644	$ 34	2%	$ 6,379	$ 5,061	$ 1,318	26%
Stock-based compensation expense	1,417	2,304	(887)	-38%	4,924	6,679	(1,755)	-26%
Other general and administrative costs	1,996	2,148	(152)	-7%	7,171	7,273	(102)	-1%
Total general and administrative expenses	$ 5,091	$ 6,096	$ (1,005)	-16%	$ 18,474	$ 19,013	$ (539)	-3%

G&A expenses decreased by $1.0 million during the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The decrease was primarily attributable to a decrease of $0.9 million in stock-based compensation expense due to terminations from the reduction in workforce as well as modification from the December 2024 option exchange and a decrease of $0.2 million in other G&A costs from legal consulting costs.

G&A expenses decreased by $0.5 million during the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The decrease was primarily attributable to a decrease of $1.8 million in stock-based compensation expense due to terminations from the reduction in workforce as well as modification from the December 2024 option exchange and a decrease of $0.1 million in other G&A costs from legal consulting costs. This was offset by an increase of $1.3 million in personnel and related costs primarily driven by severance costs from the reduction in workforce.

Impairment Charge

Impairment charge increased by zero and $3.2 million for the three months and nine months ended September 30, 2025. In May 2025, we made a decision to sublease our leased property in Palo Alto and are actively marketing the leased property for sublease. We recorded long-lived asset impairment charge based on the performed impairment analysis.

Interest Income

Interest income decreased by $1.5 million for the three months ended September 30, 2025 compared to the three months ended September 30, 2024 and by $4.1 million for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The decreases were primarily attributable to lower cash and investment balances during 2025 as compared to 2024.

Interest Expense

Interest expense remained flat for the three months ended September 30, 2025 compared to the three months ended September 30, 2024, as well as for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024 due to similar interest rates during the periods.

Other Income (Expense), Net

Other income (expense), net remained flat for the three months ended September 30, 2025 compared to the three months ended September 30, 2024, as well as for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

Since our inception, we have incurred significant operating losses and have not generated any product revenue. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all, subject to regulatory and marketing approval of any of our product candidates. To date, we have funded our operations with proceeds from the sales of shares of our common stock and convertible preferred stock and borrowings under our term loan. As of September 30, 2025, we had cash, cash equivalents and investments of $66.5 million.

Funding Requirements

We have incurred losses and negative cash flows from operations since inception and anticipate that we will continue to incur net losses for the foreseeable future. As of September 30, 2025, we had an accumulated deficit of $700.0 million. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. In addition, we expect to incur additional costs associated with operating as a public company. Management recognizes the need to raise additional capital to fully implement its business plan. The timing and amount of such future capital requirements are difficult to forecast and will depend on many factors, including:

- the timing and progress of preclinical and clinical development activities;
- successful enrollment in and completion of clinical trials;
- the timing and outcome of regulatory review of our product candidates;
- our ability to establish agreements with third-party manufacturers for clinical supply for our clinical trials and, if any of our product candidates are approved, commercial manufacturing;
- addition and retention of key research and development personnel;
- our efforts to enhance operational, financial and information management systems, and hire additional personnel, including personnel to support development of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval;
- the legal patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone and royalty payments thereunder;
- our ability to maintain our listing on Nasdaq; and

- macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, duration of the U.S. federal government shutdown, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Other than a loan and security agreement (as amended, the Loan Agreement) we entered into with Oxford Finance LLC, Oxford Finance Credit Fund II LP, and Silicon Valley Bank (SVB) (collectively, the Lenders), for a secured term loan facility of up to $100.0 million in October 2022, we do not have any committed external source of funds. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide. To the extent that we raise additional capital through the sale of equity or convertible debt securities, a stockholder's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect one's rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

In July 2020, we completed our initial public offering pursuant to a registration statement on Form S-1. In the initial public offering, we issued and sold an aggregate of 9,775,000 shares of common stock, including the underwriters' exercise in full of their overallotment option, under the registration statement at a public offering price of $19.00 per share. Net proceeds were approximately $169.5 million, after deducting underwriting discounts and commissions of $13.0 million and offering-related expenses of $3.2 million.

In December 2020, we completed our follow-on public offering pursuant to a registration statement on Form S-1. In the follow-on public offering, we issued and sold an aggregate of 2,737,000 shares of common stock, including the underwriters' exercise in full of their overallotment option, under the registration statement at a public offering price of $76.00 per share. Net proceeds were approximately $194.9 million, after deducting underwriting discounts and commissions of $12.5 million and offering-related expenses of $0.7 million.

In December 2021, we entered a sales agreement (as amended, Sales Agreement) with Cantor Fitzgerald & Co. and Credit Suisse Securities (USA) LLC (Credit Suisse), under which we may offer and sell our common stock, having aggregate gross proceeds of up to $150.0 million, from time to time through them as our sales agents in our ATM offering program. In March 2022, we filed a universal shelf registration statement (2022 Shelf Registration Statement) with the SEC, which was declared effective by the SEC on May 31, 2022. In August 2023, we entered into an amendment to the Sales Agreement to include UBS Securities LLC as an additional sales agent and to remove Credit Suisse as a sales agent.

In October 2022, we entered into the Loan Agreement as described above. Upon closing of the Loan Agreement, we drew $10.0 million. Under the original terms of the Loan Agreement, we had the right to draw an additional $40.0 million through the end of 2023. A further $50.0 million was potentially available to us, $25.0 million upon the achievement of pre-determined development milestones and $25.0 million at the Lenders' sole discretion. For a description of the terms of the Loan Agreement, see "Note 7. Term Loan" to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. On May 31, 2023, we entered into a second amendment to the Loan Agreement. The primary purpose of the second amendment was to reduce the percentage of the amount required to be held in our collateral account with SVB-First Citizens from 100% to not less than 50% of the aggregate dollar value of all our collateral accounts.

In March 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) to act as receiver. The FDIC created Silicon Valley Bridge Bank, N.A. (SVBB) as successor to SVB. First Citizens BancShares, Inc. (First Citizens Bank) acquired SVBB from the FDIC and operates SVBB as Silicon Valley Bank, a division of First Citizens Bank (SVB-First Citizens). While we have cash in operating accounts with SVB, the majority of our cash, cash equivalents and investments are deposited in custodial accounts held by U.S. Bank for which SVB Asset Management is the investment advisor. There has been no material negative impact to our cash liquidity as a result of the closure of SVB or the subsequent acquisition of SVBB by First Citizens Bank. Under the Loan Agreement, 50% of the funding comes from SVB, one of the three Lenders. Given the SVBB acquisition by First Citizens Bank, SVB-First Citizens will continue to fulfill SVB's obligations under the Loan Agreement.

In October 2023, we completed an underwritten follow-on public offering pursuant to the 2022 Shelf Registration Statement (the October 2023 Offering). In the follow-on public offering, we issued and sold an aggregate of 8,663,793 shares of common stock, including the underwriters' exercise in full of their overallotment option of 1,293,103 shares of common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,250,000 shares of common stock at a public offering price of $6.38 per share and $6.379 per pre-funded warrant. Net proceeds were approximately $58.9 million, after deducting underwriting discounts and commissions of $3.8 million and offering-related expenses of $0.6 million. As of September 30, 2025, no shares underlying the pre-funded warrants had been exercised.

In December 2023, we entered into a third amendment to the Loan Agreement. The primary purpose of the third amendment was to (i) extend the draw period for the first tranche loans from December 31, 2023 to June 30, 2024, (ii) add as a condition for the funding of any first tranche loans after the effective date of the amendment, requirement that the Phase 2 portion of the ASPEN-06 study in gastric/GEJ cancer either remains ongoing or the achievement of a milestone related to the development of the ASPEN-06 study, and (iii) add a contingency fee in the amount of $0.6 million to the Lenders if the Company prepays any of the loans under the Loan Agreement other than in connection with refinancing of the Loan Agreement with the Lenders and their affiliates.

We decided not to draw down on any portion of the $40.0 million available to us under the Loan Agreement by the deadline of June 30, 2024. As a result of this decision, the $40.0 million was added to the $25.0 million available upon the achievement of pre-determined development milestones for a total of $65.0 million available, split equally between each of the two tranches. We did not achieve all of the requirements needed to gain access to each of the two tranches available upon the achievement of pre-determined development milestones by the deadline of December 31, 2024. As a result, only the $25.0 million tranche available at the Lenders' sole discretion was available to us as of September 30, 2025.

On March 6, 2025, we filed a shelf registration statement with the SEC that became effective on April 24, 2025 (the 2025 Shelf Registration Statement). The 2025 Shelf Registration Statement replaced the 2022 Shelf Registration Statement and registered the unsold securities from the 2022 Shelf Registration Statement, including those available under the ATM program. From December 2021 to September 30, 2025, we sold an aggregate of 2,404,855 shares of common stock under our Sales Agreement for net proceeds of $30.0 million, after deducting commissions. We may terminate this ATM program and the Sales Agreement at any time, pursuant to its terms.

We believe our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2027. Additionally, the Company also has the ability to further utilize the ATM program. We have based these estimates on assumptions in which actuals may materially differ, and we could utilize our available capital resources sooner than we expect.

Cash Flows

The following table presents a summary of the net cash flow activity for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	**2024**
Net cash provided by (used in):		
Operating activities	$ (65,162)	$ (89,866)
Investing activities	71,353	53,073
Financing activities	(316)	30,489
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 5,875	$ (6,304)

Operating Activities

In the nine months ended September 30, 2025, net cash used in operating activities of $65.2 million was attributable to a net loss of $78.8 million and a change in our net operating assets and liabilities of $0.4 million, offset by non-cash charges of $14.1 million. The change in operating assets and liabilities was primarily due to (i) an increase in accounts payable, payable and accrued liabilities due to related party, and accrued expenses and other current liabilities of $6.1 million primarily due to timing of invoices and payments, (ii) a decrease in prepaid and other current assets of $0.7 million, (iii) a decrease in other non-current liabilities of $1.5 million and (iv) an increase in other assets of $5.7 million. Non-cash charges consisted primarily of stock-based compensation expense of $9.9 million, non-cash lease costs of $1.3 million, depreciation and amortization costs of $0.6 million, and impairment charge of $3.2 million offset by net amortization of premiums and accretion of discounts on investments of $1.1 million.

In the nine months ended September 30, 2024, net cash used in operating activities of $89.9 million was attributable to a net loss of $105.7 million and a change in our net operating assets and liabilities of $3.7 million, offset by non-cash charges of $19.5 million. The change in operating assets and liabilities was primarily due to (i) a decrease in accounts payable and accrued expenses and other current liabilities of $2.8 million primarily due to timing of invoices and payments, (ii) a decrease in other assets of $2.2 million, (iii) an increase in prepaid and other current assets of $1.4 million and (iv) a decrease in other non-current liabilities of $1.6 million. Non-cash charges consisted primarily of stock-based compensation expense of $21.2 million, non-cash lease costs of $1.3 million, and depreciation and amortization costs of $0.7 million offset by net amortization of premiums and accretion of discounts on investments of $3.9 million.

