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KYVERNA THERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

Filed 11/12/26 for the Period Ending 09/30/26

Address	5980 HORTON STREET SUITE 200 EMERYVILLE, CA
Telephone	5109252492
CIK	0001994702
Symbol	KYTX
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

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: 001-41947

Kyverna Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-1365441**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5980 Horton St., STE 200 Emeryville, CA	**94608**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 925-2492

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	KYTX	The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of November 6, 2026, the registrant had 63,221,970 shares of common stock, $0.00001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Kyverna Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 31,818	$ 124,093
Available-for-sale marketable securities	138,754	155,160
Prepaid expenses and other current assets	5,686	3,700
Total current assets	176,258	282,953
Restricted cash	551	551
Property and equipment, net	1,360	1,546
Operating lease right-of-use assets	7,492	3,568
Finance lease right-of-use assets	51	305
Other non-current assets	3,725	4,903
Total assets	$ 189,437	$ 293,826
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,402	$ 5,306
Accrued compensation	7,414	9,990
Accrued license expense – related party	3,750	3,750
Other accrued expenses and current liabilities	9,265	13,472
Operating lease liabilities, short-term portion	1,272	3,662
Finance lease liabilities	33	307
Total current liabilities	25,136	36,487
Operating lease liabilities, net of short-term portion	6,189	320
Term loan	24,958	24,743
Total liabilities	56,283	61,550
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.00001 par value, 10,000,000 shares authorized; none issued and outstanding at September 30, 2026 and December 31, 2025.	—	—
Common stock, $0.00001 par value, 490,000,000 shares authorized; 62,537,376 and 60,389,893 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively.	1	1
Additional paid-in capital	678,119	657,005
Accumulated other comprehensive (loss) income	(151)	97
Accumulated deficit	(544,815)	(424,827)
Total stockholders' equity	133,154	232,276
Total liabilities and stockholders' equity	$ 189,437	$ 293,826

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

Kyverna Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 27,023	$ 30,457	$ 81,884	$ 103,706
General and administrative	15,876	8,270	41,938	26,839
Total operating expenses	42,899	38,727	123,822	130,545
Loss from operations	(42,899)	(38,727)	(123,822)	(130,545)
Interest income	1,680	2,000	5,936	7,189
Interest expense	(728)	(7)	(2,069)	(45)
Other income (expense), net	6	(53)	(33)	(102)
Total other income, net	958	1,940	3,834	7,042
Net loss	(41,941)	(36,787)	(119,988)	(123,503)
Other comprehensive (loss) income				
Unrealized (loss) gain on available-for-sale marketable securities, net	(9)	49	(248)	(76)
Total other comprehensive (loss) income	(9)	49	(248)	(76)
Net loss and other comprehensive loss	$ (41,950)	$ (36,738)	$ (120,236)	$ (123,579)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.68)	$ (0.85)	$ (1.96)	$ (2.85)
Weighted-average shares of common stock outstanding, basic and diluted	61,960,238	43,415,367	61,102,693	43,284,111

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

Kyverna Therapeutics, Inc.
Condensed Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2025	60,389,893	$ 1	$ 657,005	$ (424,827)	$ 97	$ 232,276
Common shares issued upon exercise of options	90,735	—	243	—	—	243
Issuance of common stock upon settlement of restricted stock units, net of shares withheld for taxes	51,872	—	(189)	—	—	(189)
Stock-based compensation expense	—	—	3,171	—	—	3,171
Net loss	—	—	—	(39,728)	—	(39,728)
Unrealized loss on available-for-sale marketable securities, net	—	—	—	—	(193)	(193)
Balance as of March 31, 2026	60,532,500	$ 1	$ 660,230	$ (464,555)	$ (96)	$ 195,580
Issuance of common stock under ATM Facility, net of sales agent's fees and issuance costs of $332	426,038	—	3,362	—	—	3,362
Common shares issued upon exercise of options	429,616	—	1,653	—	—	1,653
Issuance of common stock upon settlement of restricted stock units, net of shares withheld for taxes	182,093	—	(188)	—	—	(188)
Stock-based compensation expense	—	—	3,507	—	—	3,507
Net loss	—	—	—	(38,319)	—	(38,319)
Unrealized loss on available-for-sale marketable securities, net	—	—	—	—	(46)	(46)
Balance as of June 30, 2026	61,570,247	$ 1	$ 668,564	$ (502,874)	$ (142)	$ 165,549
Issuance of common stock under ATM Facility, net of sales agent's fees and issuance costs of $242	733,132	—	5,330	—	—	5,330
Common shares issued upon exercise of options	202,273	—	657	—	—	657
Issuance of common stock upon settlement of restricted stock units, net of shares withheld for taxes	31,724	—	(51)	—	—	(51)
Stock-based compensation expense	—	—	3,619	—	—	3,619
Net loss	—	—	—	(41,941)	—	(41,941)
Unrealized loss on available-for-sale marketable securities, net	—	—	—	—	(9)	(9)
Balance as of September 30, 2026	62,537,376	$ 1	$ 678,119	$ (544,815)	$ (151)	$ 133,154
Balance as of December 31, 2024	43,214,918	$ —	$ 530,002	$ (263,520)	$ 105	$ 266,587
Common shares issued upon exercise of options	3,955	—	3	—	—	3
Stock-based compensation expense	—	—	2,161	—	—	2,161
Net loss	—	—	—	(44,635)	—	(44,635)
Unrealized loss on available-for-sale marketable securities, net	—	—	—	—	(106)	(106)
Balance as of March 31, 2025	43,218,873	$ —	$ 532,166	$ (308,155)	$ (1)	$ 224,010
Stock-based compensation expense	—	—	2,518	—	—	2,518
Issuance of common stock upon settlement of restricted stock units, net of shares withheld for taxes	26,057	—	(51)	—	—	(51)
Net loss	—	—	—	(42,081)	—	(42,081)
Unrealized loss on available-for-sale marketable securities, net	—	—	—	—	(19)	(19)
Balance as of June 30, 2025	43,244,930	$ —	$ 534,633	$ (350,236)	$ (20)	$ 184,377
Common shares issued upon exercise of options	523,984	—	1,651	—	—	1,651
Stock-based compensation expense	—	—	2,699	—	—	2,699
Issuance of common stock upon settlement of restricted stock units, net of shares withheld for taxes	25,173	—	(43)	—	—	(43)
Net loss	—	—	—	(36,787)	—	(36,787)
Unrealized gain on available-for-sale marketable securities, net	—	—	—	—	49	49
Balance as of September 30, 2025	43,794,087	$ —	$ 538,940	$ (387,023)	$ 29	$ 151,946

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

Kyverna Therapeutics, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (119,988)	$ (123,503)
Adjustments to reconcile net loss to net cash used in operations:		
Stock-based compensation	10,297	7,378
Accretion of discounts on available-for-sale marketable securities	(1,111)	(5,520)
Non-cash interest expense	306	—
Depreciation and amortization expense	1,059	1,431
Asset impairment	510	648
(Gain) loss on sale of property and equipment	(47)	40
Non-cash lease expense	1,319	2,151
Changes in assets and liabilities:		
Prepaid expense and other current assets	(191)	835
Other non-current assets	1,027	(1,463)
Accounts payable	(1,904)	(1,608)
Accrued compensation	(2,576)	2,077
Other accrued expenses and current liabilities	(4,207)	(156)
Operating lease liability	(1,764)	(2,495)
Net cash used in operating activities	(117,270)	(120,185)
Cash flows from investing activities		
Purchases of available-for-sale marketable securities	(193,975)	(248,672)
Proceeds from maturities of available-for-sale marketable securities	209,500	306,500
Internal-use software development costs	(606)	(590)
Proceeds from sale of property and equipment	—	70
Purchases of property and equipment	(467)	(6)
Net cash provided by investing activities	14,452	57,302
Cash flows from financing activities		
Proceeds from issuance of common stock under ATM Facility, net of sales agent's fees	8,988	—
Proceeds from exercise of common stock options	2,553	1,654
Principal paid on finance lease liabilities	(274)	(723)
Payments for offering costs	(296)	(412)
Taxes paid related to net share settlement upon vesting of restricted stock units	(428)	(94)
Net cash provided by financing activities	10,543	425
Net decrease in cash, cash equivalents and restricted cash	(92,275)	(62,458)
Cash, cash equivalents and restricted cash, at beginning of period	124,644	97,173
Cash, cash equivalents and restricted cash, at end of period	$ 32,369	$ 34,715
Reconciliation of cash, cash equivalents and restricted cash to statement of financial position		
Cash and cash equivalents	31,818	34,164
Restricted cash	551	551
Cash, cash equivalents and restricted cash at end of period	$ 32,369	$ 34,715
Supplemental disclosure for non-cash investing and financing activities		
Right-of-use asset obtained in exchange for operating lease liability	$ 5,243	$ —
Unpaid offering costs included in other current liabilities	$ —	$ 57
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,718	$ 45

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

Kyverna Therapeutics, Inc.
Notes to Unaudited Condensed Financial Statements

1. Description of Business, Organization and Liquidity

Kyverna Therapeutics, Inc. ("Kyverna" or "the Company") is a late-stage clinical immunology company pioneering transformative therapies with curative potential for people living with neurologic autoimmune diseases. The lead product candidate, mivocabtagene autoleucel, or miv-cel, and also known as KYV-101, is advancing through late-stage clinical development. The Company is currently focused on advancing its neuroimmunology CAR T franchise, which includes evaluating miv-cel in stiff person syndrome, or SPS, and generalized myasthenia gravis, or gMG. The Company was incorporated on June 14, 2018, was initially named BAIT Therapeutics, Inc., changed its name to Kyverna Therapeutics, Inc. on October 1, 2019, and is headquartered in Emeryville, California.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception. As of September 30, 2026, the Company had an accumulated deficit of $544.8 million. The Company had net losses of $120.0 million and $123.5 million for the nine months ended September 30, 2026 and 2025, respectively. The Company had cash used in operations of $117.3 million and $120.2 million for the nine months ended September 30, 2026 and 2025, respectively.

The Company has historically financed its operations primarily through issuances of redeemable convertible preferred stock and convertible notes, revenue from its collaboration agreement and sales of shares of its common stock and debt financing. On October 31, 2025, the Company entered into a Loan and Security Agreement with Oxford Finance (as defined in Note 8). The Loan and Security Agreement provides a term loan facility (the "Loan Facility") up to an aggregate principal amount of $150.0 million. On November 3, 2025, the Company borrowed $25.0 million from funds available from the first tranche of the term loan. On July 8, 2026, the Company, the Collateral Agent, and the Lenders entered into an amendment to the Loan and Security Agreement (see Note 8 for additional details). The Loan Facility matures on October 1, 2030.

As of September 30, 2026, the Company had cash and cash equivalents and available-for-sale marketable securities of $170.6 million. The Company expects to continue to incur operating losses and negative cash flows from operations to support the development of its product candidates, to expand its product portfolio and to continue its research and development activities and product launch readiness activities. The Company's activities are subject to significant risks and uncertainties, including the completion of requisite clinical activities to support regulatory approvals, market acceptance of the Company's product candidates, if approved, as well as the timing and extent of spending on research and development. There can be no assurance that the Company will ever earn revenue or achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis. Unless and until it does, the Company will need to continue to raise additional capital. The Company may seek to raise capital through equity financings, debt financings, license, and/or collaboration agreements, or other sources of financing. There is no assurance, however, that any additional financing or any revenue-generating license or collaboration will be available when needed or that the Company will be able to obtain financing or enter into a license or collaboration on terms acceptable to the Company, or at all. The condensed financial statements do not reflect any adjustments relating to the outcome of this uncertainty.

Based on its current operating plan, management estimates that its existing cash and cash equivalents and available-for-sale marketable securities balances, and the term loans available under the Loan Facility with Oxford Finance will be sufficient to fund its operating plan and capital expenditure requirements for at least the next 12 months from the issuance of these condensed financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed financial statements have been prepared on the same basis as and should be read in conjunction with the annual financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2025, filed with the SEC on March 26, 2026.

In the opinion of the Company's management, the information in these condensed financial statements reflects all adjustments, all of which are of a normal and recurring nature necessary for a fair statement of the financial position and results of operations for the reported interim periods. The Company considers events or transactions that occur after the

balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to research and development accrued expenses and stock-based compensation. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the amount reported as revenue and expenses that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Significant Accounting Policies

There have been no material changes to the accounting policies discussed in Note 2 to the financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, filed with the SEC on March 26, 2026.

Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendments in ASU No. 2024-03 require a public business entity to disclose specific information about certain costs and expenses in the notes to its financial statements for interim and annual reporting periods. The objective of the disclosure requirements is to provide disaggregated information about a public business entity's expenses to help investors (a) better understand the entity's performance, (b) better assess the entity's prospects for future cash flows, and (c) compare an entity's performance over time and with that of other entities. ASU No. 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted, and entities may apply the standard prospectively or retrospectively. The Company is currently evaluating the impact of the adoption of this standard on its financial statements.

In September 2025, the FASB issued ASU No. 2025-06, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): *Targeted Improvements to the Accounting for Internal-Use Software.* The amendments in ASU No. 2025-06 remove all references to prescriptive and sequential software development stages. This ASU requires entities to begin capitalizing software costs when management authorizes and commits to funding the software project, and it is probable that the project will be completed and the software will be used for its intended purpose. ASU No. 2025-06 is effective for fiscal years beginning after December 15, 2027. Early adoption is permitted, and entities may apply the standard prospectively or retrospectively. The Company is currently evaluating the impact of the adoption of this standard on its financial statements.

3. Fair Value Measurements and Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements, as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company's fair value hierarchy for its financial instruments measured at fair value on a recurring basis as of September 30, 2026, was as follows (in thousands):

	Fair Value Measurements			
As of September 30, 2026	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents				
Money market funds	$ 27,540	$ 27,540	$ —	$ —
Available-for-sale marketable securities				
U.S. Treasury bills and government bonds	125,389	—	125,389	—
Corporate debt obligations	13,365	—	13,365	—
Total fair value of assets	$ 166,294	$ 27,540	$ 138,754	$ —

The Company's fair value hierarchy for its financial instruments measured at fair value on a recurring basis as of December 31, 2025, was as follows (in thousands):

	Fair Value Measurements			
As of December 31, 2025	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents				
Money market funds	$ 122,165	$ 122,165	$ —	$ —
Available-for-sale marketable securities				
U.S. Treasury bills	109,719	—	109,719	—
U.S. Government bonds	45,441	—	45,441	—
Total fair value of assets	$ 277,325	$ 122,165	$ 155,160	$ —

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and available-for-sale marketable securities. Cash equivalents consisted of money market funds, and available-for-sale marketable securities consisted of U.S. Treasury bills, corporate debt obligations and U.S. Government bonds. The Company obtains pricing information from its investment manager and generally determines the fair value of available-for-sale marketable securities using standard observable inputs, including reported trades, broker/dealer quotes and bids and/or offers. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

4. Available-for-Sale Marketable Securities

As of September 30, 2026, the Company's available-for-sale marketable securities consisted of debt securities issued by the U.S. Treasury and corporate debt obligations with contractual maturities on various dates within the next 12 months.

The following table summarizes the amortized cost, unrealized gains and losses and fair value of the Company's available-for-sale marketable securities as of September 30, 2026 (in thousands):

As of September 30, 2026	**Total Amortized Cost**	**Total Unrealized Gains**	**Total Unrealized Losses**	**Total Estimated Fair Value**
Money market funds (included in cash and cash equivalents)	$ 27,540	$ —	$ —	$ 27,540
U.S. Treasury bills and government bonds	125,526	—	(137)	125,389
Corporate debt obligations	13,379	—	(14)	13,365
Total available-for-sale marketable securities	$ 166,445	$ —	$ (151)	$ 166,294

As of September 30, 2026, $27.5 million was included in cash equivalents and $138.8 million was included in available-for-sale marketable securities.

The following table summarizes the amortized cost, unrealized gains and losses and fair value of the Company's available-for-sale marketable securities as of December 31, 2025 (in thousands):

As of December 31, 2025	Total Amortized Cost	Total Unrealized Gains	Total Unrealized Losses	Total Estimated Fair Value
Money market funds (included in cash and cash equivalents)	$ 122,165	$ —	$ —	$ 122,165
U.S. Treasury bills	109,667	52	—	109,719
U.S. Government bonds	45,397	44	—	45,441
Total available-for-sale marketable securities	$ 277,229	$ 96	$ —	$ 277,325

As of December 31, 2025, $122.2 million was included in cash equivalents and $155.2 million was included in available-for-sale marketable securities.

As of September 30, 2026 and December 31, 2025, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the Company's marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future economic and market conditions and determined that its investments were not significantly impacted by such conditions. For all securities with a fair value less than its amortized cost basis, the Company determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for losses has been recorded. During the three and nine months ended September 30, 2026 and 2025, the Company did not recognize any impairment losses on its investments.

As of September 30, 2026 and December 31, 2025, accrued interest receivable was $0.9 million and $0.6 million, respectively. The Company's accounting policy is to not measure an allowance for credit losses for accrued interest receivables and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which it considers to be in the period in which the Company determines the accrued interest will not be collected. During the three and nine months ended September 30, 2026 and 2025, the Company did not write off any accrued interest receivables.

5. Balance Sheet Components

Property and Equipment, Net

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

	September 30, 2026	December 31, 2025
Laboratory equipment	$ 2,290	$ 3,064
Furniture and fixtures	1,132	1,132
Leasehold improvements	1,144	936
Computer equipment and software	159	164
Construction in progress	64	—
Property and equipment, gross	4,789	5,296
Less accumulated depreciation	(3,429)	(3,750)
Property and equipment, net	$ 1,360	$ 1,546

Depreciation and amortization expense related to property and equipment, net was $0.1 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively, and $0.6 million and $0.8 million for the nine months ended September 30, 2026 and 2025, respectively.

The Company recognized a $0.5 million asset impairment charge related to intangible assets, net as general and administrative expense in the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2026. The Company recognized a $0.6 million asset impairment charge as research and development expense in the condensed statements of operations and comprehensive loss for the nine months ended September 30, 2025.

Other Accrued Expenses and Current Liabilities

Other accrued expenses and current liabilities consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued research and development expenses - Contract Research Organizations	$ 4,853	$ 6,393
Accrued research and development expenses - Contract Manufacturing Organizations	854	4,908
Other accrued expenses	3,558	2,171
Total other accrued expenses and current liabilities	$ 9,265	$ 13,472

6. License and Collaboration Agreements

Patent License Agreements with the National Institutes of Health

In May 2021, the Company entered into two patent license agreements with the National Institutes of Health (the "NIH"), pursuant to which the Company obtained exclusive, worldwide licenses under certain patents to use an anti-CD19 CAR in the Company's autologous and allogeneic CAR T-cell product candidates for the treatment of patients with autoimmune disease. The Company paid $3.3 million for acquired licenses.

Under the NIH agreements, commencing in January 2023 and subsequently on January 1 of each calendar year thereafter, the Company is also required to make minimum annual royalty payments of $0.2 million, which shall be credited against any earned royalties due based on a low single-digit percentage of net sales made in a respective year. In addition, benchmark royalties following the completion of certain regulatory-and clinical-related benchmarks are due to the NIH, with the minimum cumulative royalty due for a product reaching FDA approval or foreign-equivalent approval totaling $5.7 million for the autologous patent license agreement and $1.7 million for the allogeneic patent license agreement. Additional benchmark royalties would be payable for a subsequent indication under each NIH agreement. If the Company enters into a sublicensing agreement, it will be required to pay the NIH a sublicense royalty payment as a percentage of the fair market value of any consideration received for each sublicense granted. The sublicensing percentage starts at a high teens to low twenties percentage if clinical trials for the product have not yet begun and decreases to a mid-single-digit percentage if the product has received FDA approval or foreign-equivalent approval.

Unless terminated sooner, the NIH agreements remain in effect until the last licensed patent right granted pursuant to the respective agreement expires.

The acquisition of the licenses, including patent rights and know-how, was accounted for as an asset acquisition. As the acquired technology did not have an alternative use for accounting purposes, the consideration of $3.3 million was recorded as research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2021.

The Company recognized $1.2 million and $0.2 million as research and development expense related to minimum annual and benchmark royalties and other payments to NIH for the nine months ended September 30, 2026 and 2025, respectively. The Company did not recognize any royalties for either of the three months ended September 30, 2026 or 2025. No royalties were probable or payable as of September 30, 2026 and December 31, 2025.

Intellia License and Collaboration Agreement

In December 2021, the Company entered into a License and Collaboration Agreement (the "Intellia Agreement") with Intellia Therapeutics, Inc. ("Intellia") to research and develop an allogeneic CD19-directed CAR cell therapy product (the "CRISPR Product"), suitable for validation through pre-clinical and clinical proof-of-concept clinical trials, including the performance of activities as agreed in the collaboration plan. Pursuant to the Intellia Agreement, Intellia granted to the Company an exclusive, worldwide, sublicensable in multiple tiers, royalty bearing license under certain of Intellia's intellectual property to research, develop, sell and otherwise exploit the CRISPR Product.

As consideration for the licenses granted to the Company pursuant to the Intellia Agreement, the Company issued to Intellia shares of its Series B Preferred Stock with the fair value of $7.0 million. The Company is also obligated to make aggregate milestone payments to Intellia of up to $64.5 million upon the achievement of specified development and regulatory milestones and is obligated to pay to Intellia low to mid-single-digit royalties as a percentage of annual worldwide

sales, subject to certain adjustments, and additional potential royalties and milestones to Intellia's licensors. The royalties are payable on a country-by-country basis, commencing upon the first commercial sale of the CRISPR Product in the applicable country and expiring upon the later of (i) 12 years after the first commercial sale or (ii) the expiration of the last-to-expire valid patent claim.

The Intellia Agreement terminates on a country-by-country basis upon the expiration of the last valid claim within Intellia's patent rights covering the CRISPR Product within such country, unless the agreement is earlier terminated in its entirety by either party for insolvency, by either party for material breach of contract, by Intellia if the Company participates in legal action or proceeding challenging the validity or enforceability of Intellia's patents, or by the execution of the Co-Co Agreement. The Company may terminate the Intellia Agreement in its entirety, or on a country-by-country basis, by providing a written notice after the expiration or termination of the Intellia Option. Following the expiration of the term for a given country, the licenses granted to the Company in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free licenses.

No milestone payments were probable or payable as of September 30, 2026 and December 31, 2025.

Kite License Agreement (Related Party)

In January 2020, the Company entered into a License Agreement with Kite Therapeutics, Inc. ("Kite"), a subsidiary of Gilead Sciences, Inc. ("Gilead") (the "Kite Agreement"). Pursuant to the Kite Agreement, Kite granted to the Company a ten-year, co-exclusive license for the SynNotch technology primarily used in the Company's own internal research and development programs for the treatment, diagnosis or prevention of autoimmune, inflammatory or allogeneic stem cell transplant inflammatory diseases (excluding post-transplant infectious diseases).

Kite had licensed certain of the SynNotch technology included in the Kite Agreement pursuant to that certain Amended and Restated Exclusive License Agreement, between The Regents of the University of California and Kite (as successor to Cell Design Labs, Inc.) (the "UCSF License Agreement"). The Company was responsible for all costs and payments arising under the UCSF License Agreement and as a result of activities under the Kite Agreement, including earned royalties based on a low single-digit percentage of net sales, milestone payments in an aggregate amount of up to $10.8 million and accrued interest payables.

Pursuant to the Kite Agreement, the Company was also obligated to pay mid-teen-and mid-single-digit percentages of annual maintenance fees, minimum annual royalties and patent prosecution costs payable under the UCSF License Agreement. The Company was also obligated to pay a $6.3 million sublicensing fee under the UCSF License Agreement, which the Company agreed to offset with future milestone payments payable by Gilead under the Gilead Collaboration, Option and License Agreement, which was terminated in January 2024.

In October 2025, the Company, Gilead and Kite agreed to settle the outstanding balance as follows: (1) a payment of $2.5 million by the Company to Kite in cash within 30 days; and (2) the remaining balance of $3.8 million to settle no later than December 31, 2026, through an issuance of the Company's common stock to Kite at market price, a cash payment, or any combination of both cash payment and common stock issuance, at the discretion of the Company. The parties also agreed to terminate the Kite Agreement and released one another from any further obligations. The Company paid $2.5 million to Kite in November 2025 and the remaining balance of $3.8 million is presented as current accrued license expense – related party in the condensed balance sheets as of September 30, 2026 and December 31, 2025.

7. Commitments and Contingent Liabilities

Leases

The Company assesses contracts at inception to determine whether a lease exists, including an embedded lease. As of September 30, 2026, the Company leased office and laboratory space in Emeryville, California under operating leases (the "Emeryville Lease"). On February 27, 2026, the Company entered into a lease amendment to reduce total office and lab space and add new office space in the same building, which commenced on July 2, 2026. The term of the Emeryville Lease is through August 31, 2030. Base rent payments under the lease amendment are approximately $0.2 million per month. In addition to the base rent, which includes escalating payments over the lease term, the Company pays variable costs related to operating expenses and taxes, which are recognized as incurred.

The Company also has multiple leases for laboratory equipment with terms of 36 months that are accounted for as finance leases. Some of the Company's office and lab space were leased under short-term lease agreements during the nine months ended September 30, 2026 and 2025.

Components of the lease expense for the three and nine months ended September 30, 2026 and 2025, were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease cost	$ 619	$ 850	$ 2,002	$ 2,550
Finance lease cost:				
Amortization of right-of-use assets	61	154	254	628
Interest on lease liabilities	2	8	12	40
Variable lease cost	123	318	873	982
Total lease expense	$ 805	$ 1,330	$ 3,141	$ 4,200

Total undiscounted lease obligations under the Company's operating and finance leases were $9.9 million and de minimis, respectively, as of September 30, 2026.

License Agreements

From time to time, the Company enters into license agreements as part of its research and development activities. Such agreements may include upfront payments, development, regulatory and commercial milestone payments, as well as royalties on sales of products developed under these agreements. The Company recognizes liabilities related to these agreements based on its assessment of the applicable terms of each agreement and the relevant accounting guidance. See Note 6 for discussions of certain license agreements.

Contractual Obligations and Commitments

The Company enters into contracts in the normal course of business with clinical research organizations ("CROs") for clinical trials, with contract manufacturing organizations ("CMOs") for clinical and commercial manufacturing and with other vendors for preclinical studies, supplies and other products and services for operating purposes. These agreements generally provide for termination at the request of either party generally with less than one-year notice. The Company did not expect any of these agreements to be terminated and did not have any non-cancellable obligations under these agreements as of September 30, 2026.

Legal Contingencies

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. Legal fees and other costs associated with such proceedings are expensed as incurred.

On December 9, 2024, a shareholder class action complaint was filed in the United States District Court for the Northern District of California (the "Court") against the Company, certain of its current and former officers and directors, and the underwriters of the IPO. Per a stipulated schedule, an amended complaint was filed on May 2, 2025 (the "Amended Complaint"). The Amended Complaint alleges that the registration statement on Form S-1 filed in connection with the IPO and the prospectus contained therein contained material misstatements or omissions in violation of federal securities laws. On March 23, 2026, the Court issued an order granting defendants' motion to dismiss on all claims, with leave to amend the complaint. On April 20, 2026, plaintiff filed another amended complaint alleging the same claims under the Securities Act of 1933, as amended. Defendants subsequently filed a motion to dismiss the entire second amended complaint. On October 20, 2026, the Court entered an order granting, in part, and denying, in part, defendants' motion to dismiss. The Court dismissed plaintiff's Section 12 claim with prejudice and without leave to amend. The Court, however, denied the motion with respect to plaintiff's Section 11 and Section 15 claims.

In addition, on May 14, 2025, a stockholder derivative complaint was filed in the United States District Court for the Northern District of California against certain of the Company's current and former officers and directors which was captioned *Perez v. Seidenberg, et al.,* Case No. 3:25-cv-04163-*PCP* (the "Perez Action"). On May 22, 2025, another stockholder derivative complaint was filed alleging the same claims against the same individual defendants captioned *McDaniel v. Seidenberg, et al.*, Case No. 3:25-cv-04393-PCP (the "McDaniel Action", and together with the Perez Action, the "Derivative Actions"). The complaints filed in the Derivative Actions allege claims related to the allegations raised in the

Amended Complaint. On June 2, 2025, the Court entered a stipulation and order to stay the Perez Action pending the disposition of a motion to dismiss the Amended Complaint in the related securities class action. On June 25, 2025, the Court entered a stipulation and order to consolidate the Derivative Actions as *In re Kyverna Therapeutics Derivative Litigation*, Case No. 5:25-cv-04163-PCP. Finally, on July 22, 2025, the Court entered a stipulation and order staying the consolidated derivative action pending the disposition of the motion to dismiss the Amended Complaint in the related securities class action. With the resolution of the motion to dismiss in the securities class action, the parties will meet and confer about a consolidated response to the complaints.

The Company believes it has good and substantial defenses to the claims in the Amended Complaint and the Derivative Actions, but there is no guarantee that it will be successful in these efforts. The Company is unable to reasonably estimate at this time whether any loss ultimately will occur or to estimate the range of such loss; therefore, no amount of loss has been accrued in the accompanying condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2026. The Company did not have any accruals for the matters described above on its condensed balance sheets as of September 30, 2026 and December 31, 2025.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2026 and December 31, 2025, the Company did not have any material indemnification claims that were probable or reasonably possible.

8. Term Loan

On October 31, 2025, the Company entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Oxford Finance LLC ("Oxford Finance") as collateral agent (the "Collateral Agent"), and certain lenders from time to time party thereto (the "Lenders"). The Loan and Security Agreement provides a term loan facility (the "Loan Facility") of up to an aggregate principal amount of $150.0 million in senior secured credit facilities. The Loan Facility provides for term loans to be funded in multiple tranches, subject to the satisfaction of specified conditions. The term loans include (i) up to $40.0 million of Term A Loans available during the initial draw period of up to June 30, 2026, (ii) a single Term B Loan of $5.0 million to $20.0 million available upon achievement of specified clinical milestones to be drawn by June 30, 2026, which date is subject to an extended deadline to the extent that the full remaining Term A Loans are drawn on as described below, (iii) up to $40.0 million of Term C Loans available upon achievement of specified revenue and clinical milestones to be drawn by December 31, 2027, which date is subject to an extended deadline to the extent that the full remaining Term A Loans are drawn on as described below and (iv) an additional discretionary Term D Loan of up to $50.0 million upon the Company's request, subject to the Lenders' approval. On November 3, 2025, the Company drew $25.0 million from funds available from the first tranche of Term A Loans.

On July 8, 2026, the Company, the Collateral Agent, and the Lenders entered into an amendment to the Loan and Security Agreement (the "Amendment"), pursuant to which the parties agreed, among other things, to extend the availability of the remaining $15.0 million of Term A Loans through December 31, 2026, in exchange for the Company paying an upfront cash fee of $187,500. In addition, if the Company does not draw the full remaining $15.0 million of Term A Loans by December 31, 2026, the Company will pay the Lenders a non-utilization fee equal to 1.0% of the aggregate undrawn amount of the Term A Loans.

The Amendment also provides that, contingent upon the Company drawing the full remaining $15.0 million of Term A Loans, the following additional modifications to the Loan Facility will become effective: (i) the availability of the single Term B Loan of $5.0 million to $20.0 million shall be extended through the earlier of September 30, 2027 and the 90th day following the date of achievement of a clinical milestone; (ii) the Company shall pay the Lenders a non-utilization fee of 1.0% of the aggregate undrawn amount of the Term B Loan if it does not draw on the Term B Loan by the end of the draw period for the Term B Loan; (iii) the Term C Loans shall be available in two tranches of $20.0 million, with the first tranche being available subject to achievement of a revenue milestone through the earlier of March 31, 2028 and the 90th day following the date of the achievement of such revenue milestone and the second tranche being available subject to achievement of a clinical milestone through the earlier of March 31, 2028 and the 90th day following the date of achievement of such clinical milestone; and (iv) the Company shall become subject to minimum revenue covenants beginning with the quarter ending June 30, 2027, September 30, 2027, or December 31, 2027, depending upon the aggregate amount of gross cash proceeds the Company receives from other capital sources during certain periods. If the Company does not draw the full

remaining $15.0 million of Term A Loans, then the additional modifications described above will not be effective and the original terms of the Loan Facility will continue to apply.