Investing Activities

In the nine months ended September 30, 2025, net cash provided by investing activities of $71.4 million was attributable to cash received for maturities of investments of $117.1 million offset by purchases of short-term and long-term investments of $45.6 million and purchases of property and equipment of $0.2 million.

In the nine months ended September 30, 2024, net cash provided by investing activities of $53.1 million was attributable to cash received for maturities of investments of $156.4 million offset by purchases of short-term and long-term investments of $103.0 million and purchases of property and equipment of $0.4 million.

Financing Activities

In the nine months ended September 30, 2025, net cash used in financing activities of $0.3 million was attributable to principal payments on finance leases of $0.7 million offset by proceeds from our ATM offering program of $0.4 million.

In the nine months ended September 30, 2024, net cash provided by financing activities of $30.5 million was attributable to proceeds from our ATM offering program of $29.3 million, proceeds from the exercise of stock options under equity incentive plans of $1.6 million, and proceeds from issuance of common stock pursuant to employee stock purchase plan of $0.3 million, offset by principal payments on finance leases of $0.8 million.

Off-Balance Sheet Arrangements

During the period presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ significantly from these estimates under different assumptions or conditions.

Our significant accounting policies and critical accounting estimates are more fully described in the notes to our audited consolidated financial statements and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates," respectively, in the Company's Annual Report on Form 10-K for the year ended December 31, 2024. During the nine months ended September 30, 2025, there were no material changes to our critical accounting policies and estimates from those discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 6, 2025.

Recent Accounting Pronouncements

See "Note 2. Significant Accounting Policies - Recent Accounting Pronouncements" to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities.

As of September 30, 2025, we had cash, cash equivalents and investments of $66.5 million. We generally hold our cash and cash equivalents in interest-bearing bank accounts and money market funds. We have invested primarily in U.S. Treasury securities, U.S. government agency securities, corporate debt securities, commercial paper and asset-backed securities and all our investments are classified as available-for-sale. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. An immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash, cash equivalents and investments.

As of September 30, 2025, we had borrowings of $10.0 million outstanding under the Loan Agreement. Borrowings under the Loan Agreement bear interest at a floating rate per annum equal to the greater of (i) 1-month term SOFR, and (ii) 2.33%, plus 6.25%. An immediate 10% change in the 1-month term SOFR would not have a material impact on our debt-related obligations, financial position or results of operations.

Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and investments. The Company invests its cash equivalents in highly rated money market funds. The Company's investments consist of debt securities issued by highly rated corporate entities, the U.S. federal government or state and local governments. The Company's exposure to any individual corporate entity is limited by our investment policy. Deposits may exceed federally insured limits, and the Company is exposed to credit risk on deposits in the event of default by the financial institutions to the extent account balances exceed the amount insured by the FDIC.

The Company is continuing to monitor any events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally.

During the periods presented, the Company has not experienced any realized losses on its deposits of cash, cash equivalents or investments.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for services with payments denominated in foreign currencies, primarily the euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our condensed consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. A 10.0% increase or decrease in current exchange rates would not have a material impact on our financial results.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our "disclosure controls and procedures" as of the end of the period covered by this report, pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act.

In connection with that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms as of September 30, 2025. For the purpose of this evaluation, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is accumulated and communicated to management, including our Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer, as appropriate to allow timely decisions regarding required disclosure.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2025 that 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 not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained elsewhere in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes, the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risk Factors Summary

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. These risks include, but are not limited to, the following:

- We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future;
- We will require substantial additional capital to finance our operations, such capital may not be available to us when needed or may only be available on terms that are unfavorable to us;
- We have a limited operating history, have no products approved for commercial sale, and have not generated any revenue from product sales, licenses or collaborations;
- We are substantially dependent on the success of our lead product candidate, evorpacept, also known as ALX 148, which is in clinical development and which has not completed a pivotal trial;
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration, or FDA, or other comparable foreign regulatory authorities;
- Clinical trials of our product candidates are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety, efficacy and potency of our product candidates or provide the basis for marketing approval;
- Our product candidates may cause significant adverse events or other undesirable side effects when used alone or in combination with other treatments;
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, which could lead to our inability to generate product revenue;
- If we are unable to obtain, maintain and enforce patent protection and other intellectual property for our product candidates and related technology, our business could be materially harmed;
- We are highly dependent on our key personnel, and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy;
- We rely on third-party manufacturers for clinical supplies of our product candidates;
- The levels of our debt and compliance with the terms of our loan agreement could restrict our ability to operate our business;
- Macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, duration of the U.S. federal government shutdown, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic, could adversely impact our business including our ongoing and planned clinical trials and preclinical research;

- The price of our stock may be volatile, and you could lose all or part of your investment; and
- In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in our financial reports.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue from product sales, licenses or collaborations to date and have financed our operations principally through public offerings of our common stock and private placements of our convertible preferred stock. Our net losses were $22.1 million and $30.7 million for the three months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $700.0 million. We have devoted substantially all of our resources and efforts to research and development. Our product candidates, evorpacept and ALX2004, are in early-stage clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for evorpacept and advance our other programs. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We have incurred and expect to continue to incur additional costs associated with operating as a public company and compliance with legal, accounting and other regulatory requirements. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts. Further, any decline in our stock price or perceived potential decline in our stock price that may be associated with stock market volatility generally, may negatively impact our ability to raise capital.

As of September 30, 2025, we had cash, cash equivalents and investments of $66.5 million. Based on our current operating plan, we believe that our existing cash, cash equivalents, and investments will be sufficient to fund our operations into the first quarter of 2027. Our estimate as to how long we expect our existing cash, cash equivalents, investments and funds available from our term loan will be sufficient to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, such as periods of a rising rate of inflation or economic downturns, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our cash, cash equivalents and investments to advance the clinical development of evorpacept, the initiation and advancement of clinical trials of ALX2004, as well as for working capital and other general corporate purposes. This may include additional preclinical research, clinical development, hiring additional personnel, capital expenditures, the potential acquisition of businesses or assets and the costs of operating as a public company, as well as for working capital and other general corporate purposes. Advancing the development of evorpacept and our other programs will require a significant amount of capital. Our current cash, cash equivalents and investments on hand, may not be sufficient to fund all of the actions that are necessary to complete the development of evorpacept or our other programs.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Our ability to raise additional funds may be adversely impacted by market perceptions of our ability to maintain our listing on the Nasdaq. Other than the loan and security agreement, or Loan Agreement, we entered into with Oxford Finance LLC, Oxford Finance Credit Fund II LP and Silicon Valley Bank, or SVB, collectively, the Lenders, in the fourth quarter of 2022 and most recently amended in December 2023, we do not have any committed external source of funds. Under the Loan Agreement, $25.0 million is available for us to draw down at the Lenders' sole discretion as of September 30, 2025. SVB was closed in March 2023, and the FDIC was appointed as receiver to SVB. The FDIC created Silicon Valley Bridge Bank, or SVBB, as successor to SVB, which was acquired by First Citizens Bank, and is now operated as a division of First Citizens Bank, or SVB-First Citizens. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, a stockholder's ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect one's rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. For example, our Loan Agreement restricts our ability to incur additional indebtedness without the consent of the Lenders. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We were incorporated and commenced operations in 2015, have no products approved for commercial sale and have not generated any revenue from product sales, licenses or collaborations. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying and developing potential product candidates and conducting preclinical and clinical trials of our product candidates, including Phase 1 and Phase 2 clinical trials of evorpacept and Phase 1 clinical trials of ALX2004. We have not yet demonstrated our ability to successfully complete any large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale drug or arrange for a third party to do so on our behalf or conduct sales and marketing activities. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

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

Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from any product sales, licenses or collaborations and do not expect to generate any revenue from the sale of product candidates in the foreseeable future. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- successful and timely completion of preclinical and clinical development of our lead product candidate, evorpacept, the initiation and advancement of clinical trials of ALX2004, and our other future product candidates;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of evorpacept and our other future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for evorpacept, ALX2004 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;

- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance of evorpacept and any future product candidates as viable treatment options by patients, the medical community and third-party payors;
- obtaining favorable coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio, including our licensed intellectual property;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidate; and
- attracting, hiring and retaining qualified personnel.

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

The terms of our Loan Agreement require us to meet certain operating and financial covenants, place restrictions on our operating and financial flexibility, and may subject us to default.

In October 2022, we entered into the Loan Agreement, most recently amended in December 2023, under which we have borrowed $10.0 million. Under the Loan Agreement, $25.0 million is available for us to draw at the Lenders' sole discretion as of September 30, 2025. The proceeds of the loans may be used by us for working capital and to fund our general business requirements.

The term loans under the Loan Agreement mature on October 1, 2027. We will begin to make principal payments in equal monthly installments beginning on December 1, 2025, and if either of the milestone related tranche term loans are funded, then we will begin to make principal payments in equal monthly installments beginning on December 1, 2026. The term loans accrue interest at a floating rate as described elsewhere in this report, and interest is payable monthly in arrears. The term loans once repaid or prepaid may not be reborrowed. The term loans may be prepaid in full or in part in increments of $10.0 million, with various prepayment premiums. Upon the earlier of prepayment or maturity of any term loan, we are required to pay a fee of 6.0% of the original principal amount of such funded term loan, and a contingency fee may apply in connection with a prepayment of such term loan under certain circumstances. We are also obligated to pay other customary fees for a loan facility of this type and size.

The term loans under the Loan Agreement are secured by substantially all of our assets, except our intellectual property, which is the subject of a negative pledge, and will be guaranteed by our future subsidiaries, subject to certain limitations.

The Loan Agreement contains customary affirmative and negative covenants, including covenants limiting our ability to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on our capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type.

If we default under the Loan Agreement, the Lenders will be able to declare all obligations immediately due and payable and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. The events of default under the Loan Agreement include, among others, payment defaults, material misrepresentations, breaches of covenants, cross defaults with certain other material indebtedness, bankruptcy and insolvency events, and judgment defaults. The occurrence of an event of default could result in the acceleration of our obligations under the Loan Agreement, the termination of the Lenders' commitments, a 5.0% increase in the applicable rate of interest and the exercise by the Lender of other rights and remedies provided for under the Loan Agreement. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, evorpacept, or our second product candidate, ALX2004, which are both in clinical development and have not completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize evorpacept or ALX2004 in one or more indications, or we experience significant delays in doing so, we may never generate any revenue or become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of our lead product candidate, evorpacept, in our ongoing clinical trials, and the initiation and advancement of clinical trials of ALX2004. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of evorpacept in one or more of these indications, such as gastric/gastroesophageal junction, or GEJ, carcinoma, breast cancer, NHL, multiple myeloma, or colorectal cancer. We cannot be certain that evorpacept will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, testing, manufacturing, safety, efficacy and potency, labeling, approval, sale, marketing and distribution of evorpacept is, and will remain, subject to comprehensive regulation by the FDA and comparable foreign regulatory authorities. Our failure to timely complete clinical trials, obtain regulatory approval or, if approved, commercialize evorpacept or any of our future product candidates, would materially harm our business, financial condition and results of operations. We are not permitted to market or promote evorpacept, or any other product candidate, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. If we do not receive marketing approvals for evorpacept, we may not be able to continue our operations.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. The clinical trials of our product candidates may not produce positive results or demonstrate adequate safety, purity and efficacy and potency to the satisfaction of regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy/potency of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. For example, in April 2025, we announced that topline data from our Phase 2 ASPEN-03 and ASPEN-04 clinical trials did not meet the primary endpoints, and we will no longer pursue evorpacept in combination with pembrolizumab in head and neck squamous cell carcinoma (HNSCC). The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain approval of their drugs.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety, purity and efficacy and potency to the satisfaction of the FDA or comparable international regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. In addition, the FDA or any comparable international regulatory authorities may conclude that the results from our clinical trials are insufficient to support any accelerated approval that we may seek with respect to evorpacept or any of our future product candidates in general or with respect to any specific indications. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. Additionally, in March 2023, the FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for providing a more robust efficacy and safety assessment, among other recommendations. To the extent the FDA requires us to collect additional data or to conduct additional clinical trials in accordance with the new guidance, including with respect to our single-arm ASPEN-Breast study in HER2-positive breast cancer, our clinical timelines may be delayed.

Clinical trials of our product candidates are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety, purity and efficacy and potency of our product candidates or provide the basis for marketing approval.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials (including initiation of any pediatric study) to demonstrate their safety, purity and efficacy and potency. Clinical trials are expensive and difficult to design and implement. Clinical trials can take many years to complete, and their ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. For example, in April 2025, we announced that topline data from our Phase 2 ASPEN-03 and ASPEN-04 clinical trials did not meet the primary endpoints, and we will no longer pursue evorpacept in combination with pembrolizumab in HNSCC. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe, pure and effective or potent for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing.

We do not know whether our future clinical trials will begin or enroll subjects on time or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining institutional review board approval at each clinical trial site;
- adding necessary new clinical trial sites;
- recruiting suitable subjects to participate in a trial;
- noncompliance with clinical trial protocols;
- investigational site or trial subjects withdrawing or dropping out of clinical trials at a higher rate than anticipated; and
- manufacturing sufficient quantities of product candidate for use in clinical trials.

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

- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results or interval changes to standards of care for the treatment of specific tumor types that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of subjects required for clinical trials is larger than anticipated, enrollment in these clinical trials is slower than anticipated or subjects dropping out of these clinical trials at a higher rate than anticipated;
- delays in clinical trials due to outbreaks or public health crises, such as the COVID-19 pandemic, that impact both trial site operations, subject selection and participation;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates are greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;
- any development and approval of FDA or other comparable foreign regulatory authorities required companion diagnostics necessary for use with our product candidates; and
- regulators revising the requirements for approving our product candidates.

As a result of any of these delays or other circumstances, we may incur unplanned costs, not obtain or be delayed in obtaining marketing approval, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have our drug removed from the market after obtaining marketing approval.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate safety and efficacy sufficient to obtain marketing approval of our product candidates or to market our drugs after any such approval.

We have experienced and, if we continue to experience delays or difficulties in the enrollment of subjects in clinical trials and/or retention of subjects in clinical trials in the future, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or comparable international regulatory authorities. Subject enrollment is a significant factor in the timing of clinical trials. In particular, because certain of our clinical trials of evorpacept are focused on indications with small patient populations, our ability to enroll eligible subjects may be limited or may result in slower enrollment than we anticipate.

In the past, clinical trial enrollment and data collection has been adversely impacted by staff shortages, site closures, travel limitations and physical distancing requirements and personal safety concerns resulting from and associated with the COVID-19 pandemic. Going forward we expect to continue to experience some of these clinical trial enrollment difficulties associated with the pandemic. For example, subjects who enroll in our clinical trials and then become infected with the COVID-19 virus may complicate the clinical trial data, procedures and analysis, which could delay the anticipated readouts from our clinical trials and our regulatory submissions and increase the costs associated with clinical trials.

Subject enrollment may also be affected if new standards of care become widely available or our competitors have ongoing competing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. In addition, regulatory requirements governing clinical trials have changed and may continue to change in the future. The timing of our clinical trials depends on our ability to recruit subjects to participate in our studies and changes to regulatory requirements, if any, governing clinical trials may impede our ability to enroll subjects. Subject enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy or potency of current or newly approved drugs for the disease under investigation and other changes in standard of care that could make our clinical trials less attractive, including the drugs or other product candidates we use in our combination studies;
- patient eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials by us and the clinical trial sites;
- patient referral practices of physicians;
- the ability to monitor subjects adequately during and after the clinical trial;
- proximity of clinical trial sites to prospective subjects;
- risk of subjects enrolled in clinical trials dropping out before completion;
- inability or delay in enrollment of subjects due to a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic;
- an inability to appropriately enroll an ethnically and racially diverse patient population representative of the target patient population;
- non-compliance with regulatory requirements; and
- subjects experiencing severe or unexpected adverse effects related to our product candidates.

Our inability to enroll a sufficient number of subjects in our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our drugs.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Further, interim, topline and preliminary data include certain assumptions, estimations, calculations and conclusions as part of our analyses of data available at that time, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. Some may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If evorpacept, ALX2004 or any of our other product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. For example, in ALX-Oncology-sponsored clinical trials, the most common adverse events of any grade associated with evorpacept (frequency ≥20%) are fatigue, anemia, nausea, diarrhea, constipation, and neutrophil count decrease. These events have been reported across the program in patients administered evorpacept as a single agent, in combination with pembrolizumab, trastuzumab, rituximab, azacitidine, or enfortumab vedotin and as a multiproduct regimen in combination with pembrolizumab, platinum, and 5 FU, or in combination with trastuzumab, ramucirumab, and paclitaxel, or in combination with azacitidine + venetoclax. Such side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any adverse events as a result of evorpacept or any of our future product candidates, including in combination with therapy, may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

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

The development and commercialization of new product candidates is highly competitive. We face competition with respect to evorpacept and ALX2004, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immuno-oncology therapies for the treatment of cancer. There are other companies working to develop immuno-oncology therapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Newly approved therapeutics could change the treatment paradigm or standard of care, which could negatively impact the design of our clinical trials and the prospects of our product candidates.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approaches, including with respect to the targeting of the CD47 pathway, targeting epidermal growth factor receptor (EGFR) as an antibody-drug conjugate target, and others are based on entirely different approaches. We are aware that Adagene, Akesobio, Bio-Thera Solutions, Boehringer Ingelheim, Bristol Myers Squibb, Byondis, Centessa, Conjupro Biotherapeutics, CTTQ (SinoBiological), Daiichi Sankyo, Exelixis, GenSci, Gilead Sciences (through its acquisition of Forty Seven), Hanchor Bio, Hisun, Hutchmed, I-Mab, Ichnos, ImmuneOncia Therapeutics, ImmuneOnco Biopharma, Innovent, Kahr, LaNova, Lightchain Bioscience, Mabwell Therapeutics, Mabworks, Novimmune, OSE Immunotherapeutics, Pfizer (through its acquisition of Trillium Therapeutics), Phanes, Pyxis Oncology (through its acquisition of Apexigen), Shandong New Time, Shattuck Labs, Sorrento Therapeutics, Sumgen, SunHo Pharmaceutical, TG Therapeutics, Waterstone, and Zai Lab, among others, are developing or have begun development of drugs targeting the CD47 pathway that may have utility for the treatment of indications that we are targeting. We are also aware that AstraZeneca, BioNTech, Bristol Myers Squibb with Systimmune, CSPC, and Henlius, among others, are developing or have begun development of antibody drug conjugates targeting EGFR. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if evorpacept, ALX2004 and/or any of our other future product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Even after approval, our manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our approved products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Regulatory approvals may contain significant limitations related to use restrictions for specific target population subsets, *e.g.*, based on biomarker analyses or age groups, warnings, precautions or contraindications, or may include costly and burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition for approval of our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk mitigation tools.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with a contract supplier, vendor, or facility where the product is manufactured or processed, a regulatory agency may impose restrictions on that product, the manufacturing facility or contractor, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, European Medicines Agency (EMA) and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions or enforcement actions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any of these sanctions, enforcement actions or penalties described above may inhibit our ability to commercialize our product candidates, even if approved, and generate revenue.

We previously relied on Tallac Therapeutics Inc., a third-party service provider, to conduct substantially all of our preclinical research activities for evorpacept. If we are unable to successfully transition preclinical research activities in-house or identify an alternative provider as needed, there may be disruptions or delays to our evorpacept development pipeline and our business could be harmed.

We previously relied on a third-party service provider to conduct all of our preclinical research activities for evorpacept. Effective as of July 1, 2020, we transferred our preclinical research capabilities at such time and nine of our employees, including a former Chief Scientific Officer, to Tallac Therapeutics Inc., a third-party service provider, formerly known as Tollnine, Inc., or Tallac Therapeutics, and entered into a research and development services agreement, or the Tallac Services Agreement, with Tallac Therapeutics. Under the terms of the Tallac Services Agreement, Tallac Therapeutics provided preclinical research services to us for the cost of these services plus a mark-up equal to 10.0% of such costs. The Tallac Services Agreement terminated on July 1, 2024.

If we are unable to successfully transition preclinical research activities in-house, or identify an alternative provider as needed, our preclinical research efforts and studies may be extended or delayed, and there may be disruptions or delays to our evorpacept development pipeline. While we haven't experienced any issue with transitioning preclinical research activities in-house, we recently completed the RIF in connection with the Company pipeline prioritization, clinical development and cash preservation strategy, which impacted a number of employees in research and preclinical development. As a result, our evorpacept product candidate research and development efforts may be delayed or harmed, and our costs could increase and our future ability to generate revenues could be delayed.

Our commercial success depends, in part, on our ability to conduct our research and develop our product pipeline without infringing the intellectual property and other proprietary rights of third parties. If we ever become involved in any dispute with Tallac Therapeutics over ownership of intellectual property or proprietary rights in the future because of the access that Tallac Therapeutics had to our intellectual property, including trade secrets, we may need to negotiate or engage in litigation to preserve our intellectual property rights, which may be time-consuming, expensive and ultimately unsuccessful. In addition, our former employees who are now employees of Tallac Therapeutics may possess our proprietary information. Although these former employees have signed confidentiality and invention assignment agreements with us, we cannot guarantee that they will not breach these agreements in the future. If these former employees disclose our proprietary information to Tallac Therapeutics or other third parties, we may not be able to obtain adequate remedies for such breaches.

We contract with third parties for the manufacture of our product candidates for preclinical development and clinical trials, and we expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our drugs if any of our product candidates receive marketing approval. No assurance can be given that long-term, scalable manufacturers can be identified or that they can make clinical and commercial supplies of our product candidates that meet the product specifications of previously manufactured batches, or are of a sufficient quality, or at an appropriate scale and cost to make it commercially feasible. Such third-party manufacturers may also be subject to delays due to circumstances outside of their control for a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic, that could shut down or cause limited staffing of their facilities. Our reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. If they are unable to do so, it could have a material adverse impact on our business.