Outstanding borrowings under the Loan Facility bear interest at a floating rate equal to the greater of (i) one-month CME Term Secured Overnight Financing Rate ("SOFR") administered by CME Group Benchmark Administrator or (ii) 3.75%, plus a margin of 5.00%, subject to a minimum interest rate floor of 8.75%. Interest is computed on the basis of a 360-day year and is payable monthly. The Company is required to make monthly interest-only payments through the applicable amortization date. Thereafter, principal is repaid in equal monthly installments over either 24 months or 12 months, depending on whether specified revenue milestones are achieved. If such milestones are not achieved, principal amortization will begin on November 1, 2028 and will be payable in equal monthly installments over a 24-month period. If the milestones are achieved, principal amortization will begin on November 1, 2029 and will be payable in equal monthly installments over a 12-month period. All outstanding principal and accrued interest are due and payable at maturity on October 1, 2030.

The obligations under the Loan Facility are secured by a first-priority security interest in substantially all of the Company's assets, including its intellectual property, subject to customary exceptions. The Loan and Security Agreement contains customary affirmative and negative covenants, including covenants relating to reporting requirements, maintenance of insurance, payment of taxes, limitations on indebtedness, liens, asset dispositions, mergers, and dividends. Beginning on February 28, 2027, the Company is required to maintain minimum unrestricted cash balances in controlled accounts equal to a specified percentage of the outstanding term loan principal, with such percentage decreasing upon achievement of specified regulatory approvals and revenue milestones. The Loan Facility also includes minimum revenue covenants beginning in 2027, subject to certain cash and market capitalization exceptions.

The Loan and Security Agreement includes customary events of default, including payment defaults, covenant violations, insolvency events, material adverse changes, delisting from Nasdaq, and certain judgments. Upon the occurrence of an event of default, the Lenders may, among other remedies, declare all outstanding obligations immediately due and payable and exercise remedies against the collateral. The Company was in compliance with applicable covenants as of September 30, 2026.

As of September 30, 2026, the term loan balance was $25.0 million, which reflects the $25.0 million borrowed under the Term A Loans net of de minimis unamortized debt discount and debt issuance costs. The Company recognized $0.7 million and $2.1 million of interest expense for the three and nine months ended September 30, 2026, respectively. As of September 30, 2026, the Company had $0.2 million accrued interest, which is included in other accrued expenses and current liabilities on the condensed balance sheets. The Company also recognized $0.1 million for the nine months ended September 30, 2026, related to debt issuance costs allocated to undrawn term loans, which were fully amortized to interest expense during the second quarter of 2026. At September 30, 2026, the effective interest rate was 10.8%.

9. Common Stock

As of September 30, 2026 and December 31, 2025, common stock shares reserved for future issuance were as follows:

	September 30, 2026	December 31, 2025
Outstanding stock option awards	9,939,059	9,330,722
Unvested restricted stock units awards and performance restricted stock units awards	2,069,871	1,282,404
Shares available for future grants under the 2024 Equity Incentive Plan and 2024 Inducement Equity Incentive Plan	4,580,116	2,944,739
Shares available for future grants under the 2024 Employee Stock Purchase Plan	1,266,000	844,000
Total shares reserved for future issuance	17,855,046	14,401,865

Shelf Registration Statement and the ATM Facility

On March 27, 2025, the Company filed a shelf registration statement on Form S-3 (the "Prior Registration Statement"), covering the offer and sale from time to time of up to $250.0 million in aggregate offering price of shares of its common stock, shares of its preferred stock, debt securities, warrants, rights, units and/or depositary shares. The Prior Registration Statement was declared effective by the SEC on April 15, 2025. The Prior Registration Statement included a sales agreement

prospectus (the "Prior ATM Prospectus"), covering the offer and sale from time to time through or to Jefferies LLC ("Jefferies"), as sales agent, of up to $50.0 million in aggregate offering price of shares of the Company's common stock under an Open Market Sale Agreement℠ entered into with Jefferies on March 27, 2025 (the "ATM Agreement"). In November 2025, the Company sold 2,477,100 shares of its common stock under the Prior ATM Prospectus for net proceeds of $16.4 million after deducting the sales agent's fees.

On March 26, 2026, the Company filed a new shelf registration statement on Form S-3 (the "2026 Registration Statement"), covering the offer and sale from time to time of up to $300.0 million in aggregate offering price of shares of its common stock, shares of its preferred stock, debt securities, warrants, rights, units and/or depositary shares. The 2026 Registration Statement was declared effective by the SEC on April 2, 2026, and the Prior Registration Statement, including the Prior ATM Prospectus, ceased to be available for further utilization at that time. The terms of any offering under the 2026 Registration Statement will be established at the time of such offering and will be described in a prospectus supplement to the 2026 Registration Statement filed with the SEC prior to the completion of any such offering.

The 2026 Registration Statement includes a sales agreement prospectus covering the offer and sale from time to time through or to Jefferies, as sales agent, of up to $100.0 million in aggregate offering price of shares of the Company's common stock under the ATM Agreement (the "ATM Facility"). During the nine months ended September 30, 2026, the Company sold 1,159,170 shares of its common stock under the ATM Facility for net proceeds of $8.7 million after deducting the sales agent's fees and issuance costs of $0.6 million.

As of September 30, 2026, $200.0 million remains available and unallocated under the 2026 Registration Statement and $90.7 million remains available and allocated for sale under the ATM Facility.

December 2025 Offering

On December 17, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") with the several underwriters named therein (the "Underwriters"), relating to the issuance and sale of an aggregate of 13,333,333 shares of the Company's common stock at $7.50 per share under the Prior Registration Statement. The offering closed on December 18, 2025. Pursuant to the Underwriting Agreement, the Underwriters were granted a 30-day option to purchase up to 1,999,999 additional shares (the "Option Shares") of common stock, which was partially exercised and the underwriters purchased 704,499 shares of common stock on December 24, 2025. Total proceeds of the transaction, including the Option Shares were approximately $98.7 million, net of underwriting discounts and issuance costs. The Prior Registration Statement was superseded by the 2026 Registration Statement once the 2026 Registration Statement was declared effective on April 2, 2026.

10. Equity Incentive Plans

In January 2024, the Company's board of directors adopted, and stockholders approved, the Company's 2024 Equity Incentive Plan (the "2024 Plan"), which became effective on February 6, 2024. The 2024 Plan superseded the Company's 2019 Equity Incentive Plan (the "2019 Plan"). No share awards can be granted under the 2019 Plan from the effective date of the 2024 Plan. Shares subject to outstanding equity awards granted under the 2019 Plan may be added to the 2024 Plan as such shares become available from time to time if awards terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price.

The Company initially reserved 4,215,000 shares of common stock for future issuance under the 2024 Plan. In addition, up to 3,960,713 shares issued and outstanding under the 2019 Plan may be added to the 2024 Plan as such shares become available from time to time if awards terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. The 2024 Plan also provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2025 and ending on January 1, 2034, by an amount equal to the lesser of (i) 5% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, and (ii) such smaller number of shares of common stock as determined by the Company's board of directors. In accordance with the foregoing, 2,160,745 and 3,019,494 shares of common stock were added to the shares reserved for future issuance under the 2024 Plan on January 1, 2025 and 2026, respectively. No more than 12,645,000 shares of common stock may be issued upon the exercise of incentive stock options under the 2024 Plan.

As of September 30, 2026, incentive stock options, nonstatutory stock options, restricted stock units and performance restricted stock units had been granted under the 2024 Plan. As of September 30, 2026, 4,241,250 shares of the Company's common stock remained available for future grant under the 2024 Plan.

In January 2024, the Company's board of directors and stockholders adopted the Company's 2024 Employee Stock Purchase Plan (the "ESPP"), which became effective on February 6, 2024. The maximum number of shares of common stock that may be issued under the ESPP will not exceed 1,266,000 shares of common stock, plus the number of shares of common stock that are automatically added on January 1st of each year, from January 1, 2027 through January 1, 2034, in an amount equal to the lesser of (i) 1.00% of the shares of common stock outstanding on December 31st of the immediately preceding calendar year, and (ii) 422,000 shares of common stock. The ESPP allows an eligible employee to purchase shares of our common stock at a discount through payroll deductions of up to 15% of the employee's eligible compensation. At the end of each purchase period, employees are able to purchase shares at 85% of the lower of the fair market value of our common stock at the beginning of the offering period or at the end of each applicable offering period. As of September 30, 2026, 1,266,000 shares of the Company's common stock remained available for future issuance under the ESPP.

In September 2024, the Company adopted the 2024 Inducement Equity Incentive Plan (as amended and restated in January 2026, the "Inducement Plan"). On January 29, 2026, the Company's compensation committee of the board of directors approved an increase of the maximum number of shares available for grant under the Inducement Plan by 1,000,000 shares to an aggregate of 5,000,000 shares of the Company's common stock. As of September 30, 2026, 338,866 shares of the Company's common stock remained available for future grant under the Inducement Plan.

Stock Options

A summary of option activity under the 2019 Plan, 2024 Plan and the Inducement Plan is as follows:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	9,330,722	$ 4.77	8.50	$ 43,821
Granted	3,250,218	$ 8.46		
Exercised	(722,624)	$ 3.53		
Forfeited	(1,699,442)	$ 4.37		
Expired	(219,815)	$ 7.41		
Outstanding at September 30, 2026	9,939,059	$ 6.08	8.22	$ 12,935
Exercisable at September 30, 2026	3,686,252	$ 5.01	7.24	$ 7,046
Vested and expected to vest at September 30, 2026	9,939,059	$ 6.08	8.22	$ 12,935

Aggregate intrinsic value represents the difference between the fair value of the underlying common stock and the exercise price. The weighted-average grant date fair value of options granted for the three and nine months ended September 30, 2026 was $5.65 and $6.48, respectively. The total fair value of options that vested during the three and nine months ended September 30, 2026 was $2.2 million and $8.0 million, respectively. The total fair value of options that vested during the three and nine months ended September 30, 2025 was $4.8 million and $9.5 million, respectively. The intrinsic value of options exercised during the three and nine months ended September 30, 2026 was $1.1 million and $4.2 million, respectively, and is calculated as the difference between the exercise price and the fair value of common stock as of the exercise date. As of September 30, 2026, total unrecognized stock-based compensation expense related to issued options was $29.6 million, which is expected to be recognized over a weighted-average period of 2.8 years.

Restricted Stock Units

	Number of RSUs	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2025	1,182,404	$ 3.96
Granted	1,614,359	8.31
Vested	(317,021)	3.10
Forfeited	(560,357)	4.09
Unvested at September 30, 2026	1,919,385	$ 7.73

Issued restricted stock units ("RSUs") vest over a four-year period. The estimated aggregate grant-date fair value of RSUs granted during the three and nine months ended September 30, 2026 was $3.8 million and $13.4 million, respectively. As of September 30, 2026, total unrecognized compensation expense for RSUs was $12.4 million, which is expected to be recognized over a weighted-average period of 3.2 years.

Performance Restricted Stock Units

During the three and nine months ended September 30, 2026, the Company granted performance restricted stock units ("PRSUs") for 181,505 and 205,806 shares with a weighted-average grant date fair value per share of $7.07 and $7.21, respectively.

In July 2026, the Company granted PRSUs that may vest in three tranches upon the attainment of certain target regulatory milestones. As of September 30, 2026, total unrecognized compensation cost related to the July 2026 PRSUs was $0.7 million, which will be recognized upon the achievement of the specified performance conditions.

In January 2026, the Company granted PRSUs that may vest in two tranches upon the attainment of certain target closing prices per share of the Company's common stock. The Company used a Monte Carlo simulation model to estimate the grant date fair value of the PRSUs. As of September 30, 2026, total unrecognized compensation cost related to the PRSUs was de minimis.

	Number of Performance RSUs	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2025	100,000	$ 8.05
Granted	205,806	7.21
Forfeited	(155,320)	7.70
Unvested at September 30, 2026	150,486	$ 7.26

Stock-Based Compensation Expense

The fair value of options granted was estimated using the Black-Scholes valuation model using the following assumptions for the three and nine months ended September 30, 2026 and 2025, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected volatility	88.6% - 88.8%	97.2% - 97.6%	88.6% - 94.9%	95.1% - 97.6%
Expected dividend yield	0%	0%	0%	0%
Expected term (in years)	6.1	6.0 - 6.1	5.5 - 6.1	5.4 - 6.1
Risk-free interest rate	4.5% - 5.1%	3.8% - 4.1%	3.6% - 5.1%	3.8% - 4.5%

The following table presents the classification of stock-based compensation expense related to stock options and RSUs, including PRSUs, granted (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 1,007	$ 936	$ 2,945	$ 2,640
General and administrative	2,612	1,763	7,352	4,738
Total stock-based compensation expense	$ 3,619	$ 2,699	$ 10,297	$ 7,378

The above stock-based compensation expense was related to the following stock-based awards (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options	$ 2,737	$ 2,339	$ 8,171	$ 6,525
RSUs	681	360	1,827	853
PRSUs	201	—	299	—
Total stock-based compensation expense	$ 3,619	$ 2,699	$ 10,297	$ 7,378

11. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss attributable to common stockholders	$ (41,941)	$ (36,787)	$ (119,988)	$ (123,503)
Denominator:				
Weighted-average shares of common stock outstanding, basic and diluted	61,960,238	43,415,367	61,102,693	43,284,111
Net loss per share attributable to common stockholders, basic and diluted:	$ (0.68)	$ (0.85)	$ (1.96)	$ (2.85)

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have had an antidilutive effect were as follows:

	September 30,	
	2026	2025
Options issued and outstanding	9,939,059	9,435,296
Unvested RSUs and PRSUs outstanding	2,069,871	1,292,104
	12,008,930	10,727,400

12. Related Party Transactions

The Company had zero and $0.1 million in other accrued expenses and current liabilities on the condensed balance sheet as of September 30, 2026 and December 31, 2025, respectively, related to severance payments for the Company's former chief executive officer.

13. Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing therapies for autoimmune and inflammatory diseases. The chief executive officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for purposes of allocating resources, assessing performance and monitoring budget versus actuals. The CODM assesses performance based on net loss as reported on the statement of operations and comprehensive loss. Segment assets are not regularly reviewed by the CODM for purposes of assessing segment performance or allocating resources; total assets are, however, presented on the balance sheet. Segment depreciation expense and segment asset additions are consistent with amounts reported within the statement of cash flows given the Company's operations are aggregated within a single reportable segment. All of the Company's long-lived assets are located in the United States.

The following table sets forth the Company's summary of segment loss, including significant segment expenses for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expenses:				
Miv-cel	$ 12,326	$ 16,233	$ 38,942	$ 60,894
Other programs	1,000	870	1,230	2,368
Other research and development expenses[(a)]	13,697	13,354	41,712	40,444
General and administrative expenses[(b)]	15,876	8,270	41,938	26,839
Interest income	(1,680)	(2,000)	(5,936)	(7,189)
Interest expense and other expense, net	722	60	2,102	147
Segment loss and net loss	$ 41,941	$ 36,787	$ 119,988	$ 123,503

[(a)] Primarily includes personnel costs, license fees, R&D consulting services, CRO and CMO costs and allocated overhead and facilities expenses.

[(b)] Primarily includes personnel costs, allocated overhead and facilities expenses, legal, IT, accounting and general and administrative expenses.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited interim condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q as well as our audited financial statements and related notes thereto as of and for the year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in Part II of the Annual Report on Form 10-K for the fiscal year ended December 31, 2025 filed with the Securities and Exchange Commission, or the SEC, on March 26, 2026. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. See also the section below titled "Special Note Regarding Forward-Looking Statements."

Throughout this Quarterly Report on Form 10-Q, unless the context otherwise requires, the terms "Kyverna," "we," "us" and "our" in this Quarterly Report on Form 10-Q refer to Kyverna Therapeutics, Inc.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of preclinical studies and clinical trials, research and development plans and costs, plans for manufacturing, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, for example, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical studies, clinical trials, and research and development programs for our product candidates;
- our ability to demonstrate, and the timing of, preclinical proof-of-concept for our product candidates;
- our ability to successfully complete our clinical trials;
- our ability to quickly leverage our initial product candidates and to progress additional candidates;
- the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain diseases and conditions we intend to treat and the number of patients that we will enroll in our clinical trials;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;
- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our product candidates;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications which we may pursue;

- our ability to identify additional product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the rate and degree of market acceptance and therapeutic benefits of our product candidates, if approved, and any other product candidates we may develop;
- the implementation of our strategic plans for our business, product candidates, research programs and technologies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technologies;
- anticipated developments related to our competitors and our industry;
- our competitive position and ability to leverage the clinical, regulatory and manufacturing advancements to accelerate our clinical trials and regulatory approval of product candidates;
- the success of competing therapies that are or may become available;
- our ability to identify and enter into future license agreements and collaborations;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory, manufacturing or commercialization expertise;
- our ability to prosecute, grow and defend our intellectual property portfolio against infringement claims;
- our ability to efficiently and cost-effectively conduct our current and future clinical trials;
- our reliance on third parties to conduct clinical trials of our product candidates;
- our reliance on third parties for the manufacture of our product candidates;
- our plans relating to sales strategy, manufacturing and commercializing our product candidates, if approved;
- our ability to attract and retain sales personnel, or to contract with a sales organization, if our product candidates are approved;
- anticipated regulatory and legal developments in the United States and foreign countries in which we may seek regulatory approval for our product candidates in the future;
- our ability to expand internationally;
- our ability to attract and retain key scientific and management personnel;
- our expected or anticipated financial performance;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, or a smaller reporting company;
- estimates of our expenses, capital requirements and needs for additional financing; and
- potential unfavorable macroeconomic conditions or market volatility resulting from global economic conditions or geopolitical developments, including international tariffs, trade protection measures, economic sanctions, supply chain issues, inflationary pressures, economic slowdowns or recessions, acts of war and civil or political unrest.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part II, Item 1A of this Quarterly Report on Form 10-Q titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q, and involve a number of assumptions and limitations. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to

time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, other strategic transactions or investments we may make or enter into.