The facilities used by contract manufacturers to manufacture our product candidates must be approved by the FDA or any applicable foreign regulatory authority pursuant to inspections that may be conducted after we submit our marketing applications to the FDA or any such foreign regulatory authority. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any applicable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact, including causing substantial delay in, our ability to develop, obtain regulatory approval for or market our product candidates. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

Our product candidates and any drugs that we may develop may compete with other product candidates and approved drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

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

Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval or commercial drug supply after marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement.

Material modifications in the methods of product candidate manufacturing or formulation may result in additional costs or delay.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented. We have previously encountered challenges in the production of a drug substance batch, and as a result incurred additional costs to address and rectify the manufacturing process. Also, as product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing, suppliers and formulation, are altered in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the modified manufacturing, materials or process. This could delay completion of clinical trials, require the conduct of additional clinical trials, such as bridging studies to demonstrate the product is substantially equivalent to product used during earlier clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Development of product candidates in combination with other therapies could expose us to additional risks. Lack of third-party combination drugs may materially and adversely affect demand for our product candidates.

Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being less successful commercially. We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any other product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Further, to the extent the regulatory authorities require concurrent updates to the drug labeling of an approved drug product to include the combination use to allow approval of one of our product candidates, we will need to coordinate with the third-party manufacturer regarding such combination labeling changes, which could delay or impact the approval of our product candidate. Changes in standard of care and treatment paradigm can materially and adversely affect our business and results of operations, including the design of our clinical trials. Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our product candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. In addition, we currently use, and plan to use in the future, third-party drugs in our development and clinical trials as controls for our studies, such as conducting Phase 2/3 clinical trials of evorpacept in combination with trastuzumab for gastric/GEJ carcinoma. As a result, the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. For instance, we entered into clinical trial collaboration and supply agreements with Eli Lilly, pursuant to which our collaboration counterparties will supply doses of ramucirumab for use in certain clinical trials. If the agreement with Eli Lilly is terminated before the trial is completed, we may need to find another source of ramucirumab in order to continue our trial.

If other pharmaceutical companies discontinue these drugs for combination therapies in the future, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs at all or in a timely manner and on a cost-effective basis. Use of new combination drugs with our approved product candidates will require further regulatory approval before we can promote such new combination therapies. As a result, demand for our product candidates may be lowered, which would in turn materially and adversely affect our business and results of operations.

We may not be able to obtain regulatory approval for our product candidates or commercialize any product candidates that may result from our development efforts, or may miss expected deadlines, if we are not able to maintain or secure agreements with the third parties that conduct the activities related to our clinical trials on acceptable terms, if these third parties do not perform their services as contractually required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll subjects on a timely basis or otherwise conduct our clinical trials as planned. In addition, there is no guarantee that these third parties will devote adequate time and resources to our clinical trials or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. For example, these third parties may be adversely impacted by outbreaks and public health crises, such as the COVID-19 pandemic. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA or other regulatory agencies. Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCPs, regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed, or the FDA or foreign regulatory authority may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA or foreign regulatory authority could determine that any of our clinical trials fail or have failed to comply with applicable cGCPs.

Our business also may be implicated if any of our CROs violates fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our third-party clinical trial sites terminate for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer the care of those subjects to another qualified clinical trial site. Further, our CROs are not required to work indefinitely or exclusively with us. Our existing agreements with our CROs may be subject to termination by the counterparty upon the occurrence of certain circumstances. If any CRO terminates its agreement with us, the research and development of the relevant product candidate would be suspended, and our ability to research, develop and license future product candidates would be impaired. We may be required to devote additional resources to the development of our product candidates or seek a new CRO partner, and the terms of any additional arrangements that we establish may not be favorable to us. Switching or adding CROs or other service providers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or service provider commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative arrangements, the resulting delays and potential inability to find suitable replacements could materially and adversely impact our business.

Even if we receive marketing approval for any of our product candidates, we may not achieve market acceptance, which would limit the revenue that we can generate from sales of any of our approved product candidates.

Even if the FDA and applicable foreign regulatory authorities approve the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use our product candidates. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Market acceptance of evorpacept and any other product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of evorpacept and our other product candidates to treat cancer or other applicable targeted diseases, as compared with other available drugs, treatments or therapies;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- the approval of other new therapies for the same indications;
- the prevalence and severity of any adverse side effects associated with evorpacept and our other product candidates;
- limitations or warnings contained in the labeling approved for evorpacept or our other product candidates by the FDA or foreign regulatory authorities;
- availability of alternative treatments and the potential and perceived advantages of our product candidates over alternative treatments;
- the size of the target patient population and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength and effectiveness of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost-effectiveness in relation to alternative treatments;
- relative convenience and ease of administration;
- our ability to obtain sufficient third-party coverage or reimbursement by government, insurers or third-party payors, and the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- the likelihood that the FDA or any foreign regulatory authority may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

Adverse events in clinical trials for our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for evorpacept or any other product candidate that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry generally could also result in greater governmental regulation and stricter labeling requirements.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by patients, physicians and/or third-party payors, we may not generate sufficient revenue to become or remain profitable and our business may be harmed.

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval.

We currently have no marketing and sales organization and we have never commercialized a product candidate. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own medical affairs, sales, marketing and supply capabilities or outsource these activities to a third party.

If any of our product candidates ultimately receives regulatory approval, we may choose to establish an internal marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization. Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

We may also 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. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, 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. We have no internal sales, marketing or distribution capabilities.

The market opportunities for the product candidates we develop, if approved, may be limited to certain smaller patient subsets.

There is no guarantee that the product candidates we develop, even if approved, would be approved for the currently proposed indications. We may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk. Regulators, like the FDA, may require us to narrow our indications to smaller patient subsets, and the number of patients in such subsets may turn out to be lower than expected. If this were to occur, it could have a material adverse effect on our business.

Our current and future product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe, pure, potent or effective for use by the target patient population for any indication.

Our lead product candidate, evorpacept, is at an early stage of clinical development and not all adverse effects can be predicted or anticipated. Unforeseen side effects from evorpacept or any of our future product candidates may arise at any time during clinical development or, if approved by regulatory authorities, after the approved drug product has been marketed. Any undesirable or unacceptable side effects of evorpacept or our future product candidates could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or comparable international regulatory authorities, or result in marketing approval from the FDA or comparable international regulatory authorities with restrictive label warnings or for limited patient populations. Ultimately, such side effects could result in product liability claims. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication.

Even if any of our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindication, precaution or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, including changing the dose and/or schedule of administration, limit the patient population who can use the product or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future product candidates.

Failure to obtain or maintain adequate coverage and reimbursement for our product 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 products such as our product candidates, if approved. Our ability to achieve and maintain 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 product candidates. Coverage under certain government programs, such as Medicare, Medicaid and TRICARE, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product 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 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 when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy and potency or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product 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 product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

Obtaining and maintaining reimbursement status is time-consuming and costly. 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 products 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 at short notice, and we believe that changes in these rules and regulations are likely.

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 product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain and maintain coverage and adequate reimbursement for a product;
- our ability to generate revenue and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates manufacturers' promotional claims of drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the FDA-approved labeling. The FDA, the Department of Justice, the Inspector General of the Department of Health and Human Services, or HHS, among other government agencies, actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including large civil and criminal fines, penalties and enforcement actions. The FDA has also imposed consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed for companies that engaged in such prohibited activities. If we cannot successfully manage the promotion of our approved product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to Government Regulation

Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review with respect to our drugs, which will result in significant additional expense.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed, or subject to certain conditions of approval and may contain requirements for potentially costly post-approval trials and surveillance to monitor the safety, purity and efficacy/potency of the marketed product. For any approved drug, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug;
- withdrawal of the drug from the market or voluntary or mandatory product recalls;
- adverse publicity, fines, warning letters or holds on clinical trials;
- refusal by the FDA or any other applicable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- drug product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the policies of the FDA or other comparable foreign regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates or impact any already approved drugs. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. Further, changes in the leadership of the FDA and other federal agencies under the current U.S. presidential administration may lead to new policies and changes in the regulations that can increase our compliance costs or delay our clinical development and timelines. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to generate revenue or achieve or sustain profitability.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, which could lead to our inability to generate product revenue. Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, the FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. Our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA and comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for or obtained regulatory approval for any product candidate and it is possible that we may never obtain regulatory approval for evorpacept, or any other product candidates we seek to develop in the future. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable international regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or comparable international regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and potency and safety in the full population for which we seek approval;
- the FDA or comparable international regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, New Drug Application or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable international regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable international regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or international foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In order to market any product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and potency and approval standards. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, government shutdowns, return-to-office policy and other policies and executive actions under the current U.S. presidential administration, including as a result of budget delays or other circumstances like the COVID-19 pandemic, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

Further, under the new leadership at the HHS, reorganization of that department, departure of senior leadership at the FDA and other agencies under HHS, mass layoffs at HHS, government shutdown, and a lapse in U.S. government appropriations may impact operations at the FDA as well as other federal agencies, which can materially delay our timelines. The FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. These new policies are also expected to lead to fewer agency guidance documents that could result in interference with FDA programs or lead to delays or refusals to approve products. Further, FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our competitive advantage and intellectual property. It is unclear how our industry and our clinical programs will be impacted by policies or regulations implemented under the current presidential administration and the new FDA commissioner or other executive orders. To the extent the agency reorganization and other agency changes lead to disruptions in the FDA's operations, our interactions, correspondence, and regulatory review processes with the FDA may be delayed.

While we have received certain FDA Fast Track designations, such Fast Track designations may not lead to a faster development or regulatory review or approval process, and do not increase the likelihood that the drug will receive marketing approval.

The FDA granted Fast Track designation for evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-overexpressing advanced gastric or GEJ adenocarcinoma with disease progression on or after prior trastuzumab, and fluoropyrimidine or platinum-containing chemotherapy in January 2020. If a product candidate is intended for the treatment of a serious condition and preclinical or clinical data demonstrate the potential to address unmet medical need for such condition, a sponsor may apply for FDA Fast Track designation. Even though we received these Fast Track designations for evorpacept, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

While we have received certain orphan drug designations from the FDA and the European Commission, we may be unable to maintain the benefits associated with such orphan drug designation. If we decide to seek orphan drug designation for additional indications for our product candidates in the future, we may be unsuccessful.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In January 2022, the FDA's Office of Orphan Products Development granted Orphan Drug Designation, ODD, to evorpacept for treatment for gastric/GEJ cancer. We may seek ODD for certain additional indications for our product candidates in the future. ODD neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process. Generally, if a product candidate with ODD subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity that precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. Therefore, if our competitors are able to obtain orphan product exclusivity for their product candidates in the same indications we are pursuing, we may not be able to have competing product candidates approved in those indications by the FDA for a significant period of time. There are also limited circumstances where the FDA may reduce the seven-year exclusivity for a product candidate with an orphan drug designation where other product candidates show clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. However, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture a sufficient supply of our product. In response to recent litigation, the FDA clarified in a January 2023 notice that the FDA will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. Further, in view of the overturn of the Chevron doctrine, this landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies, which could lead to uncertainties in the industry. Changes in the leadership of the FDA and other federal agencies under the current U.S. presidential administration may also lead to new policies and changes in the regulations and operations of the FDA, which may impact our clinical development plans.