Overview

We are a late-stage clinical immunology company pioneering transformative therapies with curative potential for people living with neurologic autoimmune diseases. Our development strategy is supported by our breadth of experience in treating more than 100 autoimmune patients with our lead product candidate, mivocabtagene autoleucel, or miv-cel, also known as KYV-101, an anti-CD19 autologous CAR T with a differentiated CAR construct. This has been documented through the scientific publication of multiple autoimmune case studies, our proprietary dataset of patients treated through named patient forms of compassionate use, our experience in ongoing investigator-initiated trials, or IITs, at leading academic institutions, as well as early clinical data from our ongoing company-sponsored trials illustrating the potential of these therapies to deeply deplete B cells with the aim of achieving durable treatment-free remission. This validation provides us with a clear path to continue advancing miv-cel through late-stage clinical development and commercialization across multiple autoimmune indications.

Miv-cel, our lead program, is an autologous, fully-human CD19-targeting CAR T-cell product candidate incorporating a CD28 costimulatory domain that was designed for potency and tolerability and licensed from the National Institutes of Health, or the NIH, specifically for use in autoimmune diseases. In addition to a fully human scFv domain, the CAR in miv-cel was also designed with a human CD8α hinge and transmembrane domain, a highly potent human CD28 costimulatory domain, and a human CD3ζ activation domain. This same underlying CAR in miv-cel has completed a 20-patient Phase 1 clinical trial in oncology conducted by the NIH, and the results from this Phase 1 clinical trial published in Nature Medicine reported similar rates of durable antitumor responses while delivering improved tolerability in the clinic among adult oncology patients, as compared to the CAR used to create Yescarta®. We believe the unique miv-cel CAR construct has the potential to deliver a differentiated therapeutic profile in autoimmune disease over current standard-of-care therapies by addressing the underlying immune dysfunction – deeply depleting B cells with the goal of achieving an immune reset and durable, treatment-free remission.

In the over 100 patients treated, miv-cel has demonstrated a consistent, well-tolerated safety profile, with no high-grade cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), and no cases of immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS). We believe miv-cel's positive benefit-risk profile and well-tolerated safety profile are attributed to its unique construct design as well as its well-established, validated manufacturing process.

We are currently focused on advancing our neuroimmunology CAR T franchise, starting with evaluating miv-cel in stiff person syndrome, or SPS, and generalized myasthenia gravis, or gMG, both serious and highly debilitating autoimmune diseases with significant unmet medical need. We received RMAT designations and Orphan Drug Designations, or ODD, from the FDA for both SPS and MG as well as Orphan Drug Designation from the European Medicines Agency in MG.

SPS is a rare and progressive neurologic autoimmune disease with no therapies approved by the U.S. Food and Drug Administration, or the FDA. Patients with SPS have substantial disease burden, with symptoms characterized by muscle stiffness and painful muscle spasms, impacting mobility. 80% of patients lose mobility over time and need walking aid assistance or a wheelchair. In addition, patients face risk of permanent disability and increased mortality. In SPS, we have completed a registrational 26-patient Phase 2 clinical trial (KYSA-8). We presented the positive primary analysis results from the KYSA-8 trial at the 2026 American Academy of Neurology, or AAN, Annual Meeting in April 2026, and one-year follow-up data at MS Toronto 2026, the joint ACTRIMS-ECTRIMS meeting in October 2026. In the primary analysis, miv-cel achieved the primary and all secondary endpoints, demonstrating statistically significant, durable clinical benefit at 16 weeks, with reversal of disability scores following a single dose of miv-cel. 100% of patients remained free of immunotherapies for SPS as of week 16. Further, miv-cel demonstrated a well-tolerated safety profile. In the one-year follow-up data, miv-cel demonstrated sustained clinical benefit across all primary and secondary endpoints, with nearly all patients remaining off chronic immunotherapies. In addition, miv-cel continued to be well-tolerated, with no high-grade

CRS, ICANS or IEC-HS. Data compare favorably to the results of a large, multicenter, retrospective natural history study we conducted to examine the impact of SPS on walking speed. The data, which were presented at AAN 2026, demonstrated that patients experienced no or minimal improvement in mobility and increased their use of walking aids and off-label immunotherapies over time.

We initiated the rolling BLA submission of miv-cel in SPS in the second quarter of 2026 and completed the submission in the fourth quarter of 2026, seeking priority review under the program's Regenerative Medicine Advanced Therapy, or RMAT, designation. In anticipation of a potential FDA approval and commercial launch in 2027, we are progressing launch readiness activities through targeted site activation engagements with CAR-T experts, neurologists and payers, and building an integrated patient support and reimbursement network to streamline the treatment journey. With experienced commercial leaders in place, we continue to hire field-based sales and medical specialists.

Myasthenia gravis, or MG, is a B-cell and antibody-mediated neuromuscular autoimmune disease that causes fluctuating muscle weakness and fatigue. The disease includes gMG, which impacts muscles beyond the eyes and may involve bulbar, limb, and respiratory muscles. Most patients develop gMG within two years after MG diagnosis. Symptoms are highly disruptive to quality of life and can include muscle weakness and fatigue, difficulty chewing and swallowing, trouble with speech, and in severe cases, respiratory failure, which can be life-threatening. Despite available treatment options, including immunosuppressants and biologics, patients still struggle with symptom control and require chronic and costly treatment options in addition to background therapies.

In October 2025, we reported positive interim data from our registrational KYSA-6 Phase 2 clinical trial of miv-cel in gMG. In April 2026, we presented the positive longer-term follow-up data from the Phase 2 portion of the KYSA-6 trial at the 2026 AAN Annual Meeting. The updated data demonstrated durable clinical responses across all key clinical outcome measures with sustained benefit observed out to one year following a single dose of miv-cel. 100% of patients achieved clinically meaningful, rapid and robust reductions in Myasthenia Gravis Activities of Daily Living, or MG-ADL, and Quantitative Myasthenia Gravis, or QMG, scores from baseline (the co-primary endpoints of the Phase 3 portion of the trial), regardless of prior biologic exposure and at deeper levels observed compared to prior interim analysis. In addition, biomarker and mechanistic data further supported miv-cel's differentiated clinical profile and miv-cel was well-tolerated. In October 2026, we reported positive longer-term, Phase 2 follow-up data in gMG demonstrating robust and durable effects sustained for up to 1.5 years across MG-ADL, QMG, and Myasthenia Gravis Composite scores, with the majority of patients maintaining minimal symptom expression (MSE) and remaining off chronic immunosuppressants. We continue to advance our FDA-aligned, Phase 3 registrational trial and expect to complete patient enrollment by mid-2027. Beyond SPS and gMG, our focused neurologic pipeline opportunities include expanding into progressive multiple sclerosis (PMS).

In August 2026, the FDA granted RMAT designation for miv-cel in non-active secondary progressive multiple sclerosis, or naSPMS, which provides the opportunity for increased FDA engagement and eligibility for priority and rolling reviews, as well as accelerated approval pathways. The RMAT designation was based on promising IIT data of miv-cel in PMS from Stanford University (Stanford) and the University of California, San Francisco (UCSF), where a single-dose of miv-cel has demonstrated robust CAR T-cell penetration in the central nervous system (CNS) and improved disability scores while removing the need for chronic immunotherapies. In addition, miv-cel demonstrated a consistent and well-tolerated safety profile with no high-grade CRS and no cases of ICANS or IEC-HS. In October 2026 at MS Toronto, Stanford presented updated Phase 1 clinical data of miv-cel in PMS, demonstrating sustained stable to improved expanded disability status scale scores (EDSS) in all five patients with available data as of last follow-up, with the majority showing sustained clinical benefit through one year. In addition, the first patient treated with miv-cel achieved sustained clinical benefit beyond two years. We expect to provide an update on our PMS development strategy by early 2027.

Additional pipeline opportunities include the potential to expand into broader autoimmune indications such as rheumatoid arthritis, or RA, where encouraging data have been generated in a Phase 1/2 IIT.

We are strengthening our CMC capabilities to support late-stage clinical development and anticipated commercialization. In July 2026, we entered into a clinical and commercial supply agreement, or the Elevate CCSA, with ElevateBio BaseCamp, Inc., or Elevate, for both U.S. commercial and global clinical supply of miv-cel. The new manufacturing agreement provides us with flexible and scalable supply of miv-cel, supporting our potential launches in SPS and gMG, as well as other ongoing clinical studies.

In January 2026, the Investigational New Drug, or IND, application for KYV-102, our proprietary whole blood, rapid manufacturing process, was accepted by the FDA. In November 2026, we announced that we have deprioritized our KYV-102 manufacturing program to continue to focus on accelerating our late-stage neurologic indications with miv-cel.

Since our inception in June 2018, we have devoted substantially all of our resources to performing research and development, enabling manufacturing activities in support of our product development and commercial readiness efforts, hiring personnel, acquiring and developing our technology and product candidates, performing business planning, developing

and establishing our intellectual property portfolio, raising capital and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales.

We have incurred significant losses and negative cash flows from operations since our inception. As of September 30, 2026, we had an accumulated deficit of $544.8 million. Our net losses were $41.9 million and $120.0 million for the three and nine months ended September 30, 2026, respectively, compared with $36.8 million and $123.5 million for the three and nine months ended September 30, 2025, respectively. Our cash used in operations was $117.3 million and $120.2 million for the nine months ended September 30, 2026 and 2025, respectively. We have historically financed our operations primarily through issuances of redeemable convertible preferred stock and convertible notes, revenue from our collaboration agreement, sales of shares of our common stock, including through our ATM Facility (as defined below), and borrowings under our Loan Facility (as defined below). Management has determined that as of September 30, 2026, our cash and cash equivalents and available-for-sale marketable securities of $170.6 million, and the term loans available under the Loan Facility with Oxford Finance will be sufficient to fund our operating plan and capital expenditure requirements for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. We plan to monitor expenses and raise additional capital through equity or debt financings, strategic alliances and licensing arrangements. Our ability to access capital when needed is not assured and if capital is not available to us when, and in the amounts, needed, we could be required to delay, scale back or abandon some or all of our development programs and other operations, which could materially harm our business, financial condition and results of operations.

We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon the successful development, approval and commercialization of our product candidates and upon the receipt of sufficient revenues to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. We may never achieve profitability, and unless we do and until then, we will need to continue to raise additional capital.

We expect our expenses will increase substantially in connection with our ongoing and planned activities, as we:

- continue to progress the development of our product candidates, including miv-cel in clinical trials;
- explore additional indications for our existing product candidates;
- procure manufacturing of clinical supply and manufacturing operations for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- continue commercial readiness efforts for miv-cel in SPS following our BLA submission in the fourth quarter of 2026;
- acquire, discover, validate and develop additional product candidates;
- attract, hire and retain additional personnel;
- implement operational, financial and management systems;
- pursue regulatory approval for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out;
- obtain, maintain, expand and protect our portfolio of intellectual property rights; and
- operate as a public company.

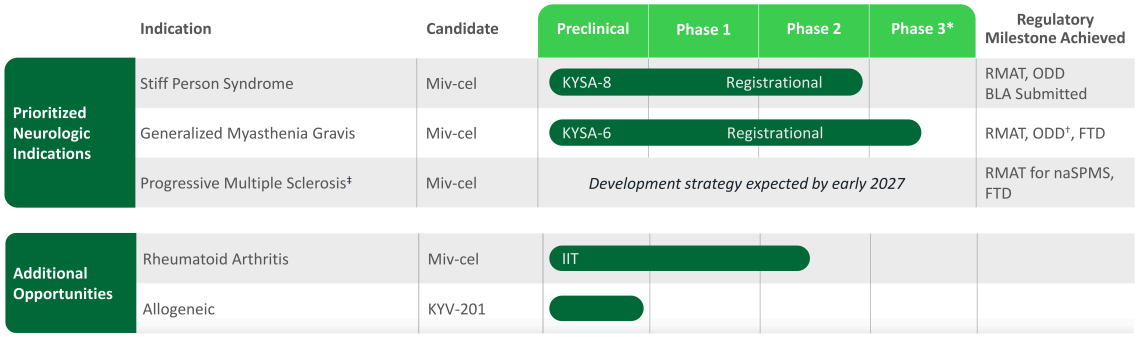
We do not currently own or operate any manufacturing facilities. We rely on contract manufacturing organizations, or CMOs, to produce our product candidates in accordance with the FDA's current Good Manufacturing Practices regulations for use in our clinical studies. The Elevate CCSA replaced the July 2023 development and manufacturing services agreement with Elevate under which Elevate provided us with cell manufacturing, release and testing services for our miv-cel product candidate. Under the master services agreement with Minaris Advanced Therapies, Inc., or MAT, MAT's facility in Philadelphia, Pennsylvania, provides us with certain customized cell manufacturing, release and testing services for our miv-cel product candidate. Pursuant to our license and supply agreement with Oxford Biomedica (UK) Limited, or Oxford, Oxford provides us with lentiviral vector process development services.

We continue to advance our product-launch readiness activities. However, we have not yet established a fully operational commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our product candidates, we expect to incur additional expenses to expand our infrastructure to support product sales, marketing, market access, distribution and other commercial activities.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability, if at all. Even if we are able to generate revenue from the sale of our product candidates, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Our pipeline and programs

Our focused neurologic autoimmune pipeline of product candidates is summarized in the figure below:



RMAT, Regenerative Medicine Advanced Therapy; ODD, Orphan Drug Designation; FTD, Fast Track Designation; IIT, investigator-initiated trial; naSPMS, non-active secondary progressive multiple sclerosis.

Fast track designation does not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional US Food and Drug Administration procedures.

*Phase 3 may not be required if Phase 2 is registrational. †EU & US. ‡ Kyverna is also exploring miv-cel in progressive multiple sclerosis through IITs from Stanford University and the University of California, San Francisco.

License and Collaboration Agreements

Information regarding our license and collaboration agreements is included in Note 6, “License and Collaboration Agreements,” to the condensed financial statements included in this Quarterly Report on Form 10-Q.

Macroeconomic Trends

We may be affected by worldwide economic conditions and challenges, such as the effects of the ongoing geopolitical conflicts in Ukraine, war in Iran and other conflicts and instability in the Middle East, tensions between not only the U.S. and China, but also between the U.S. and other countries in the international community, and inflationary trends, and the imposition, or threatened imposition, of tariffs and potential retaliatory trade restrictions. The past several years have been marked by significant market uncertainty, increasing inflationary pressures and volatility in the capital markets. These market dynamics continue and similar adverse market conditions may negatively impact our business, financial position and results of operations. For further discussion of the potential impacts of macroeconomic events on us, refer to the section titled “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Components of Operating Results

Operating Expenses

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

Research and Development Expenses

The largest component of our total operating expenses since inception has been research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development employees, including stock-based compensation; expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites that conduct preclinical and clinical studies; costs of acquiring and manufacturing clinical study materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs; and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

Research and development costs include:

- costs incurred under agreements with third-party CROs, CMOs and other third parties that conduct preclinical and clinical activities on our behalf and manufacture our product candidates;
- consulting fees associated with our research and development activities;
- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses, milestone payments and annual license maintenance fees under our licensing agreements;
- other costs associated with our research and development programs, including laboratory materials and supplies;
- employee-related costs, including salaries, benefits, travel and meals expenses, and stock-based compensation expense for our research and development personnel; and
- allocated facilities and overhead costs, including software and other miscellaneous expenses incurred in connection with our research and development programs.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never receive regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and personnel-related expenses, including: salaries, employee benefit costs and stock-based compensation expense, professional fees for legal, accounting and tax services; allocated overheads, including rent, equipment, information technology costs and utilities; and other general operating expenses not otherwise classified as research and development expenses. General and administrative expenses also include costs associated with our commercial readiness and market access activities.