In June 2023, the European Commission granted ODD to evorpacept for the treatment of patients with gastric/GEJ cancer. In the European Union approved orphan medicines are granted 10 years of market exclusivity, which can be extended to 12 years if a pediatric investigation plan is completed. The market exclusivity period can be shortened if the approved orphan drug becomes commercially successful. An orphan designation can also be revoked if, for example, the prevalence of the condition increased to more than 5 per 10,000 individuals of the total population, if additional therapies are introduced after the initial designation and have improved the morbidity or mortality of a condition so that it is no longer chronically debilitating and/or life-threatening, or if we are unable to demonstrate significant benefit over existing authorized products. We can provide no assurance that we will be able to maintain all the benefits associated with the designation or that we will be successful in commercializing our product if approved.

Current and future legislation may increase the difficulty and cost for us to commercialize our products, if approved, and affect the prices we may obtain. We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA and other federal agencies, which could lead to uncertainties in the industry and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively ACA, was enacted in 2010 and includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. The ACA continues to impact the U.S. pharmaceutical industry. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional challenges and healthcare reform measures of the current U.S. presidential administration will impact the ACA. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2032, with the exception of temporary suspension under COVID-19 relief legislation.

There also has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their drugs, which has resulted in several U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Programs rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have material impact on our business. Further, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least seven years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders, including the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. On September 30, 2025, the government announced the first agreement with a major pharmaceutical company to bring American drug prices in line with the lowest paid by other developed nations, requiring the company to offer medicines at a deep discount off the list price when selling directly to American patients. Such agreements and other measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increases generic and biosimilar drug entry sooner than expected, can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as other legislative, executive, and administrative actions and agency rules implemented by the current U.S. presidential administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

At the state level, legislatures have increasingly passed legislation and implemented 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. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization. FDA has authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved drug product. Any denial in coverage or reduction in reimbursement from Medicare or other government funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future product candidates. In addition to continuing pressure on prices, price controls and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future product candidates, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such product candidates and third-party payors' reimbursement policies might adversely affect our ability to sell any future product candidates profitably.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay the commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower-priced cross-border sales, our profitability will be negatively affected.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, our operations may be directly, or indirectly through our prescribers, consultants, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate are described in the following paragraphs:

- The U.S. federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward 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. Moreover, the ACA provides that the government may assert that a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the civil False Claims Act, or FCA.
- The federal civil and criminal false claims, including the civil FCA, that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. No specific intent to defraud is required under the civil FCA. The criminal FCA provides for criminal penalties for submitting false claims, including imprisonment and criminal fines.
- The Civil Monetary Penalty Act of 1981 and implementing regulations impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

- The Health Insurance Portability and Accountability Act, or HIPAA, 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.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act and Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, impose certain obligations, including mandatory contractual terms, on covered entities subject to the Final HIPAA Omnibus Rule, *i.e.*, health plans, healthcare clearinghouses and healthcare providers, and their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The U.S. Federal Food, Drug and Cosmetic Act prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services, or CMS, information regarding payments and other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, price reporting, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.
- Analogous state laws and regulations impose additional obligations, 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; 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; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.
- European and other foreign law equivalents of each of the laws also impose legal requirements, 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 U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight, and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

If we, our employees, independent contractors, principal investigators, consultants, vendors or agents acting on our behalf fail to comply with healthcare laws and regulatory requirements, we could be subject to fines, penalties or enforcement actions, or incur costs that could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct as well as risks of noncompliance by contractors or agents acting on our behalf. Misconduct by employees and independent contractors, such as principal investigators, consultants and vendors, could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with health care fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of research, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a written code of business conduct and ethics, but it is not always possible to identify and deter employee or independent contractor misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines, exclusion from participation in government-funded healthcare programs, or other sanctions.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development involve, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the State of California to cover us for costs and expenses, we may incur costs and expenses due to injuries to our employees resulting from the use of these materials, as this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional laws and regulations affecting our operations may be adopted in the future. Current or future laws and regulations may impair our research, development or commercialization efforts. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel, return-to-office policies and other executive actions by the current U.S. presidential administration, and changes in the leadership and operations of the FDA. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. For example, the U.S. government has shut down in the past, forcing regulatory authorities such as the FDA and SEC to furlough employees, and in response to the COVID-19 pandemic, the FDA has postponed certain inspections. If global health concerns or other causes continue to prevent the FDA or other regulatory authorities from conducting their normal operations, such as regular inspections, reviews, or other regulatory activities in a timely manner, or if the FDA and other agencies experience other delays, backlogs or disruptions, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations, all of which can subject us to criminal liability and other serious consequences for violations.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. These laws generally prohibit companies and their employees and third party business partners, representatives and agents from engaging in corruption and bribery, including offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a government official or commercial party in order to influence official action, direct business to any person, gain any improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with government officials, including officials of non-U.S. governments.

Additionally, in many countries, healthcare providers are employed by the government, and the purchasers of biopharmaceuticals are government entities. As a result, our dealings with these providers and purchasers are subject to regulation and such healthcare providers and employees of such purchasers may be considered "foreign officials" as defined in the FCPA. In addition to our own employees, we leverage third parties to conduct our business abroad, such as obtaining government licenses and approvals. We and our third-party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies, state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of our employees, our third-party business partners, representatives and agents, even if we do not explicitly authorize such activities. There is no certainty that our employees or the employees of our third-party business partners, representatives and agents will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, debarment from U.S. government contracts, substantial diversion of management's attention, significant legal fees and fines, severe criminal or civil sanctions against us, our officers or our employees, disgorgement and other penalties and remedial measures and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, financial condition and stock price.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations, including increased tariffs. Governmental regulation of the import or export of our products, including the potential negative impact of tariff increases, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our business. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges.

Data collection under European and U.S. laws is governed by restrictive regulations addressing the collection, use, processing and, in the case of Europe, cross-border transfer, of personal information (i.e., information that relates to an identified or identifiable individual).

We may collect, process, use or transfer personal information from individuals located in the European Economic Area, or EEA, Switzerland and the United Kingdom in connection with our business, including in connection with conducting clinical trials in these regions.

Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the EEA or the United Kingdom or Switzerland. The collection and use of personal information (which includes health data) in the EEA is governed, in part, by the provisions of the General Data Protection Regulation (EU) 2016/679, or the GDPR, or its UK equivalent, the UK General Data Protection Regulation, or, together with the UK's Data Protection Act 2018, the UK GDPR, or the new Swiss Federal Act on Data Protection, or FADP. These regulations impose requirements relating to having a legal basis for processing personal information and transferring such information outside of the EEA, the United Kingdom and Switzerland, respectively, as applicable, including to the United States, informing concerned individuals about the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information on our behalf, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal information to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping.

Any actual or alleged failure to comply with the GDPR, UK GDPR, FADP, or other data protection laws may result in regulatory inquiries and other proceedings, substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

The GDPR, UK GDPR and FADP also restrict the transfer of personal information outside of the EEA, United Kingdom and Switzerland, respectively, unless appropriate safeguards are in place.

One primary set of safeguards, the Standard Contractual Clauses adopted by the European Commission, has been updated recently. With regard to data transfers outside of the EEA to the United States, in March 2022, the European Union and United States established a new framework for personal information transfers, the EU-U.S. Data Privacy Framework, or the EU-U.S. DPF. A related framework, the Swiss-U.S. Data Privacy Framework, or Swiss-U.S. DPF, also was established, and was the subject of an adequacy decision by the Swiss Federal Council on August 14, 2024. On July 10, 2023, the European Commission adopted an adequacy decision relating to the EU-U.S. DPF. Additionally, a UK Extension to the EU-U.S. DPF, became effective on October 12, 2023. We are evaluating whether to make use of the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF to transfer personal information from the EEA to the United States.

Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. Although the European Commission granted "adequacy" status to the United Kingdom in June 2021, and personal information can flow from the European Union to the United Kingdom and back, the United Kingdom may change its policy with respect to the export of personal information to third countries, such as the United States, and the European Commission's adequacy determination for the United Kingdom requires renewal in 2025 and it may be modified or revoked in the interim. The United Kingdom made targeted amendments to the UK GDPR in the UK Data (Use and Access) Act 2025, or DUAA, which was enacted on June 19, 2025. The European Commission has proposed to renew the UK's adequacy decision after assessing the DUAA, but additional procedural steps remain, causing some uncertainty to remain regarding the UK's adequacy determination. In addition, in February 2022, the United Kingdom's Information Commissioner's Office issued new Standard Contractual Clauses for the transfer of personal information outside of the United Kingdom. The data transfers enforcement landscape and the longer-term stability of the EU-U.S. DPF and related programs remain uncertain, which could require us to modify our policies and practices and increase our compliance costs.

The EU also has implemented new and revised laws and regulations relating to cybersecurity, including the Network and Information Security Directive II, or NIS2, adopted in 2023, which aims to enhance cybersecurity across critical infrastructure and essential services in the EU. NIS2 provides for all EU member states to have issued implementing legislation by October 2024; however, several EU member states have not finalized their respective legislation and guidance.

We may, therefore, incur liabilities, expenses, costs, and other operational losses under the GDPR, the UK GDPR, the FADP, and applicable laws and regulations of European Union member states in connection with any measures we take to comply with them.

In addition, U.S. states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements related to personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, in 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and which can include any of our current or future employees who may be California residents or any other California residents whose data we collect or process) and provide such residents new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.

Additionally, the California Privacy Rights Act, or the CPRA, was approved by California voters in November 2020. The CPRA modified and augmented the CCPA significantly, effective as of January 1, 2023, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Numerous other states have proposed, and in certain cases enacted similar laws, including comprehensive privacy laws similar to the CCPA enacted in Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia. Other states have proposed, and in certain cases enacted, legislation addressing privacy and cybersecurity in the context of specific subject matter such as biometrics and health-related personal information. The U.S. Department of Justice also has issued rules regarding certain bulk sensitive personal data transfers. As we expand our operations, preclinical studies and clinical trials, these new state laws and other state laws and regulations relating to privacy, data security, and the collection, use, transfer, and other processing of data may increase our compliance costs and potential liability. Laws and regulations relating to these matters are not consistent across jurisdictions, and they may impose conflicting or uncertain obligations. Compliance with these and any other applicable laws and regulations relating to these matters is a rigorous, costly and time-intensive process, and we may be required to put in place additional mechanisms to address new and changing obligations under these laws and regulations. Actual or alleged noncompliance with any such laws and regulations may lead to regulatory investigations, enforcement actions, claims and litigation, and if we fail to comply with any such laws or regulations, we may face significant fines and penalties. Any of these could adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our product candidates and related technology, our business could be materially harmed.