Our general and administrative expenses are expected to increase modestly as we continue to enhance corporate infrastructure and support commercial readiness activities for a potential approval of miv-cel in SPS while maintaining compliance with stock exchange listing and various regulatory requirements.

Interest Income

Interest income consists primarily of interest and accretion of premiums and discounts on our investments in available-for-sale marketable securities and cash equivalents.

Interest Expense

Interest expense consists primarily of amounts related to our Loan Facility and laboratory equipment finance leases.

Other Expense, Net

Other expense, net primarily consists of settlement and revaluation of transactions and accounts payable in foreign currency.

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods presented:

	Three Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Operating expenses				
Research and development	$ 27,023	$ 30,457	$ (3,434)	(11)%
General and administrative	15,876	8,270	7,606	92%
Total operating expenses	42,899	38,727	4,172	11%
Loss from operations	(42,899)	(38,727)	(4,172)	11%
Interest income	1,680	2,000	(320)	(16)%
Interest expense	(728)	(7)	(721)	*
Other income (expense), net	6	(53)	59	(111)%
Total other income, net	958	1,940	(982)	(51)%
Net loss	$ (41,941)	$ (36,787)	$ (5,154)	14%

** Not meaningful.*

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented:

	Three Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Miv-cel	$ 12,326	$ 16,233	$ (3,907)	(24)%
Other programs	1,000	870	130	15%
Personnel-related expenses	9,534	8,715	819	9%
Other research and development expenses	4,163	4,639	(476)	(10)%
Total research and development expenses	$ 27,023	$ 30,457	$ (3,434)	(11)%

Research and development expenses decreased by $3.4 million, or 11%, during the three months ended September 30, 2026, compared to the same period in the prior year.

External research and development expenses related to our miv-cel program decreased by $3.9 million, or 24%, during the three months ended September 30, 2026, compared to the same period in the prior year, primarily driven by a $4.7 million decrease in CMO costs, partially offset by a $0.4 million increase in manufacturing supplies. We incurred higher CMO costs during the three months ended September 30, 2025 to support significant BLA readiness efforts.

Other program expenses include research and development expenses, primarily for our KYV-201, KYV-102 and other programs. Other program costs increased by $0.1 million, or 15%, during the three months ended September 30, 2026, compared to the same period in the prior year, primarily driven by $1.0 million in license costs, partially offset by a $0.7 million decrease in CMO costs.

Personnel-related expenses increased by $0.8 million, or 9%, during the three months ended September 30, 2026, compared to the same period in the prior year, due to increased headcount to support the development of miv-cel and our other programs.

Other research and development expenses decreased by $0.5 million, or 10%, during the three months ended September 30, 2026, compared to the same period in the prior year, primarily driven by a $0.8 million decrease in rent and allocated overhead expenses, partially offset by a $0.6 million increase in outside services.

General and Administrative Expenses

General and administrative expenses increased by $7.6 million, or 92%, during the three months ended September 30, 2026, compared to the same period in the prior year, primarily driven by a $3.4 million increase in personnel-related expenses, including a $0.9 million increase in stock-based compensation expense due to increased headcount. Professional services and overhead expenses increased by $2.4 million and $1.3 million, respectively, to continue supporting commercial readiness and market access activities. Other general and administrative expenses increased by $0.5 million due to an asset impairment charge recorded during the three months ended September 30, 2026.

Other Income, Net

Interest income decreased by $0.3 million during the three months ended September 30, 2026, compared to the same period in the prior year, primarily driven by lower effective interest yield on our cash equivalents and available-for-sale marketable securities.

Interest expense increased by $0.7 million during the three months ended September 30, 2026, compared to the same period in the prior year, due to the Loan Facility entered into in the fourth quarter of 2025.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods presented:

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Operating expenses				
Research and development	$ 81,884	$ 103,706	$ (21,822)	(21)%
General and administrative	41,938	26,839	15,099	56%
Total operating expenses	123,822	130,545	(6,723)	(5)%
Loss from operations	(123,822)	(130,545)	6,723	(5)%
Interest income	5,936	7,189	(1,253)	(17)%
Interest expense	(2,069)	(45)	(2,024)	*
Other expense, net	(33)	(102)	69	(68)%
Total other income, net	3,834	7,042	(3,208)	(46)%
Net loss	$ (119,988)	$ (123,503)	$ 3,515	(3)%

* *Not meaningful.*

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented:

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Miv-cel	$ 38,942	$ 60,894	$ (21,952)	(36)%
Other programs	1,230	2,368	(1,138)	(48)%
Personnel-related expenses	28,068	25,506	2,562	10%
Other research and development expenses	13,644	14,938	(1,294)	(9)%
Total research and development expenses	$ 81,884	$ 103,706	$ (21,822)	(21)%

Research and development expenses decreased by $21.8 million, or 21%, during the nine months ended September 30, 2026, compared to the same period in the prior year.

External research and development expenses related to our miv-cel program decreased by $22.0 million, or 36%, during the nine months ended September 30, 2026, compared to the same period in the prior year, primarily driven by a $23.2 million decrease in CMO costs and a $1.6 million decrease in CRO costs due to lower costs incurred for our clinical trials, partially offset by a $1.2 million increase in outside services and a $1.2 million increase in royalty and other payments under our license agreements. We incurred higher CMO costs during the nine months ended September 30, 2025 to support significant BLA readiness efforts, related to our SPS product candidate.

Other program expenses include research and development expenses, primarily for our KYV-201, KYV-102 and other programs. Other program costs decreased by $1.1 million, or 48%, during the nine months ended September 30, 2026, compared to the same period in the prior year, primarily driven by a $1.9 million decrease in CMO and CRO costs, partially offset by higher license costs.

Personnel-related expenses increased by $2.6 million, or 10%, during the nine months ended September 30, 2026, compared to the same period in the prior year, due to increased headcount to support the clinical development of miv-cel and our other programs.

Other research and development expenses decreased by $1.3 million, or 9%, during the nine months ended September 30, 2026, compared to the same period in the prior year, primarily driven by a $1.8 million decrease in rent and allocated overhead expenses and a $0.6 million asset impairment charge incurred in the same period in the prior year, partially offset by a $1.5 million increase in outside services related to the BLA readiness activities and regulatory submission.

General and Administrative Expenses

General and administrative expenses increased by $15.1 million, or 56%, during the nine months ended September 30, 2026, compared to the same period in the prior year, primarily driven by a $7.5 million increase in personnel-related costs, including a $2.6 million increase in stock-based compensation expense, due to increased headcount. Professional services and overhead expenses increased by $5.2 million and $1.2 million, respectively, to continue supporting commercial readiness and market access activities. Other general and administrative expenses increased by $1.2 million, primarily due to a $0.5 million asset impairment charge recorded during the three months ended September 30, 2026.

Other Income, Net

Interest income decreased by $1.3 million during the nine months ended September 30, 2026, compared to the same period in the prior year, primarily driven by lower effective interest yield on our cash equivalents and available-for-sale marketable securities.

Interest expense increased $2.0 million during the nine months ended September 30, 2026, compared to the same period in the prior year, due to the Loan Facility entered into in the fourth quarter of 2025.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred significant losses and negative cash flows from operations since our inception. We have historically financed our operations primarily through issuances of redeemable convertible preferred stock and convertible notes, revenue from our collaboration agreement, sales of shares of our common stock, including through our ATM Facility, and borrowings under our Loan Facility.

Shelf Registration Statement and the ATM Facility

On March 27, 2025, we filed a shelf registration statement on Form S-3, or the Prior Registration Statement, covering the offer and sale from time to time of up to $250.0 million in aggregate offering price of shares of our common stock, shares of our preferred stock, debt securities, warrants, rights, units and/or depositary shares. The Prior Registration Statement was declared effective by the SEC on April 15, 2025. The Prior Registration Statement included a sales agreement prospectus, or the Prior ATM Prospectus, covering the offer and sale from time to time through or to Jefferies LLC or Jefferies, as sales agent, of up to $50.0 million in aggregate offering price of shares of our common stock under an Open Market Sale Agreement℠ entered into with Jefferies on March 27, 2025, or the ATM Agreement. In November 2025, we sold 2,477,100 shares under the Prior ATM Prospectus for net proceeds of $16.4 million after deducting the sales agent’s fees.

On March 26, 2026, we filed a new shelf registration statement on Form S-3, or the 2026 Registration Statement, covering the offer and sale from time to time of up to $300.0 million in aggregate offering price of shares of our common stock, shares of our preferred stock, debt securities, warrants, rights, units and/or depositary shares. The 2026 Registration Statement was declared effective by the SEC on April 2, 2026, and the Prior Registration Statement, including the Prior ATM Prospectus, ceased to be available for further utilization at that time. The terms of any offering under the 2026 Registration Statement will be established at the time of such offering and will be described in a prospectus supplement to the 2026 Registration Statement filed with the SEC prior to the completion of any such offering. The 2026 Registration Statement included a sales agreement prospectus covering the offer and sale from time to time through or to Jefferies, as sales agent, of up to $100.0 million in aggregate offering price of shares of our common stock under the ATM Agreement, or the ATM Facility. During the nine months ended September 30, 2026, we sold 1,159,170 shares of our common stock under the ATM Facility for net proceeds of $8.7 million after deducting the sales agent's fees and issuance costs of $0.6 million. As of September 30, 2026, $200.0 million remains available and unallocated under the 2026 Registration Statement and $90.7 million remains available and allocated for sale under the ATM Facility.

Loan and Security Agreement

On October 31, 2025, we entered into a Loan and Security Agreement, or the Loan and Security Agreement, with Oxford Finance LLC, or Oxford Finance, as collateral agent, or the Collateral Agent, and certain lenders from time to time party thereto, or the Lenders. The Loan and Security Agreement provides a term loan facility, or the Loan Facility, of up to an aggregate principal amount of $150.0 million in senior secured credit facilities.

On July 8, 2026, we, the Collateral Agent, and the Lenders entered into an amendment to the Loan and Security Agreement, or the Amendment, pursuant to which the parties agreed, among other things, to extend the availability of the remaining $15.0 million of Term A Loans through December 31, 2026, in exchange for us paying an upfront cash fee of $187,500. In addition, if we do not draw the full remaining $15.0 million of Term A Loans by December 31, 2026, we will pay the Lenders a non-utilization fee equal to 1.0% of the aggregate undrawn amount of the Term A Loans.

As of September 30, 2026, the term loan balance was $25.0 million, which reflects the $25.0 million borrowed under the Term A Loans net of de minimis unamortized debt discount and debt issuance costs.

Refer to Note 8, "Term Loan" to the condensed financial statements included in this Quarterly Report on Form 10-Q for additional details regarding the Loan and Security Agreement, as amended by the Amendment.

December 2025 Offering

On December 17, 2025, we entered into an underwriting agreement, or the Underwriting Agreement, with several underwriters named therein, or the Underwriters, relating to the issuance and sale of our common stock in an underwritten public offering pursuant to the Prior Registration Statement. On December 18, 2025, we closed the offering and issued an aggregate of 13,333,333 shares of our common stock for net proceeds of $93.7 million. Additionally, under the terms of the Underwriting Agreement, the Underwriters had an option to purchase up to an additional 1,999,999 shares of common stock,

which the Underwriters exercised on December 24, 2025 and purchased 704,499 shares of our common stock for net proceeds of $5.0 million to us.

As of September 30, 2026, we had $170.6 million in cash, cash equivalents and available-for-sale marketable securities.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and administrative expenditures to support our operations. We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, further our research and development initiatives for our product candidates and incur costs associated with the potential commercialization of our product candidates, if approved. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We have incurred significant losses and negative cash flows from operations since our inception. As of September 30, 2026, we had an accumulated deficit of $544.8 million. Based on the current cash forecast, management estimates that its existing cash and cash equivalents and available-for-sale marketable securities balances and the term loans available under the Loan Facility with Oxford Finance will be sufficient to fund our operating plan and capital expenditure requirements for at least the next twelve months from the issuance date of the condensed financial statements included in this Quarterly Report on Form 10-Q. There can be no assurance that we will ever earn revenue or achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis. Unless and until it does, we will need to continue to raise additional capital. We may seek to raise capital through equity financings, debt financings, license, and/or collaboration agreements, or other sources of financing. There is no assurance, however, that any additional financing or any revenue-generating license or collaboration will be available when needed or that we will be able to obtain financing or enter into a license or collaboration on terms acceptable to us, or at all. The condensed financial statements do not reflect any adjustments relating to the outcome of this uncertainty. The forecast of cash resources and planned operations involves risks and uncertainties, and the actual amount of expenses could vary materially as a result of a number of factors.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Our future funding requirements will depend on many factors, including, but not limited to, the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to conduct more studies or generate additional data beyond that which we currently expect would be required to support a Biologics License Application;
- the cost of manufacturing clinical and commercial supplies, as well as scale-up of our current and future product candidates;
- the potential increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- litigation expenses we incur to defend against any claims, including the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;

- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- the impact of inflation, as well as other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials, product launch-readiness activities and other research and development expenditures.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and 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 capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Cash Flows

The following table summarizes our primary sources and uses of cash for the periods presented:

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash used in operating activities	$ (117,270)	$ (120,185)
Net cash provided by investing activities	14,452	57,302
Net cash provided by financing activities	10,543	425
Net decrease in cash, cash equivalents and restricted cash	$ (92,275)	$ (62,458)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026, was $117.3 million and primarily consisted of a net loss of $120.0 million and a $9.6 million net change in operating assets and liabilities, partially offset by non-cash charges of $12.3 million. The non-cash charges primarily consisted of $10.3 million of stock-based compensation expense, $1.3 million of non-cash lease expense, $1.1 million of depreciation and amortization expense and $0.5 million of asset impairment, partially offset by $1.1 million of income related to the accretion of discounts on available-for-sale marketable securities. The net change in operating assets and liabilities was primarily due to a $4.2 million decrease in other accrued expenses and current liabilities, a $2.6 million decrease in accrued compensation, a $1.9 million decrease in accounts

payable, a $1.8 million decrease in operating lease liability, and a $0.2 million increase in prepaid expense and other current assets, partially offset by a $1.0 million decrease in other non-current assets.

Net cash used in operating activities for the nine months ended September 30, 2025, was $120.2 million and primarily consisted of a net loss of $123.5 million and a $2.8 million net change in operating assets and liabilities, partially offset by non-cash charges of $6.1 million. The non-cash charges primarily consisted of $7.4 million of stock-based compensation expense, $2.2 million of non-cash lease expense, $1.4 million of depreciation and amortization expense and $0.6 million of asset impairment, partially offset by $5.5 million of income related to the accretion of discounts on available-for-sale marketable securities. The change in net operating assets and liabilities was primarily due to a $2.5 million decrease in operating lease liability, a $1.6 million decrease in accounts payable, a $1.5 million increase in other non-current assets and a $0.2 million decrease in other accrued expenses and current liabilities, partially offset by a $2.1 million increase in accrued compensation and a $0.8 million decrease in prepaid expense and other current assets.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2026, was $14.5 million and primarily consisted of $209.5 million in proceeds from maturities of available-for-sale marketable securities, partially offset by $194.0 million of purchases of available-for-sale marketable securities, $0.6 million of capitalized internal-use software development costs, and $0.5 million of purchases of property and equipment.

Net cash provided by investing activities for the nine months ended September 30, 2025, was $57.3 million and primarily consisted of $306.5 million in proceeds from maturities of available-for-sale marketable securities and $0.1 million in proceeds from the sale of property and equipment, partially offset by $248.7 million of purchases of available-for-sale marketable securities and $0.6 million of capitalized internal-use-software development costs.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026, was $10.5 million and primarily consisted of $8.7 million in proceeds from issuance of common stock shares under the ATM Facility, net of sales agent's fees and issuance costs, and $2.6 million in proceeds from exercise of common stock options, partially offset by $0.4 million in taxes paid related to net share settlement upon vesting of restricted stock units, and $0.3 million in principal paid on finance lease liabilities.