Our strategy depends on our ability to identify, seek, obtain and maintain patent protection for our product candidates and other research and development discoveries. Our patent portfolio is relatively small compared to many large and more established pharmaceutical and biotechnology companies. As our patent portfolio grows, we expect patent protection will continue to be an important part of our strategy. The patent protection process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development discoveries in a timely manner to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. Therefore, our in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in foreign countries or may fail to effectively prevent third parties from commercializing competitive product candidates.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, and such prior art may affect the scope of any allowable claims or it may prevent our patent applications from issuing as patents. Further, the issuance of a patent does not ensure that it is valid or enforceable, nor is the issuance conclusive as to inventorship or the scope of any claims. Third parties may challenge the validity, enforceability or scope of our issued patents or claim that they should be inventors on such patents, and such patents may be narrowed, invalidated, circumvented or deemed unenforceable and such third parties may gain rights to such patents. We could also become involved in reexamination, *inter partes* review, post-grant review, opposition or derivation proceedings challenging our patent rights or the patent rights of others.

In addition, changes in law may introduce uncertainty in the enforceability or scope of patents we own. If our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is no prior art that may ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions.

For all of the foregoing reasons, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

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

Filing, prosecuting and defending patents on product 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 to develop their own products in jurisdictions where we have not obtained patent protection 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 current or future products, if any, and our patents or other intellectual property rights may not be valid 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, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court, or UPC. Also, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. 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 court proceedings to enforce our intellectual property rights, and the damages or other remedies awarded to us, 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.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors.

Additionally, the requirements for patentability may differ in certain countries. For example, in certain countries, there is no link between regulatory approval of a drug and its patent status, and patenting of medical uses of a claimed drug are prohibited. In addition, certain countries in Europe and other countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees automatically when due, but we must notify the provider of any new patents or applications. Additionally, the USPTO and various foreign patent offices require compliance with many procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents or in third-party patents. The United States has enacted and implemented wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a higher level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The AIA and its implementation may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or does file a patent application in the USPTO after March 16, 2013 but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to file third party submissions of prior art to the USPTO during patent prosecution and to challenge any issued patent in the USPTO (*e.g.*, via post-grant reviews or *inter partes* reviews). Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Our patents covering one or more of our product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, 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, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which the patent examiner and we 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 a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Patent protection, prosecution, assertion and defense for some of our product candidates may be dependent on third parties.

There may be times in the future when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors, such as with respect to our license agreements. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers. If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

If we are unable to protect the confidentiality of our trade secrets and proprietary information or obtain proper assignment of such intellectual property, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets and other proprietary information. Trade secrets and know-how can be difficult to protect. Trade secrets and know-how can also in some instances be independently derived or reverse-engineered by a third party. We maintain the confidentiality of trade secrets and proprietary information in part by entering into confidentiality agreements with our employees, consultants, other service providers, including former service provider Tallac Therapeutics, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies in addition to our service provider agreements, such as the Tallac Services Agreement, also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and even when we obtain these agreements, individuals with whom we have these agreements may not comply with their terms. Any of the parties to these agreements may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also become involved in inventorship disputes relating to inventions and patents developed by our employees, consultants, contractors and other service providers, including former service provider Tallac Therapeutics, under such agreements. To the extent that our employees, consultants, contractors or other service providers use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced, and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time-consuming and unsuccessful.

Third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates or biosimilar versions of any approved product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for an invalidity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or enablement. 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition or other proceedings challenging the validity or scope of our patent rights, requiring us and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us, including disputes that may arise from our previous reliance on Tallac Therapeutics as the sole provider of our preclinical research services and the intellectual property generated under the Tallac Services Agreement; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to the expiration of relevant patents owned by or licensed to us under the Biologics Price Competition and Innovation Act of 2009, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

Any litigation or other proceedings would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved drug. In addition, there is a risk that a court will order us to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or on our business, results of operations, financial condition and prospects. Any of these outcomes could have a material adverse effect on our business.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

We employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such license may not be available on commercially reasonable terms or at all. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against these claims, litigation would expose us to the risk described above under "We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time-consuming and unsuccessful."

Our commercial success depends in part on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties.

We are aware of third-party patents and patent applications containing claims in the immuno-oncology field based on scientific approaches that are the same as or similar to our approach, including with respect to the targeting of the CD47 and signal regulatory protein alpha, or SIRPα, pathways, and others that are based on entirely different approaches. These patents and applications could potentially be construed to cover our product candidates and their use. For example, we are aware of U.S. patent 10,907,209 and U.S. patent application 16/118,038 (now abandoned in favor of a divisional application 18/518,353, which has claims that are not related to polypeptides comprising soluble human SIRPα) owned by University Health Network, or UHN, and The Hospital for Sick Children that may encompass certain therapies for the treatment of cancer using polypeptides comprising soluble human SIRPα, as well as related applications in other jurisdictions. This patent and patent application relate to the treatment of cancer with polypeptides comprising soluble human SIRPα. Pfizer, through its acquisition of Trillium Therapeutics, has an exclusive license to the U.S. patent and application. The European counterpart patent (EP 2 429 574) was revoked by the Opposition Division of the European Patent Office (Opposition Division) on November 6, 2017. The revocation was appealed by UHN and The Hospital for Sick Children, and on October 18, 2022, the Board of Appeal of the European Patent Office (Board of Appeal) ruled in favor of UHN with respect to the matter on appeal, but remanded the case back to the Opposition Division for consideration of a further ground of invalidity (sufficiency of disclosure). On December 8, 2023, the Opposition Board held that the disclosure in EP 2 429 574 was sufficient and upheld the patent in amended form. On February 15, 2024, the Board of Appeal announced that it had received a notice of appeal with respect to the Opposition Board's ruling regarding sufficiency of disclosure. The hearing before the Board of Appeal has been scheduled for December 9, 2025. Additionally, on December 27, 2023, a second European Patent (EP 2 995 315), a divisional of European patent (EP 2 429 574), was granted to UHN and The Hospital for Sick Children. This patent relates to the eradication of hematological CD47+ cancer cells and tumors with polypeptides comprising soluble human SIRPα, or a CD47-binding fragment thereof. On February 27, 2024, the Opposition Division announced that it had received a notice of opposition with respect to EP 2 995 315. A date for the opposition hearing has been scheduled for November 28, 2025. The patent claims of both EP 2 429 574 and EP 2 995 315, if not revoked or otherwise limited by the European Patent Office, could potentially limit our ability to pursue evorpacept in certain indications in certain geographies in the future. With respect to U.S. patent 10,907,209, we believe that we do not infringe claims listed in this U.S. patent. Further, with respect to the development of our ALX2004 program, many companies have filed, and continue to file, patent applications related to antibody drug conjugates and components thereof that are similar to our approach. As the biotechnology industry expands and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that there are not third-party patents or patent applications of which we are aware, but which we do not believe are relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates. These patents may not expire before we receive any marketing approval for our product candidates, and they could delay the commercial launch of one or more future product candidates. If our product candidates were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms or at all, our business, financial condition and results of operations could be materially harmed. Furthermore, even if a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Our failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations, and we would be exposed to a threat of litigation.

Any litigation resulting from claims of infringement or failure to license patents and proprietary rights of others would expose us to the risk described above under "We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful." Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

Our intellectual property rights will not necessarily provide us with competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for product candidates many years before we obtain marketing approval for such product candidates and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with product candidate name approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names and potential pharmacy dispensing errors. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we will lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our rights to develop and commercialize our product candidates may be subject, in part, to the terms and conditions of agreements with others.

Our current agreements do not, and future agreements we may enter into in the future may not, provide exclusive rights to use certain intellectual property and technology retained by a collaborator in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that utilize technology retained by such collaborators to the extent such products are not also covered by our intellectual property.

We may need to obtain additional intellectual property rights from others to advance our research or allow commercialization of product candidates we may develop. We may be unable to obtain additional intellectual property rights at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Furthermore, our current or our future collaborators' patents may be subject to a reservation of rights by one or more third parties. The U.S. government may have certain rights to resulting intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of the government funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in facilities in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third-party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Our current agreements do, and our future agreements may, impose various economic, development, diligence, commercialization and other obligations on us. Such agreements may also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products. It might be concluded that we have materially breached our obligations under such agreements and licensors or collaborators might therefore terminate or seek damages under the agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. Termination of these agreements could cause us to lose the rights to certain patents or other intellectual property, or the underlying patents could fail to provide the intended exclusivity, and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products similar to or identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

Moreover, disputes may arise regarding intellectual property subject to a collaboration agreement, including:

- the scope of the option or license rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the collaborator that is not subject to the option or license rights granted under the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our collaborators and us and our other partners; and
- the priority of invention of patented technology.

We may enter into agreements to option or license intellectual property or technology from third parties that are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our 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 growth prospects. Moreover, if disputes over intellectual property that we have optioned or licensed prevent or impair our ability to maintain such arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

Risks Related to Our Operations

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2025, we had 44 employees, including 30 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect we will need additional managerial, scientific, technical, medical, operational, sales, marketing, financial and other personnel. Future growth may impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for evorpacept and any other future product candidates, while complying with applicable contractual obligations to contractors and other third parties; and
- maintaining and updating our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize evorpacept and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, which may require our management team to divert its attention away from day-to-day activities of the business and devote a substantial amount of time to the added responsibilities associated with managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on specific independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of evorpacept and any other future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other qualified outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively maintain our organization by retaining employees or expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize evorpacept and other future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated our product research and development efforts on our novel immuno-oncology approach, and our future success depends on the successful development of our lead product candidate, evorpacept, and any future product candidates that we develop. There can be no assurance that any development problems we experience in the future related to our novel immuno-oncology approach will not cause significant delays or unanticipated costs or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and life science industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and our scientific, technical, business and medical personnel. The loss of the services provided by any of our executive officers, other key employees and other scientific and medical advisors, our inability to find suitable replacements, and the impacts of any executive officer changes, could result in delays in the development of our product candidates and harm our business. Additionally, layoffs or furloughs, including the recently completed RIF, pausing recruiting efforts, or employee attrition could also create delays in the development of our product candidates, yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended reduction in force, the distraction of employees and reduced employee morale, which could all adversely affect our reputation as an employer, making it more difficult for us to hire new employees in the future and harm our business.

We conduct our operations at our facility in the San Francisco Bay Area of California, a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, manufacturing and sales and marketing personnel, and we face significant competition for experienced personnel. We expect that we may need to recruit talent from outside of our region and doing so may be costly and difficult. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Additionally, the U.S. has recently experienced historically high levels of inflation and an acute workforce shortage generally, which has created a hyper-competitive wage environment that may increase our operating costs.