Net cash provided by financing activities for the nine months ended September 30, 2025, was $0.4 million and primarily consisted of $1.7 million in proceeds from exercises of common stock options, partially offset by $0.7 million in principal paid on finance lease liabilities, $0.4 million in payments for offering costs related to the filing of the Prior Registration Statement, and $0.1 million in taxes paid related to net share settlement upon vesting of restricted stock units.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with CROs for clinical trials, with CMOs for clinical and commercial supply manufacturing and with other vendors for preclinical studies, supplies and other products and services for operating purposes. These agreements generally provide for termination at the request of either party generally with less than one-year notice and, therefore, we believe that our non-cancellable obligations under these agreements are not material.

We have milestone, royalty and other payments due to third parties under our existing license and collaboration agreements. Refer to Note 6, "License and Collaboration Agreements" to the condensed financial statements included in this Quarterly Report on Form 10-Q for additional details. We cannot estimate when such payments will be due and none of these events were probable to occur as of September 30, 2026. As of September 30, 2026, and December 31, 2025, we recognized a sublicensing fee of $3.8 million in our condensed balance sheets payable to Kite Therapeutics, Inc. by December 31, 2026 as discussed in Note 6 to the condensed financial statements included in this Quarterly Report on Form 10-Q.

As of September 30, 2026, we lease office and laboratory space in Emeryville, California under operating leases, or the Emeryville Lease. On February 27, 2026, we entered into a lease amendment to reduce total office and lab space and added new office space in the same building commencing on July 2, 2026. The term of the Emeryville Lease is through August 31, 2030.

As of September 30, 2026, our non-cancellable operating lease obligation was $9.9 million, of which $2.4 million is due within the next 12 months. As of September 30, 2026, our non-cancellable finance lease obligation was de minimis.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2, "Summary of Significant Accounting Policies", to the condensed financial statements included in this Quarterly Report on Form 10-Q.

Critical Accounting Estimates

Our significant accounting policies and critical accounting estimates are described in Note 2 to our audited financial statements for the year ended December 31, 2025 included in Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 26, 2026. There have been no material changes to our significant accounting policies or critical accounting estimates during the nine months ended September 30, 2026.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (a) are no longer an emerging growth company or (b) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our condensed financial statements may not be comparable to those of companies that comply with the new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a "smaller reporting company." If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, or the CEO, and Chief Financial Officer, or the CFO (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Based on their evaluation, the CEO and the CFO have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2026.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or would be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. In addition, the design of disclosure controls and procedures reflects the fact that there are resource constraints and the benefits of controls and procedures will be considered relative to their costs.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. In December 2024, a shareholder class action complaint was filed in the United States District Court for the Northern District of California, or the Court, against our Company, certain of our current and former officers and directors, and the underwriters of our IPO. Per a stipulated schedule, an amended complaint was filed on May 2, 2025, or the Amended Complaint. The Amended Complaint alleges that the registration statement on Form S-1 filed in connection with our IPO and the prospectus contained therein contained material misstatements or omissions in violation of federal securities laws. On March 23, 2026, the Court issued an order granting defendants' motion to dismiss on all claims, with leave to amend the complaint. On April 20, 2026, plaintiff filed another amended complaint alleging the same claims under the Securities Act of 1933, as amended. Defendants subsequently filed a motion to dismiss the entire second amended complaint. On October 20, 2026, the Court entered an order granting, in part, and denying, in part, defendants' motion to dismiss. The Court dismissed plaintiff's Section 12 claim with prejudice and without leave to amend. The Court, however, denied the motion with respect to plaintiff's Section 11 and Section 15 claims.

In addition, on May 14, 2025, a stockholder derivative complaint was filed in the United States District Court for the Northern District of California against certain of our current and former officers and directors which was captioned Perez v. Seidenberg, et al., Case No. 3:25-cv-04163-PCP, or the Perez Action. On May 22, 2025, another stockholder derivative complaint was filed alleging the same claims against the same individual defendants captioned McDaniel v. Seidenberg, et al., Case No. 3:25-cv-04393-PCP, or the McDaniel Action, and together with the Perez Action, the Derivative Actions. The complaints filed in the Derivative Actions allege claims related to the allegations raised in the Amended Complaint. On June 2, 2025, the Court entered a stipulation and order to stay the Perez Action pending the disposition of a motion to dismiss the Amended Complaint in the related securities class action. On June 25, 2025, the Court entered a stipulation and order to consolidate the Derivative Actions as In re Kyverna Therapeutics Derivative Litigation, Case No. 5:25-cv-04163-PCP. Finally, on July 22, 2025, the Court entered a stipulation and order staying the consolidated derivative action pending the disposition of the motion to dismiss the Amended Complaint in the related securities class action. With the resolution of the motion to dismiss in the securities class action, the parties will meet and confer about a consolidated response to the complaints.

We believe we have good and substantial defenses to the claims in the Amended Complaint and the Derivative Actions, but there is no guarantee that we will be successful in these efforts. We are unable to reasonably estimate at this time whether any loss ultimately will occur or to estimate the range of such loss; therefore, no amount of loss has been accrued by us in our financial statements as of and for the quarter ended September 30, 2026. 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. Before making an investment decision, you should carefully consider the risks described herein, as well as the risks and uncertainties discussed above under "Special Note Regarding Forward-Looking Statements". Our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 26, 2026, in Part I, Item 1A, Risk Factors, describes important risk factors that could cause our business, financial condition, results of operations and growth prospects to differ materially from those indicated or suggested by forward-looking statements made in this Quarterly Report on Form 10-Q or presented elsewhere by management from time to time. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business. Risk factors marked with an asterisk (*) below include a change from or an update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, filed with the SEC on March 26, 2026.

Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in

this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties:

- We have limited operating history, have incurred substantial net losses and anticipate that we will continue to incur net losses for the foreseeable future. We have no products approved for commercial sale, have never generated any revenue from product sales, and may never be profitable.
- 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 launch readiness and commercialization efforts.
- Our business depends entirely on the success of our product candidates and we cannot guarantee that any or all of our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Results of any patient who receives our product candidate in an investigator-initiated trial or on a named patient basis should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for regulatory approval.
- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business. In addition, if we lose key management or other scientific or clinical personnel, or if we fail to recruit additional highly skilled personnel, our business, results of operations, and financial condition could be adversely affected.
- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.
- If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, results of operations, and financial condition.
- We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, some of which already have approved therapies in our current indications.
- Use of our product candidates could be associated with side effects, adverse events, or safety risks, which could cause us to suspend or discontinue clinical trials, cause us to abandon a product candidate, delay or preclude approval, prevent market acceptance, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, results of operations and financial condition.
- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines, or terminate the relationship, our development programs could be delayed, or become more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for, or commercialize our product candidates.
- We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which could adversely affect our business, results of operations and financial condition.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or

identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.

- We may not be successful in obtaining or maintaining necessary rights to develop current and any future product candidates on acceptable terms.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- The FDA has investigated a serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies, such as miv-cel, and implemented boxed warnings and class labeling changes for certain currently marketed CAR T cell immunotherapies. In addition, the FDA noted that patients and clinical trial participants receiving treatment with these products should be monitored life-long for secondary malignancies. In April 2024, the FDA issued a public safety statement announcing its initiation of the class labeling changes described above. The FDA's investigation may impact the FDA's review of product candidates that we are developing, or that we may seek to develop in the future, which may, among other things, result in additional regulatory scrutiny of our product candidates, delay the timing for receiving any regulatory approvals, require us to include a boxed warning on any of our product candidates that receive regulatory approval or impose additional post-approval requirements on any of our product candidates that receive regulatory approval.
- Our principal stockholders and management own a significant percentage of our common stock and will be able to control matters subject to stockholder approval.
- Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, could adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials.

Risks Related to Our Business, Limited Operating History and Financial Position

We have limited operating history, have incurred substantial net losses and anticipate that we will continue to incur net losses for the foreseeable future. We have no products approved for commercial sale, have never generated any revenue from product sales and may never be profitable.

We are a late-stage clinical biopharmaceutical company with a limited operating history. We were formed in 2018 and we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights, and conducting research and development activities for our product candidates, including miv-cel. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success and viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing product candidates. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. Although we have completed a registrational Phase 2 clinical trial of miv-cel in SPS and submitted a BLA to the FDA, we have not yet obtained regulatory approval for, or commercialized, any product candidate. We have no products approved for commercial sale and we have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and we have incurred net losses since our inception through September 30, 2026. For the nine months ended September 30, 2026 and 2025, we reported a net loss of $120.0 million and $123.5 million, respectively. As of September 30, 2026, we had an accumulated deficit of $544.8 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development, and seek regulatory approvals for our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct further clinical trials for miv-cel and our other product candidates;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;

- procure the manufacturing of preclinical, clinical and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;
- protect, maintain, expand, enforce and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies, clinical trials, or regulatory approval for our product candidates, including as a result of macroeconomic conditions, geopolitical conflicts or other factors;
- consider international expansion; and
- incur additional costs associated with operating as a public company.

To become and remain profitable, we and any current or potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials; obtaining marketing approval for product candidates; manufacturing, marketing, and selling products if we obtain marketing approval; obtaining market acceptance for such products and satisfying any post-marketing requirements. We may never succeed in any or all of these activities 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 the price of our common stock, and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We also may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. 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 stockholders' equity and working capital.

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 launch readiness and 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 our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of, and seek regulatory approval for, miv-cel and any future product candidates.

In addition, if we obtain regulatory approval to market any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing and expanding and optimizing manufacturing and distribution channels. We expect our expenses to increase as we advance our SPS launch-readiness activities, including commercial site activation activities, payer engagement and healthcare professional education, as well as increasing manufacturing capacity to support a potential commercial launch of miv-cel. Other unanticipated costs may also arise.

Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations beyond our current expected operating cash runway.

Until such time as we can generate significant revenue from sales of our product candidates, if ever, 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. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or commercialization efforts.

Our business depends entirely on the success of our product candidates and we cannot guarantee that any or all of our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale. We have invested a significant portion of our efforts and financial resources in the development of our product candidates, and expect that we will continue to invest heavily in these product candidates, as well as in any future product candidates we may develop. Our business and our ability to generate revenue, which will not occur unless and until we obtain regulatory approval for miv-cel in SPS or another product candidate, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional preclinical and clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenue from product sales. We currently generate no revenue and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we will not be permitted to market or promote any of our product candidates until we receive regulatory approval from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, and we may never receive sufficient regulatory approval that will allow us to successfully commercialize any product candidates. We recently submitted our first biologics license application, or BLA, for SPS in the fourth quarter of 2026. However, there can be no assurance that the FDA will accept or approve the BLA or any other BLA that we submit in the future for other product candidates or indications. The FDA and other foreign regulatory agencies have substantial discretion in the approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. Even if we comply with all FDA requests, the FDA may ultimately reject our BLA. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations, and prospects.

We cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with its review of our investigational new drug applications, or INDs, or other submissions, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design. Such changes could delay approval or necessitate withdrawal of our INDs or other submissions.

If any of our product candidates is approved for marketing by applicable regulatory authorities, our ability to generate revenue from such product will depend on our ability to:

- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing;
- manufacture products through contract manufacturing organizations, or CMOs, in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;

- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our products through our own marketing and sales activities, and any other arrangements to promote these products that we may otherwise establish;
- effectively commercialize any of our products that receive regulatory approval;
- seek and obtain reimbursement and collections for any of our products that receive regulatory approval as part of the commercialization process;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect, and enforce patent and other intellectual property protection and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations and guidance specific to commercialization, including interactions with healthcare professionals and patient advocacy groups, and communication of healthcare economic information to payors and formularies;
- achieve market acceptance of our products by patients, the medical community, and third-party payors;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites; and
- ensure that our products will be used as directed and that additional unexpected safety risks will not arise.

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC, or Nasdaq, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, has made and will make some activities more difficult, time consuming, or costly, and has increased and will increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We have hired and plan to continue to hire additional accounting, financial reporting, internal controls and other finance personnel or consultants, which has increased and will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If 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 their application and practice, regulatory authorities may initiate legal proceedings against us, and our business, financial condition, results of operations and prospects may be significantly harmed.

We have previously identified material weaknesses in our internal control over financial reporting, which were subsequently remediated. If we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We previously identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

These material weaknesses related to (i) an insufficient number of qualified resources to ensure adequate oversight and accountability over the performance of controls, including retention of control evidence, (ii) ineffective identification and assessment of risks impacting internal control over financial reporting, and (iii) insufficient evaluation and determination as to whether the components of internal controls were present and functioning based upon evidence maintained for management review controls and activity level controls across substantially all financial statement areas.

These material weaknesses contributed to the following additional material weakness: we did not design and maintain effective (i) general controls over information systems that support the financial reporting process, (ii) controls over the completeness and accuracy of information used in the operation of control activities across substantially all financial statement areas, and (iii) management review controls at a sufficient level of precision to detect a material misstatement across substantially all financial statement areas that involve complex and judgmental areas of accounting and disclosure.

During the year ended December 31, 2025, our management, with the oversight of the audit committee of our board of directors, designed and implemented measures to remediate the control deficiencies contributing to the material weaknesses and completed testing of the design and operating effectiveness of all remediated controls. Through testing of our internal controls, our management determined that the controls related to the remediation actions were effectively designed and operated effectively for a sufficient period of time to enable us to conclude that the material weaknesses had been remediated as of December 31, 2025.

However, we may discover new weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we identify additional material weaknesses or deficiencies in internal controls in the future and we are unable to correct them in a timely manner, our ability to record, process, summarize, and report financial information accurately and within the time periods specified in the rules and forms of the SEC will be adversely affected. Any such failure could negatively affect the market price and trading liquidity of our common stock, lead to delisting, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

If, in the future, we identify material weaknesses in our internal control over financial reporting or fail to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our business, financial condition, and results of operations could suffer.

If our product candidates, if approved, do not achieve broad market acceptance, the revenue that we generate from their sales will be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability, and ease of administration of our product candidates;
- the prevalence and severity of side effects and adverse events associated with our product candidates, and how the safety and tolerability profile of our product candidates compares to those of existing therapies, or those under development;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory risk evaluation and mitigation strategy, or REMS, or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty and cost of administration of such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy, and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy and/or logistical ease of newer products;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

Covenants and other provisions in the Loan and Security Agreement with Oxford Finance may restrict our business and operations, and if we do not effectively manage our covenants, our financial condition and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the Loan and Security Agreement.

Pursuant to the Loan and Security Agreement, dated October 31, 2025, as amended effective June 30, 2026, or the Loan and Security Agreement, we granted to Oxford Finance LLC, or Oxford Finance, a security interest in substantially all of our assets, including our intellectual property. If an event of default occurs under the Loan and Security Agreement, Oxford Finance may foreclose on its security interest and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, Oxford Finance would have a prior right to substantially all of our assets to the exclusion of our general unsecured creditors. Only after satisfying the claims of Oxford Finance and any unsecured creditors would any amount be available for our equity holders. The pledge of these assets and other restrictions imposed in the Loan and Security Agreement may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged to secure the Loan and Security Agreement obligations, our ability to incur additional indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

In addition, if we are unable to comply with certain financial and operating restrictions in the Loan and Security Agreement, we may be limited in our business activities and access to credit or may default under the Loan and Security Agreement. Provisions in the Loan and Security Agreement require prior approval or impose restrictions on our ability to, among other things:

- Incur additional debt;
- Make certain investments and acquisitions;
- Guarantee the indebtedness of others;
- Create liens or encumbrances;
- Engage in new lines of business;
- Enter into transactions with affiliates;
- Pay cash dividends and make distributions;
- Redeem or repurchase certain capital shares;
- Sell, lease, or transfer certain parts of our business or property;
- Prepay other indebtedness; and
- Acquire new companies and merge or consolidate.

The Loan and Security Agreement also contains other customary covenants, including financial covenants requiring us to maintain certain liquidity levels. We may not be able to comply with these covenants in the future. Our failure to comply with these covenants may result in the declaration of an event of default, which, if not cured or waived, may result in, among other things, the acceleration of our repayment obligations under the Loan and Security Agreement. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us or at all. Our failure to repay our obligations under the Loan and Security Agreement would result in Oxford Finance foreclosing on all or a portion of our assets, which could force us to curtail or cease our operations.

Our business entails a significant risk of product liability and our inability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates and as our product candidates are used in named patient activities, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in the FDA, the European Medicines

Agency, or the EMA, or other investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop, and a decline in our stock price. We believe we may face greater risks with respect to our product candidates than many other biotechnology product candidates because our product candidates are being developed to address conditions for which many prior products and product technologies have been unsuccessful. In addition, the patient populations that our product candidates are seeking to target is often heavily immunosuppressed and may be more likely to experience serious adverse events with potential treatments and have higher morbidity rates generally than other patient populations. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business. In addition, if we lose key management or other scientific or clinical personnel, or if we fail to recruit additional highly skilled personnel, our business, results of operations and financial condition could be adversely affected.

As of September 30, 2026, we had 172 full-time employees. As our development and commercialization plans and strategies develop, we expect to continue to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in manufacturing, marketing and commercialization. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

In addition, our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical, and scientific personnel. We are highly dependent upon our Chief Executive Officer and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will, with or without notice, and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the greater San Francisco Bay Area. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among biotechnology businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. If we are not able to attract, integrate, retain, and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could adversely affect our business, results of operations and financial condition.

We are exposed to the risk of fraud or other misconduct by our employees, contractors or partners. Misconduct by these parties could include failures to comply with FDA regulations or comparable foreign regulations, provide accurate information to the FDA or comparable foreign authorities, comply with federal, state or foreign healthcare fraud and abuse laws and regulations, report financial information or data timely, completely or accurately, disclose unauthorized activities to us, or comply with comparable foreign requirements. It is not always possible to identify and deter 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 resulting from this misconduct 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign equivalents, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition, and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes, or services made, used, sold, or performed pursuant to the agreements and from claims arising from our or our potential sublicensees' exercise of rights under the agreement. With respect to our other vendor agreements, we indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Our ability to use our net operating loss, or NOL, carryforwards, and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had federal NOL carryforwards of $245.1 million and state NOL carryforwards of $333.8 million. Under the Internal Revenue Code of 1986, as amended, or the Code, our U.S. federal net operating losses will not expire and may be carried forward indefinitely but the deductibility of federal net operating losses is limited to no more than 80% of current year taxable income (with certain adjustments). In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have performed a Section 382 study as of December 31, 2025, and expect approximately $2.0 million of federal net operating losses, $12.1 million of federal research and development credits and $1.9 million of California net operating losses to expire unused due to Section 382 limitations. Furthermore, there may be additional ownership changes in the future, including as a result of subsequent changes in our stock ownership, some of which may be outside of our control. As a result, if we undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and JOBS Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act, or the IRA, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Additionally, new income, sales, use, or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act, or the OBBBA, was signed into law. The OBBBA includes significant provisions, such as the extension of many tax law provisions that were set to expire in 2025. The aggregate impact of the OBBBA remains uncertain, but could have a material impact on our business, cash flows, financial condition or results of operations. Further changes to the tax laws or changes to the administrative or judicial interpretations of such laws are possible and may apply with retroactive effect. It is also uncertain if and to what extent various states will conform to federal tax laws. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future tax expense.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire, an earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure, or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and contract research organizations, or CROs, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage, or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations, and prospects.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments

about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, could adversely affect our business, financial condition, results of operations, or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. Following the COVID-19 pandemic and in connection with geopolitical conflicts, global economic and business activities continue to face widespread uncertainties. A severe or prolonged economic downturn, or additional global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, the failures of Silicon Valley Bank, Signature Bank, and First Republic Bank in the first half of 2023 resulted in significant disruption in the financial services industry. If any of the banks which hold our cash deposits were to be placed into receivership, we may be unable to access our cash, cash equivalents and available-for-sale marketable securities, which would adversely affect our business. In addition, if any of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials are unable to access funds pursuant to such instruments, or lending arrangements with such a financial institution, such parties' ability to fulfill their obligations to us could be adversely affected.

****We or our directors or officers may be subject to securities litigation, which is expensive and could divert management attention.***

We may be the target of securities litigation in the future, including based on volatility in the market price of our stock and, as described more fully below, we are currently named as a defendant in a securities class action complaint. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. The market price of our common stock is volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. In addition, certain of our directors and officers are involved in ongoing securities or other lawsuits in the context of their roles with other public companies, and our directors or officers may in the future become involved in such litigation. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation, and divert our management's and board of directors' attention from other business concerns, which could seriously harm our business.

As noted above, in December 2024, a shareholder class action complaint was filed in the United States District Court for the Northern District of California, or the Court, against our company, certain of our current and former officers and directors, and the underwriters of our IPO. Per a stipulated schedule, an amended complaint was filed on May 2, 2025, or the Amended Complaint. The Amended Complaint alleges that the registration statement on Form S-1 filed in connection with our IPO and the prospectus contained therein contained material misstatements or omissions in violation of federal securities laws. On March 23, 2026, the Court issued an order granting defendants' motion to dismiss on all claims, with leave to amend the complaint. On April 20, 2026, plaintiff filed another amended complaint alleging the same claims under the Securities Act of 1933, as amended. Defendants subsequently filed a motion to dismiss the entire second amended complaint. On April 20, 2026, plaintiff filed another amended complaint alleging the same claims under the Securities Act of 1933, as

amended. Defendants subsequently filed a motion to dismiss the entire second amended complaint. On October 20, 2026, the Court entered an order granting, in part, and denying, in part, defendants' motion to dismiss. The Court dismissed plaintiff's Section 12 claim with prejudice and without leave to amend. The Court, however, denied the motion with respect to plaintiff's Section 11 and Section 15 claims.

In addition, on May 14, 2025, a stockholder derivative complaint was filed in the United States District Court for the Northern District of California against certain of our current and former officers and directors which was captioned *Perez v. Seidenberg, et al.*, Case No. 3:25-cv-04163- PCP, or the Perez Action. On May 22, 2025, another stockholder derivative complaint was filed alleging the same claims against the same individual defendants captioned *McDaniel v. Seidenberg, et al.*, Case No. 3:25-cv-04393-PCP, or the McDaniel Action, and together with the Perez Action, the Derivative Actions. The complaints filed in the Derivative Actions allege claims related to the allegations raised in the Amended Complaint. On June 2, 2025, the Court entered a stipulation and order to stay the Perez Action pending the disposition of a motion to dismiss the Amended Complaint in the related securities class action. On June 25, 2025, the Court entered a stipulation and order to consolidate the Derivative Actions as *In re Kyverna Therapeutics Derivative Litigation*, Case No. 5:25-cv-04163-PCP. On July 22, 2025, the Court entered a stipulation and order staying the consolidated derivative action pending the disposition of the motion to dismiss the Amended Complaint in the related securities class action. With the resolution of the motion to dismiss in the securities class action, the parties will meet and confer about a consolidated response to the complaints.

We believe we have good and substantial defenses to the claims in the Amended Complaint and the Derivative Actions, but there is no guarantee that we will be successful in these efforts. We are unable to reasonably estimate at this time whether any loss ultimately will occur or to estimate the range of such loss; therefore, no amount of loss has been accrued by us in our financial statements for the quarter ended September 30, 2026. 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.

Risks Related to Research, Development and Commercialization

We have not yet obtained regulatory approvals for any product candidate, and we may be unable to do so for any product candidates we have developed or may develop.

We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. While we completed our BLA submission in the fourth quarter of 2026, we do not have experience as a company supporting a marketing application through FDA review. Although our key employees have significant experience in leading clinical development programs, our experience conducting clinical trials with our product candidates is still somewhat limited. Developing cell therapies, in particular autologous cell therapies, is a complex and resource-intensive process requiring a team of scientists, clinicians, and technical and regulatory experts. We may not be able to file INDs for any of our other product candidates on the timelines we expect, if at all. For example, we cannot be certain that the IND-enabling studies for our product candidates will be completed in a timely manner or be successful or that the manufacturing process will be validated in a timely manner. Even if we submit an IND for a product candidate, the FDA may not clear the IND and allow us to begin clinical trials in a timely manner or at all. The timing of submissions of INDs for our product candidates will be dependent on further preclinical and manufacturing success. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect.

We believe that, through our interactions with the FDA under our Regenerative Medicine Advanced Therapy, or RMAT, designation, our Phase 2 clinical trial in SPS, which is a pivotal trial, will be sufficient for use as a registration-enabling study, and in the fourth quarter of 2026, we completed the BLA for SPS and are pending acceptance of our submission from the FDA. However, the FDA may conclude that the trial is not sufficient to support approval, or comparable foreign authorities may reach a similar conclusion. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we have contemplated or currently contemplate, if we are unable to successfully complete clinical trials of our other product candidates or other testing, if the results of our trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing requirements; or
- be required to have the product removed from the market after obtaining marketing approval.

Results of any patient who receives our product candidate in an investigator-initiated trial or on a named patient basis should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for regulatory approval.

We supply our investigational product candidate, miv-cel, in investigator-initiated trials and on a named patient basis to patients who have exhausted other treatment options and for whom there is a strong scientific rationale to support the use of an unapproved product candidate. The investigator-initiated trials we supply to are located in the United States and Germany, and the independent investigators of such trials file INDs for the treatment of multiple or individual patients with miv-cel. We also supplied miv-cel for use in single named patients in Germany, through a European distributor. In Germany, these single-patient efforts are termed "Individueller Heilversuch," or single-patient treatment healing attempts, and occur outside of a controlled clinical trial setting and are not part of a codified German regulatory path. "Individueller Heilversuch" is a form of compassionate use treatment for an individual patient in Germany, where a procedure or treatment that has not received marketing authorization may be used for the expected benefit of a patient who has exhausted all available treatment options, under the discretion of the treating physician. The provision of miv-cel on a named patient basis and in investigator-initiated trials are not a substitute for, or intended to replace, our clinical trials. The primary goal of these compassionate use treatments is not to assess the effectiveness, but rather to provide a treatment option to patients who have exhausted all other options. We evaluate whether to grant such access or similar access in other foreign countries to miv-cel outside of our sponsored clinical trials on a case-by-case basis.

We do not control the design, administration or timing of investigator-initiated trials. Similarly, named patient treatments are carried out by independent physicians in a manner that the physician determines in his or her discretion to be appropriate, which may be inconsistent from patient to patient and may not be conducted in strict compliance with good clinical practices, or GCPs, which can lead to a treatment effect that may differ from that in our controlled clinical trials. In addition, we rely on each investigator and physician to ensure their own compliance with clinical and regulatory requirements in using our product candidate for investigator-initiated trials and named patient activities, and we could be subject to liability if they are out of compliance. Individual patient results from named patient settings, including, but not limited to, data, experiences, images, or videos, are observational, patient-specific and reported by the patients' respective physicians. Because of our lack of control over the settings in which these patients are given miv-cel, there can be no assurances that any positive results from such named patient activities are attributable to miv-cel, or that administration of miv-cel to other patients will have similar positive results. Patient data from these trials and named patient activities are not designed to be aggregated or reported as results and may be highly variable.

Before we can seek regulatory approval for any of our product candidates, we must demonstrate in well-controlled clinical trials statistically significant evidence that the product candidate is both safe and effective for the indication for which we are seeking approval. The results of investigator-initiated trials and named patient activities may not be used to establish safety or efficacy for purposes of obtaining regulatory approval.

In contrast, such trials and named patient activities could potentially identify significant concerns with respect to our product candidates that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities. To the extent the results of investigator-initiated trials or named patient activities are inconsistent with, or different from, the results of our sponsored trials or raise concerns regarding our product candidates, the FDA or a foreign regulatory authority may question the well-controlled results of the company-sponsored trial, or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of our product candidates. In addition, the risk for serious adverse events in the patient population of such trials and named patient activities is high. Adverse events, if attributed to our product candidate, could have a negative impact on the safety profile of our product candidates, and in turn cause significant delays or an inability to obtain regulatory approval or successfully commercialize our product candidates.

Furthermore, there is no guarantee that we will be able to continue to receive or publicize observational data through investigator-initiated trials or named patient activities using our product candidates. Our supply capabilities may limit the number of patients who are able to enroll in these trials or the number of named patients that can be treated, and we may in the future need, without advance notice, to restructure or pause such supply in order to enroll sufficient numbers of patients in

our sponsored clinical trials, which could prompt adverse publicity or other disruptions. In addition, there is no clear regulatory framework under which we may supply our unapproved investigational product candidate in named patient settings, particularly for multiple named patients, outside of a clinical trial or a compassionate use program that is registered with applicable regulatory authorities. Our single-patient healing attempts are not part of a clinical trial or a compassionate use program that is registered with German regulatory authorities. As a result, if such supply of, or publication or other use of the observational data from named patient activities, is found to contravene regulatory requirements, we could potentially be subjected to liability, fines, or other consequences, which could be further exacerbated if such patients experience adverse safety events. Furthermore, if we supply our unapproved investigational product candidate to a named patient who would have qualified for enrollment in our company-sponsored clinical trials in Germany, we may be subject to additional penalties.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

Most of our product candidates are either in preclinical or clinical development and their risk of failure is high. Some of the product candidates and technologies we are developing are novel and unproven, which makes it difficult to accurately predict the challenges we may face with respect to our product candidates as they proceed through development. We believe we may face greater risks with respect to our product candidates than many other biotechnology product candidates because our product candidates are being developed to address conditions for which many prior products and product technologies have been unsuccessful. In addition, the patient populations that our product candidates are seeking to target is often heavily immunosuppressed and may be more likely to experience serious adverse events with potential treatments and have higher morbidity rates generally than other patient populations. It is also impossible to predict whether our clinical trials will continue and when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a similar foreign regulatory authority.

Even after we make our submission, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional trials or amend our protocols or impose stricter conditions on the commencement of clinical trials. In addition, the FDA or other regulatory authority may require information beyond what we plan to provide in or expect to be required for a marketing application, including additional chemistry, manufacturing and control information, or additional preclinical or clinical data to support approval. These requirements may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the clinical trial process. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We expect to continue to rely in part on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory agencies, Institutional Review Boards, or IRBs, or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or require that we modify or amend our clinical trial protocols;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the cost of clinical trials may be greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the submission of a BLA or new drug application, or NDA;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs.

We may in the future experience participant withdrawals or discontinuations from our trials. Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

We could also encounter delays if a clinical trial is suspended, put on clinical hold, or terminated by us, the IRBs of the institutions in which such trials are being conducted, the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our CROs to perform in accordance with GCP requirements, or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations, or administrative actions, or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA, or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also conduct preclinical and clinical research in collaboration with academic, pharmaceutical and biotechnology entities in which we combine our development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations and the need to obtain agreement from multiple parties, and may increase our future costs and expenses.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, results of operations and financial condition.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in a trial until its conclusion. We may not be able to initiate, continue, or complete clinical trials that may be required by the FDA or comparable foreign regulatory authorities to obtain regulatory approval for any of our product candidates if we are unable to locate, enroll and retain a sufficient number of eligible patients to participate in these clinical trials. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies; and
- other factors outside of our control, such as the effects of global economic conditions and volatility in the credit and financial markets, tariffs imposed by the U.S. and other countries, inflationary pressures, trade wars, the conflict between Russia and Ukraine, war in Iran and other conflicts and instability in the Middle East and other geopolitical conditions.

We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Other pharmaceutical companies with more resources and greater experience in drug development and commercialization are targeting similar treatments, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is also limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites, and may delay or make it more difficult to fully enroll our clinical trials. We also rely on CROs and clinical trial sites to enroll subjects in our clinical trials and, while we have agreements governing their services, we will have limited influence over their actual performance.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development, and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may

differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

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

We may expend our limited resources on particular projects or initiatives or to pursue a particular product candidate in specific indications and fail to capitalize on projects, initiatives, 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 our development efforts on certain projects or initiatives or selected product candidates in certain selected indications. As a result, we may forgo or delay pursuit of other projects, initiatives or opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable product candidates. 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.

We may seek to establish commercial collaborations for our product candidates, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates. In December 2021, we entered into a License and Collaboration Agreement, or the Intellia Agreement, with Intellia Therapeutics, Inc., a clinical-stage biotechnology company focused on developing novel therapeutics leveraging CRISPR-based technologies, or Intellia, to research and develop an allogeneic cell therapy product, or the CRISPR Product Candidate. Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, 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.

We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, some of which already have approved therapies in our current indications.

The development and commercialization of therapies is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do and we may not be able to

successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, hospitals and clinics, academic research institutions and governmental agencies, public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of their products as compared to our product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or any future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data emerge.

Our current product candidates, initially under development for treatment of various immunological indications, if approved, would face competition from existing approved immunological treatments, some of which have achieved commercial success, and potential new therapies that may become available in the future. For example, we are currently developing miv-cel for the treatment of B-cell-driven autoimmune diseases. Life sciences companies have been focused on similar therapeutics for B-cell-driven autoimmune diseases, including autologous and allogeneic CAR T-cell candidates as well as emerging in-vivo platforms and engineered immunotherapy approaches such as T-cell engagers. If approved, miv-cel would compete with currently approved therapeutics, including Rituxan and Ocrevus, both from Roche Holding AG, and generic immunosuppressive or biosimilar drugs, such as mycophenolate mofetil, glucocorticoids, azathioprine, cyclophosphamide, and IVIG, among others we anticipate will receive approvals in the near term. There are also a number of product candidates in clinical development by third parties that are intended to treat some B-cell-driven autoimmune diseases, such as obinutuzumab (targeting CD20 on B cells), which is also from Genentech/Roche Holding AG.