Many of the other biotechnology companies that we compete against for qualified personnel have considerably more financial and other resources, different risk profiles and a more extended history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we can offer. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and therefore any declining value in our equity grants could negatively impact our ability to successfully retain existing employees or effectively recruit new employees. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our predecessor company, which after our internal reorganization is now our wholly-owned subsidiary, was an Irish private company limited by shares. Our business is subject to risks associated with conducting business internationally. Some of our subsidiaries and operations, in addition to suppliers, industry partners and clinical study centers, are located outside of the United States. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we expect to hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks and complexities, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, including changes in tariff and trade policies, employment laws, regulatory requirements and other governmental approvals, permits and licenses, including within the European Union and in the United Kingdom as a result of Brexit;
- our failure to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property, including as a result of potentially relevant third-party patent rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our drugs;
- exposure to foreign currency exchange rate fluctuations;
- political and economic instability, such as the geopolitical unrest and regional economic disruptions caused by Russia's war with Ukraine, and war and instability in Israel and the surrounding region, and including wars, terrorism and political unrest, boycotts, curtailment of trade and other business restrictions;

- natural disasters, such as a fire, an earthquake or a flood, or outbreaks or public health crises, such as the COVID-19 pandemic;
- a security breach or incident or a related breach of our information systems or data;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the FCPA, its accounting provisions or its anti-bribery provisions, or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

If any of the third parties that we rely on for various operational and administrative aspects of our business fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third-party consultants and contractors to provide specific operational and administrative services, including research and clinical consultation and management. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on cloud-based platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

We may become exposed to costly and damaging product liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. In addition, we have agreed to indemnify various counterparties related to our product candidates against certain liability claims and any agreements or collaborations in the future may include such indemnification obligations. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects or that certain patients should not use our drugs for various reasons.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities.

Our spending on current and future research and development programs, such as evorpacept, for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. For example, we entered into clinical trial collaborations with our collaborators, including I-SPY, Sanofi, Jazz and the ISTs, to supply evorpacept for clinical trials to advance new combination therapies. We have limited control over the amount and timing of resources that our collaborators dedicate to the development of our products. Any termination or disruption of collaborations could result in delays in the development of products, increases in our costs to develop the products or the termination of development of a product.

We may seek to enter into collaborations, including strategic collaborations, licenses and other similar arrangements related to our product candidates and may not be successful in doing so, and even if we are, we may not be able to maintain or realize the benefits of such relationships. If we are not able to establish future collaborations, we may have to alter some of our future development and commercialization plans and our business could be adversely affected.

We may seek to enter into collaborations, licenses and other similar arrangements for the development or commercialization of our product candidates, due to strategic advantages to partnering with third parties and capital costs required to develop or commercialize the product candidate in such markets. For instance, we entered into a collaboration agreement with Tallac Therapeutics pursuant to which we expect to jointly develop, manufacture, and commercialize a novel cancer immunotherapy. We may not be successful in our efforts to establish such collaborations for our product candidates because our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product are unsatisfactory. We also may not be able to realize the benefit of such collaborations if we are unable to successfully integrate them with our existing operations and company culture. In any such collaborations, we may likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we may enter into.

We face significant competition in seeking appropriate collaborators and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. We also may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our future collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program, or delay its potential commercialization. Further, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. Any of the foregoing factors would likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may acquire businesses or assets and we may not realize the benefits of such acquisitions.

We may acquire businesses or assets or create joint ventures with third parties that we believe may complement our existing product candidates. For example, in October 2021, we acquired ScalmiBio, Inc., or ScalmiBio. We are developing new anti-cancer drug candidates based on ScalmiBio's platform, and the acquisition of ScalmiBio enhanced our internal research and development capabilities. In order to realize the continuing benefits of the ScalmiBio acquisition, we will need to continue to make a substantial investment of time and resources to support research and development efforts. Additionally, we may not be able to realize the benefit of acquiring businesses or assets or joint ventures if we are not able to successfully integrate them with our existing operations and company culture. We may encounter difficulties in developing, manufacturing and marketing any new product candidates resulting from an acquisition, which may delay or prevent us from realizing their expected benefits.

Also, the anticipated benefit of any joint venture or acquisition may not materialize, and any potential or future joint venture or acquisition may be prohibited. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

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

Under the U.S. Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity by its shareholders holding 5% or more over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future, in either case as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2024, we had net operating loss carryforwards of approximately $162.6 million and $69.0 million for U.S. federal and state income tax purposes, respectively. Our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to our company. The federal net operating losses carry forward indefinitely and may only offset 80% of taxable income in periods of future utilization. The state net operating loss carryforwards will begin to expire beginning in 2038. Other limitations may apply under state law. For example, California legislation suspends the use of state net operating losses by taxpayers with net business income or modified adjusted gross income of $1 million or more for tax years beginning on or after January 1, 2024 and before January 1, 2027.

As of December 31, 2024, we had Irish net operating loss carryforwards of approximately $5.5 million. These Irish net operating loss carryforwards do not expire but may not be fully utilized unless we generate sufficient income in Ireland. We may also be limited in the amount of net operating loss carryforwards that we can use in the future to offset taxable income for Irish corporation tax purposes if we experience ownership changes in the future as a result of subsequent movements in our share ownership, some of which are outside of our control, or if we experience a major change in the nature or conduct of our trade or our trade becomes small or negligible. Furthermore, in the event we incur net income in certain jurisdictions but incur losses (or have net operating loss carryforwards) in other jurisdictions, we cannot offset the income from one jurisdiction with the loss from another, which could increase our effective tax rate.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

We are or may become subject to income and non-income taxes in the United States under federal, state and local jurisdictions and in certain foreign jurisdictions in which we operate. Tax laws, regulations and administrative practices in these jurisdictions may be subject to significant change, with or without advance notice. For example, on July 4, 2025, the United States enacted tax legislation commonly referred to as the One Big Beautiful Bill Act, or OBBB Act. In accordance with U.S. GAAP, we account for the tax effects of changes in tax law in the period of enactment which is Q3 of calendar year 2025. We analyzed the tax impact of the OBBB Act and it did not have a material impact on our financial statements. Additionally, the Organisation for Economic Co-operation and Development has proposed implementing a global minimum tax of 15%, or Pillar Two, which has been implemented into the domestic laws of European Union member countries and is being considered for implementation by other countries. However, on June 28, 2025, the G7 released a joint statement that it had reached an understanding with the United States for a side-by-side system that would exempt U.S.-parented multinational businesses from certain provisions of Pillar Two; however, no agreement regarding implementation of the proposal has been reached yet. We continue to assess the effect of the Pillar Two rules in all jurisdictions and do not currently expect Pillar Two to have a material impact on our financial position. Changes in tax laws, regulations, or rulings, changes in interpretations of existing laws and regulations, or changes in accounting principles could negatively and materially affect our financial position, cash flows, and results of operations.

Risks Related to Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will be sustained for our common stock.

Prior to our initial public offering, no market for shares of our common stock existed. Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

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 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. 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. For example, our 2025 Shelf Registration Statement provides for aggregate offerings of up to $364.1 million of the Company's securities inclusive of up to $119.1 million of shares of our common stock through the at-the-market (ATM) offering. From December 2021 to September 30, 2025, we sold an aggregate of 2,404,855 shares of common stock under our ATM offering. On October 10, 2023, we completed the October 2023 Offering for the issuance and sale of an aggregate of 8,663,793 shares of common stock and pre-funded warrants to purchase 1,250,000 shares of common stock at a public offering price of $6.38 per share and $6.379 per pre-funded warrant. Our stockholders may be further diluted by the exercise of the pre-funded warrants issued in the October 2023 Offering. As of September 30, 2025, no shares underlying the pre-funded warrants had been exercised. If we issue common stock or securities convertible into common stock, our stockholders will experience additional dilution and our stock price may decline.

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

The trading price of our common stock has been and may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to those discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, the following factors may cause the market price of our common stock to fluctuate:

- results and timing of our preclinical studies and clinical trials and studies and trials of our competitors;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or any future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- actual or anticipated changes in our growth and development relative to our competitors;
- developments or disputes concerning patents or other proprietary rights;
- introduction of new product candidates or technological innovations by us or our competitors;
- announcements by us, our future strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- actual or anticipated changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common stock by us, our insiders or our other stockholders including pursuant to the existing primary and secondary shelf registration statements that we have filed with the SEC;
- expiration of market stand-off or lock-up agreements;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market perceptions of our ability to maintain our listing on Nasdaq;
- additions or departures of key personnel;
- announcement of actual or anticipated reduction in force, including the RIF;
- changes in the structure of health care payment systems in the United States or overseas;

- failure of any of our product candidates, if approved, to achieve commercial success;
- macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, duration of the U.S. federal government shutdown, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of payment or receipt of any future milestone or other payments under commercialization or licensing agreements;
- announcements or expectations of additional financing efforts;
- overall fluctuations in U.S. equity markets, general market conditions and market conditions for biotechnology stocks; and
- other factors that may be unanticipated or out of our control.

In addition, the stock market has recently experienced significant volatility, particularly with respect to biotechnology and other life sciences company stocks. The volatility of biotechnology and other life sciences company stock often does not relate to the operating performance of the companies presented by the stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

If we are unable to maintain listing of our securities on the Nasdaq Global Select Market or another reputable stock exchange, it may be more difficult for our stockholders to sell their securities.

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, it could have a materially adverse effect on our ability to raise additional funds as well as on the price and liquidity of our common stock.

For example, if at any time the bid price of our common stock closes below $1.00 per share for more than 30 consecutive business days, we may be subject to delisting from the Nasdaq Global Select Market. On April 23, 2025, we received a notice from Nasdaq notifying us that we have not been in compliance with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market set forth in Nasdaq Listing Rule 5450(a)(1) for a period of 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided a compliance period of 180 calendar days from the date of the Notice, or until October 20, 2025, to regain compliance (subject to any additional 180-day compliance period which may be available to us). To regain compliance with Nasdaq's minimum bid price requirement, the closing price per share of our common stock must be at least $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day compliance period, unless the Staff exercises its discretion to extend this ten-business day period. In September 2025, we received written confirmation from the Staff of Nasdaq that we had regained compliance with the minimum bid price requirement, as the closing bid price of our common stock had been at $1.00 per share or greater for ten consecutive business days. However, there can be no assurance that we will be able to maintain compliance with the minimum bid price requirement or other Nasdaq listing standards. To the extent that we are unable to maintain compliance with Nasdaq listing standards, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock.

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 or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time. For example, inflationary pressures have increased and we expect will continue to increase costs for our clinical trials;
- our ability to enroll subjects in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of clinical trials for evorpacept, and any of our other product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with evorpacept and any of our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of evorpacept or any of our other product candidates;
- the level of demand for evorpacept and any of our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with evorpacept and any of our other product candidates;
- our ability to commercialize evorpacept and any of our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- any increase in interest expense due to an increase in the floating rate under the Loan Agreement as described elsewhere in this Quarterly Report on Form 10-Q;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies;
- a weak or declining economy resulting from adverse macroeconomic conditions such as inflation, interest rate changes, uncertainty in the financial services industry, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, duration of the U.S. federal government shutdown, and any U.S. federal government debt default due to a failure to increase the debt ceiling; and
- the impact of outbreaks or public health crises, such as the COVID-19 pandemic, geopolitical unrest related to Russia's conflict with Ukraine, war and instability in Israel and the surrounding region, and bank failures or instability in the financial services sector on the global economy.

The cumulative effect 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 guidance we may provide.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations. Further, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies. In February and April 2025, the current U.S. presidential administration imposed new tariffs on China and China responded with tariffs on select U.S. goods. While we cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, if we are unable to obtain or use services or products from existing service providers, including those of contract development and manufacturing organizations, or if alternative service providers cannot be secured at an acceptable cost or at all, or if such actions cause broader disruption in drug manufacturing and related industries that impact drug product availability or pricing, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, a substantial amount of our common stock in the public market, the market price of our common stock could decline significantly.

Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act.

On October 10, 2023, we completed the October 2023 Offering for the sale of an aggregate of 8,663,793 shares of common stock and pre-funded warrants to purchase 1,250,000 shares of common stock at a public offering price of $6.38 per share and $6.379 per pre-funded warrant. Our stockholders may be further diluted by the exercise of the pre-funded warrants issued in the October 2023 Offering. As of September 30, 2025, no shares underlying the pre-funded warrants had been exercised. Furthermore, we currently have an effective resale shelf registration statement which enables the selling stockholders thereunder, three of our largest stockholders, to sell shares in the public market which could cause our stock price to decline. In addition, any future sales of shares of common stock or other securities under our 2025 Shelf Registration Statement, including pursuant to our ATM facility, could put downward pressure on our stock price. Moreover, certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable coverage. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. If one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We have incurred and will continue to incur significant increased costs and management resources as a result of operating as a public company.

We have incurred and will continue to incur significant legal, accounting, compliance and other expenses as a public company. Our management and other personnel need to devote a substantial amount of time and incur significant expense in connection with compliance initiatives. For example, as a public company, we must maintain additional internal controls and disclosure controls and procedures and have retained a transfer agent and adopted an insider trading policy. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

We maintain an enterprise resource planning, or ERP, system, which is designed to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. The ERP system has and will continue to require the investment of significant financial and human resources in order to ensure effective use of the system. Additionally, in the future, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in using an ERP system could adversely affect our internal controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act, or SOX, and the related rules and regulations implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have and will continue to increase legal and financial compliance costs and make some compliance activities more time-consuming. We have invested and will continue to invest additional resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. As a public company, we maintain directors' and officers' insurance coverage, which has significantly increased in recent years. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

While we were a large-accelerated filer for fiscal year 2022, we have been a "non-accelerated filer" since fiscal year 2023 and we anticipate we will continue to be one throughout fiscal year 2026. This status could make our common stock less attractive to investors.

Each year, we re-evaluate our SEC filing status. Accordingly, we are a non-accelerated filer, and due to our public float as of June 30, 2025, we anticipate we will be a non-accelerated filer throughout calendar year 2026. This will be re-evaluated each June 30. Pursuant to Section 404(a) of SOX, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer, we will not be required to include an attestation report issued by our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. If, after our next June 30 re-evaluation, we are no longer a non-accelerated filer, we would be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm and adhere to earlier filing dates based on our determined status beginning with our Form 10-K for the fiscal year. We cannot predict if investors will find our common stock less attractive if we choose to rely on this exemption. If some investors find our common stock less attractive as a result of our non-accelerated filer status, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

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

As of September 30, 2025, our executive officers, directors, and affiliated holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 21.9% of our outstanding voting stock.

Therefore, this group of stockholders, if they act together, will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other material corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Market conditions and changing circumstances could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others. For example, in March 2023, SVB, where we maintain certain immaterial accounts, was placed into receivership with the FDIC, and all funds held at SVB were temporarily inaccessible to SVB's customers. If other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, or we may lose, some or all of our existing cash, cash equivalents and investments, to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to timely pay key vendors, employees, and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. In addition, any U.S. federal government debt default due to a failure to increase the debt ceiling may lead to lack of access to our investments in U.S. treasury securities or losses or lower returns on such investments, in addition to broader macroeconomic risk that would follow any such default. Any delay in our ability to access our cash, cash equivalents and investments, or the loss of some or all of such funds, or inability to pay key vendors and others timely, could have a material adverse effect on our operations and cause us to seek additional capital sooner than planned.

We do not anticipate paying cash dividends and, accordingly, stockholders must rely on share appreciation for any return on their investment.

We have never paid any dividends on our capital stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and do not anticipate that we will declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, a stockholder's ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect one's rights as a common stockholder. Sales of equity securities may be made under our 2025 Shelf Registration Statement and pursuant to our related ATM facility described therein. Additionally, our stockholders may be further diluted by the exercise of the pre-funded warrants issued in the follow-on public offering. As of September 30, 2025, no shares underlying the pre-funded warrants had been exercised. Debt financing, if available, may involve fixed payment obligations or agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. Our Loan Agreement with the Lenders restricts our ability to incur additional indebtedness without the consent of the Lenders. If we raise additional funds through partnerships, collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our clinical or discovery programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. 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.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, with each class serving staggered three-year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of convertible preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on behalf of us;
- any action asserting a claim of breach of a fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, or DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, as either may be amended from time to time; and
- any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or Exchange Act, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

In the past, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting, both of which have since been remediated. We did not identify any material weakness for the fiscal years ended December 31, 2024 and 2023.

If in the future, we have a material weakness in our internal controls over financial reporting, we may not be able to prevent or detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm, if required, 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 are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. 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 our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, which would harm our business and the trading price of our common stock.

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. In addition, any testing by our independent registered public accounting firm in connection with Section 404(b) of SOX, as long as such attestation report is required pursuant to such section by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. As discussed above, we have identified material weaknesses in the past which have since been remediated. However, our remediation of previous material weaknesses may not prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Any failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition and results of operations and the trading price of our common stock.

We are required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management are required to assess the effectiveness of these controls annually. We were no longer an "emerging growth company" as of December 31, 2021 and as such, pursuant to Section 404(b) of SOX, our independent registered public accounting firm attested to the effectiveness of our internal control over financial reporting as of December 31, 2021. However, we became a "non-accelerated filer" for fiscal year 2023. While we remain a non-accelerated filer, we will not be required to include an attestation report issued by our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. Upon a change in status to an accelerated or large-accelerated filer, our independent registered public accounting firm would be required to attest to the effectiveness of our internal control over financial reporting as of the filing of the Form 10-K of that year. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not and therefore we may be less likely to detect deficiencies in our internal controls over financial reporting in the future and during any fiscal year for which we remain a non-accelerated filer.

We are organized in a holding company structure and we are, and will be, dependent upon the results of operations and cash flows of our subsidiaries and distributions we receive from our subsidiaries.

ALX Oncology Holdings Inc. is a holding company that currently has no material assets other than cash and our ownership of all of the equity issued by ALX Oncology Limited. As such, ALX Oncology Holdings Inc. will have no independent means of generating revenue or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, will be dependent upon the results of operations and cash flows of ALX Oncology Limited and its consolidated subsidiaries, including any distributions we receive from ALX Oncology Limited. There can be no assurance that our direct and indirect subsidiaries will generate sufficient cash flow to distribute funds to us or that applicable law and contractual restrictions, such as negative covenants in any debt instruments, will permit such distributions. In addition, in the event that the board of directors and stockholders of ALX Oncology Holdings Inc. were to approve a sale of all of our equity in ALX Oncology Limited or any of our other indirect subsidiaries, your equity interest would be in a holding company with no material assets other than those assets and other consideration received in such transaction.

General Risks

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

Our operations, and those of our service providers and suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical or public health crises, such as the COVID-19 pandemic, and other natural or man-made disasters such as the ongoing geopolitical unrest related to Russia's war with Ukraine, war and instability in Israel and the surrounding region, or business interruptions, for which we are partly uninsured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

The majority of our operations including our corporate headquarters are located in the San Francisco Bay Area in California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches or incidents.

Despite our implementation of security measures, any of the computer systems and networks belonging to or used by us or our employees and our CROs and other third-party service providers are vulnerable to damage and disruption from computer viruses, ransomware and other malicious code, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure, as well as security breaches and incidents from inadvertent or intentional actions, or from cyber-attacks by malicious third parties (including supply chain cyber-attacks, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise system infrastructure or lead to the loss, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information) or data that is processed or maintained on our behalf, or other assets, which could result in financial, legal, business and reputational harm to us. Any system failure, accident or security breach or incident that causes interruptions in our own or in our CROs' or other third-party service providers' operations could result in a material disruption of our drug discovery and development programs or other aspects of our operations. We may be more susceptible to security breaches and other security incidents while a large percentage of our employees continue to work from home for some portion of time because we and our service providers have less capability to monitor and enforce policies for those employees. Also, ongoing geopolitical unrest and related events such as Russia's war with Ukraine and war and instability in Israel and the surrounding region may subject us and our CROs and other third-party service providers to heightened risks of cyber-attacks and security breaches and incidents, any of which could materially disrupt our drug discovery and development programs or other aspects of our operations.

A system failure or security breach or incident that leads to the loss, corruption or unavailability of clinical trial data from completed, ongoing, or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost, corrupted, or unavailable data. In addition, if any disruption or security breach or incident results in loss, destruction, alteration, or unavailability of, or damage or unauthorized access to, our data or applications or unauthorized access to, disclosure, dissemination or other processing of confidential or proprietary information that we or our third-party service providers process, including personal information related to the subjects in our clinical trials, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected and further development of our product candidates may be delayed. Any such disruption, failure or security breach or incident could also cause us to incur additional costs to remedy the damages that arise from such disruption, failure or security breach or incident. Additionally, in the event of any such disruption, failure or security breach or incident, or any perception that one has occurred, we could be exposed to claims, demands, and litigation and governmental investigations and other proceedings, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant liabilities, including fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach or incident. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified by SEC rules and regulations. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by the collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

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

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

Use of Proceeds from Initial Public Offering of Common Stock

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on July 17, 2020 pursuant to Rule 424(b)(4). We invested the funds received in accordance with our investment policy. None of such payments were direct or indirect payments to any of our directors or officers (or their associates), to persons owning ten percent or more of our common stock or to any other affiliates.

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During our last fiscal quarter, none of our officers or directors, as defined in Rule 16a-1(f), adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408.

Item 6. Exhibits

NUMBER	EXHIBIT TITLE	INCORPORATED BY REFERENCE				FILED HEREWITH
		FORM	FILE NO.	EXHIBIT	FILING DATE	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document. - the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and included in exhibit 101)					X

* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the registrant 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, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated**.**

ALX ONCOLOGY HOLDINGS INC.

Date: November 7, 2025

By: /s/ Jason Lettmann

Jason Lettmann
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2025

By: /s/ Harish Shantharam

Harish Shantharam
Chief Financial Officer
(Principal Financial Officer)

Date: November 7, 2025

By: /s/ Shelly Pinto

Shelly Pinto
Senior Vice President, Finance and Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

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

I, Jason Lettmann, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ALX Oncology Holdings 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 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 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 7, 2025

By: /s/ Jason Lettmann

Jason Lettmann
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Harish Shantharam, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ALX Oncology Holdings 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 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 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 7, 2025

By: /s/ Harish Shantharam

Harish Shantharam
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of ALX Oncology Holdings Inc. (the "Company"), on Form 10-Q for the period ended September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to section 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 results of operations of the Company.

Date: November 7, 2025

By: /s/ Jason Lettmann

Jason Lettmann
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of ALX Oncology Holdings Inc. (the "Company"), on Form 10-Q for the period ended September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to section 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 results of operations of the Company.

Date: November 7, 2025

By: /s/ Harish Shantharam

Harish Shantharam
Chief Financial Officer
(Principal Financial Officer)