To compete successfully, we need to disrupt these currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provides a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standard of care. Furthermore, even if our product candidates demonstrate meaningful improvements in these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our programs may be delayed and our expenses may increase and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our programs may be delayed or never achieved and, as a result, our stock price may decline.

Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

Use of our product candidates could be associated with side effects, adverse events or safety risks, which could cause us to suspend or discontinue clinical trials, cause us to abandon a product candidate, delay or preclude approval, prevent market acceptance, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, results of operations and financial condition.

Before obtaining regulatory approvals for the commercial sale of any of our products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our current product candidates, including our lead product candidates, and any future product candidates are safe, pure and potent, or safe and effective, for use in such product candidate's target indication. Clinical testing is expensive, can take many years to complete, and has an inherently uncertain outcome. In addition, some of the product candidates and technologies we are developing are novel and unproven, which makes it impossible to predict whether our clinical trials will continue. The patient populations that our product candidates are seeking to target is also often heavily immunosuppressed and may be more likely to experience serious adverse events with potential treatments and have higher morbidity rates generally than other patient populations. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to generate desired safety and efficacy data despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of our current product candidates or any of our future product candidates or ultimately their approval. We do not expect to be able to use the results from any investigator-initiated trials or named patient activities conducted with our product candidates in any regulatory submission for marketing approval.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. In addition, negative results from investigator-initiated trials as well as named patient activities involving our product candidates could cause similar issues. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, results of operations, and financial condition significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies, clinical trials, investigator-initiated trials or named patient activities, 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, results of operations, and financial condition significantly.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation, or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, in any investigator-initiated trials conducted with our product candidates, or in our named patient activities, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable foreign regulatory authorities or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics

developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, results of operations and financial condition.

Our product candidates are CAR T cell therapies. CAR T cell therapies can be associated with unique and potentially severe safety risks, including cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), immune effector cell-associated hemophagocytic lymphohistioctytosis-like syndrome (IEC-HS), prolonged cytopenias, infections, and other immune-mediated or delayed adverse events. The identification, grading, management, and timely reporting of these adverse events require specialized training and experience that differ significantly from those required for traditional therapies. Inadequate or delayed identification and reporting of safety events could increase risks to patients, lead to incomplete or inconsistent safety data, or result in inaccurate characterization of the safety profile of our product candidates.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. Such delayed side effects might be observed during the long-term follow-up FDA has insisted upon for certain gene therapy products. For example, in 2024, the FDA initiated class safety labeling changes for BCMA- or CD19-directed genetically modified autologous CAR T cell immunotherapies after it concluded that changes to the boxed warning were warranted to highlight the serious risk of T cell malignancies. In addition to labeling changes, if we were to identify delayed side effects with any of our product candidates, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to healthcare practitioners, patient education, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace, if approved;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

Changes in product candidate manufacturing, formulation or analytical methods may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and future commercialization, it is common that various aspects of the development program, such as manufacturing methods, formulation, or analytical methods, are altered throughout the development process in an effort to optimize processes 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 altered materials or utilizing different analytical methods. Such changes also may require additional testing, or notification to, or authorization by, the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates

and/or jeopardize our ability to commence product sales and generate revenue. If we or our CMOs are not able to successfully manufacture our product candidates in sufficient quality and quantity, clinical development and timelines for our product candidates and subsequent approval could be adversely impacted.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

We plan to globally develop our product candidates. In addition, our enrollment timelines for our product candidates depend on initiating clinical trial sites outside of the United States. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- differing standards and privacy requirements for the conduct of clinical trials;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- challenges with obtaining any local supply of drugs or agents used with our product candidates, which are required by certain local clinical trial sites before conducting any study; and
- business interruptions resulting from health epidemics or pandemics, or natural or man-made disasters, including earthquakes, tsunamis, fires or other medical epidemics, or geo-political actions, including war and terrorism.

Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, if approved, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policies that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. The U.S. has continued to impose tariffs on certain imports to the U.S., which has led and could continue to lead to corresponding punitive or retaliatory actions by the countries with which the U.S. trades. Historically, tariffs have led to increased trade and political tensions, between the U.S. and other countries in the international community. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

These and other risks associated with our global development and collaboration with other pharmaceutical and biotechnology companies, may materially adversely affect our ability to attain or maintain profitable operations.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign authority approval process, and we currently, and will need to continue to, contract with manufacturers who can meet our and all applicable FDA or comparable foreign authority requirements on an ongoing basis.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign authority approval process, and any contractors with which we contract for manufacturing must meet all applicable FDA or comparable foreign authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or comparable foreign authority, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in accordance with requirements from the FDA or comparable foreign authority, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production or recalls of the product candidates or marketed biologics, operating restriction and criminal prosecutions, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality and complying with applicable regulatory requirements. An inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We rely on third party CMOs to manufacture and supply cell therapy products for our research and development purposes and for our clinical trials. Under our July 2023 Development and Manufacturing Services Agreement, or the Prior Elevate Agreement, with ElevateBio BaseCamp, Inc., or Elevate, we engaged Elevate in November 2024 to provide us with cell manufacturing, release and testing services for our miv-cel product candidate. In July 2026, we entered into a Clinical and Commercial Supply Agreement, or the Elevate CCSA, which replaced the Prior Elevate Agreement. Under the Elevate CCSA, Elevate agreed to provide us with development and manufacturing services for the clinical and commercial supply of miv-cel.

Under our Master Services Agreement with Minaris Advanced Therapies Inc., or MAT, dated March 2022, or the MAT Agreement, MAT provides us with cell manufacturing, release and testing services for our miv-cel product candidate. Pursuant to our License and Supply Agreement with Oxford Biomedica (UK) Limited, or Oxford, dated September 2023, or the Oxford Agreement, we engaged Oxford to undertake lentiviral vector process development services, with the intention for Oxford to ultimately manufacture and supply to us lentiviral vectors for research and development purposes and for use in connection with our clinical trials. Although we believe we currently have sufficient clinical-grade vector in inventory to move forward with our anticipated clinical trials, there is no guarantee that sufficient clinical-grade vector will be available in the quantities we require in the future or on terms that are acceptable to us.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;

- international or multi-national activities that are related to business activities outside of our scope, but may have an impact on a CMO's ability to conduct business in a manner consistent with governmental or our regulatory and ethical standards; and
- our ability to synchronize operations and standards to ensure that all aspects of manufacturing are consistent without deviations across facilities.

Should we continue to use CMOs, we may not succeed in maintaining our relationships with our current CMOs or establishing relationships with additional or alternative CMOs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under current Good Manufacturing Practice, or cGMP, regulations and that are both capable of manufacturing for us and willing to do so. If our CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate, or not renew these agreements. If we were to need to find alternative manufacturing facilities, it would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Moreover, if we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes, including in connection with preparing for a potential commercial launch of miv-cel in SPS and any actual commercialization thereafter, or our relationships with MAT, Elevate, Oxford, or other manufacturers, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms would have a material adverse effect on our business, financial condition, and results of operations.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Risks Related to Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which could adversely affect our business, results of operations and financial condition.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. For example, we have patent license agreements, or the NIH Agreements, with the National Institutes of Health, or the NIH, pursuant to which we obtained exclusive, worldwide licenses to certain patents to use an anti-CD19 CAR, including the CAR we used to create our lead product candidate, miv-cel, in autologous, allogeneic and other CAR T-cell products for the treatment of patients with autoimmune diseases. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- the priority of invention of patented technology;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and future commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of and rights to use inventions and know-how resulting from the joint or individual creation or use of intellectual property by our licensors and us and our partners.

In addition, certain of our current and future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We generally also are subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described in this "Risk Factors" section. If we or our licensors fail to adequately protect this intellectual property, our business, results of operations and financial condition could be adversely affected.

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

We rely upon a combination of in-licensed patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. For example, pursuant to the NIH Agreements, we obtained exclusive, worldwide licenses to certain patents to use an anti-CD19 CAR, including the CAR we used to create our lead product candidate, miv-cel, in autologous, allogeneic, and other CAR T-cell products for the treatment of patients with autoimmune diseases.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. We cannot assure you that our existing patents and any future issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our technologies or product candidates.

We are dependent on our outside counsel or our licensors to take necessary action to comply with patent protection requirements with respect to our owned or in-licensed intellectual property. The United States Patent and Trademark Office, or the USPTO, and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. Non-compliant events could result in abandonment or lapse of a patent or patent application. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the

relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our or our collaborators' or licensors' pending patent applications directed to composition of matter of our product candidates will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of our or our licensors' issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued that protect our technologies or product candidates, effectively prevent others from commercializing our technologies or product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own or our licensors' patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our or our licensors' patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our or our licensors' pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our or our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review, or PGR, proceedings, oppositions, derivations, reexaminations, interferences, inter partes review, or IPR, proceedings or other similar proceedings, in the United States or elsewhere. Certain submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our

inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

In addition, 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. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that our issued patents or patents that issue in the future will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future licensors will be successful in protecting our product candidates by obtaining and defending patents. We have pending and issued U.S. and foreign patents and patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any issued patent will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications will result in issued patents with claims that cover each of our product candidates or uses thereof in the United States or in other foreign countries.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may rely on more than one patent to provide multiple layers of patent protection for our product candidates. If the latest-expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the product candidate may be adversely affected. For example, if the latest-expiring patent is invalidated, the overall patent term for our product candidate could be adversely affected.

Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our product candidates. Further, with respect to particular compositions of interest known to the public, third parties may be able to obtain patents on improvements or other inventions relating to such compositions if they were to discover the same patentable inventions relating to such compositions after us but manage to file a patent application before

we do. In addition, we may enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, consultants, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, our patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic or biosimilar versions of any approved products and in so doing, claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or may find that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Moreover, some of our patents may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing 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 under our patent licenses with third parties, we could lose license rights that are important to our business, which could adversely affect our business, results of operations and financial condition.

We are a party to license agreements pursuant to which we in-license patent and patent applications, know-how, trade secrets and data rights for our product candidates. These include, for example, the NIH Agreements, pursuant to which we obtained exclusive, worldwide licenses to certain patents to use an anti-CD19 CAR in our autologous, allogeneic and other CAR T-cell products for the treatment of patients with autoimmune disease, and the Intellia Agreement, which provides for the research and development of the CRISPR Product Candidate. These existing licenses impose on us various diligence, milestone payment, royalty, insurance and other obligations. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

We may also enter into license agreements with third parties under which we are a sub-licensee. If our sub-licensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sub-license. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, such activities by these licensors may not have been or may not be conducted in compliance with applicable laws and regulations or may not result in valid and enforceable patents and other intellectual property rights. Our licensors may not successfully prosecute the patent applications that are licensed to us in a manner consistent with the best interests of our business. We may need the cooperation of our licensors in order to enforce any licensed patents against third parties, and such cooperation may not be provided to us. In addition, we have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

We cannot prevent other companies from licensing some of the same intellectual property that we have licensed or from otherwise duplicating our business model and operations.

Since parties we have licenses with are developing therapies using similar technologies, they may make their methods and data available to third parties, who may want to enter into our line of business and compete against us. Although we currently exclusively license certain intellectual property for each of our product candidates, there can be no assurance we will not need to license other intellectual property on a non-exclusive basis in the future or that our exclusively licensed intellectual property could be used to prevent third parties from duplicating our business plan or from otherwise directly competing against us. Further, no assurance can be given that our existing exclusive rights are or will be sufficient to prevent others from competing with us and developing substantially similar products.

We may not be successful in obtaining or maintaining necessary rights to develop current and any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and expenses and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions and governmental authorities to accelerate our research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, including our competitors. If such intellectual property is solely owned by the institution, we may have to abandon development of such program, and our business, results of operations and financial condition could be adversely affected. If such intellectual property is jointly owned by us and the institution, our loss of exclusivity may permit others to market competing products and technology.

The licensing and acquisition of third-party intellectual property rights is a highly competitive area, and companies, which may be more established or have greater resources than we do, also may be pursuing strategies to license or acquire third-party intellectual property rights that we consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Our product candidates licensed from various third parties may be subject to retained rights.

Our licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions. In particular, under the NIH Agreements, the NIH reserves, on behalf of the United States federal government and certain third parties, an irrevocable, nonexclusive, worldwide, royalty-free license to practice all of the inventions licensed under such agreements, and the NIH also reserves the right to grant third parties research licenses on reasonable terms. We are also required to manufacture licensed products substantially in the United States, absent an advance waiver, to the extent the licensed products are used or sold in the United States. Under the Intellia Agreement, Intellia is granted an irrevocable, nonexclusive, worldwide, royalty-free license to fully exploit certain Intellia-developed products that are not directed to CD19 or other B-cell antigens and which are not intended for treatment or prevention of autoimmune or inflammatory diseases or conditions and not for humoral rejection for solid organ transplantation.

In addition, we may at times choose to collaborate with academic institutions to accelerate our research or development. If the co-developed intellectual property is subject to the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act, the United States federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates. We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, some of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of, and patents issued to, third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our technologies or product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our technologies and product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. We are aware of third-party U.S. and European patents related to CAR T cells for use in treating autoimmune diseases, which may be relevant to our product candidates. If these patent rights were enforced against us, we believe that we have defenses against any such action, including that these patents are not valid. There could be additional issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Third-party patents can be challenged in administrative proceedings, such as *inter partes* review, *ex parte* re-exam or post-grant review proceedings at the USPTO, or patent opposition proceedings at the European Patent Office, but the outcome of such proceedings is highly uncertain. An adverse determination in any such proceeding may result in our inability

to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. Even if we ultimately prevail in any such claims or proceedings, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the claims or proceedings. In addition, competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates by new patents.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or delay commercialization of our products in the corresponding jurisdiction until the patents expire.

We cannot provide any assurances that no valid third-party patents and other intellectual property rights can be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof. If we are sued for infringing intellectual property rights of third parties, such litigation could result 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. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or one of our licensing partners may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Our or our licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or our licensors' patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. 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 patent infringement proceeding, there is a risk that a court will decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the

court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or our licensors' patent claims do not cover the invention, or decide that the other party's use of our or our licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). In addition, the U.S. Supreme Court has changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria, which also could make it more difficult to obtain or defend patents. An adverse outcome in a litigation or proceeding involving our or our licensors' patents could limit our ability to assert our or our licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during 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 adversely affect the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third party can request that the USPTO review the patent claims such as in an inter partes review, ex parte re-exam or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings at the European Patent Office or similar proceedings in other foreign patent offices, where either our owned or in-licensed foreign patents are challenged.

We may become subject to claims challenging the inventorship or ownership of our or our licensors' patents and other intellectual property or claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or our licensors' patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors or the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent. Furthermore, ownership disputes may arise from alleged contributions of third parties involved in developing our product candidates, or their methods of use or manufacture, and may result in joint ownership of our inventions in the absence of agreements with such third parties assigning ownership rights to us. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome

could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, and we may in the future be subject to claims that our former employees, consultants, or other third parties have an interest in our patents or other intellectual property as an inventor, co-inventor, or owner of trade secrets. Although it is our policy to require our employees and consultants who may be involved in the conception or development of intellectual property to execute agreements assigning that intellectual property to us, we may be unsuccessful in executing such an agreement with each party who conceives or develops intellectual property that we regard as our own or such party may breach the assignment agreement, or we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

Patent terms may be inadequate to protect our competitive position with respect to products or product candidates for an adequate amount of time. If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

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 or international patent application 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 products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one or more of our or our licensors' issued U.S. patents or issued U.S. patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under a Supplemental Protection Certificate. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which significantly impacts European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unified Patent Court, or UPC. As the UPC is a relatively new court system, there is little precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries that are signatories to the UPC. We cannot predict with certainty the long-term effects of the unitary patent system.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will

not be disclosed or that competitors will not otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared merely descriptive, generic or determined to be infringing on other marks. The use of our registered and unregistered marks is also limited by certain agreements with third parties. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, the USPTO and comparable agencies in many foreign jurisdictions provide third parties an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. For example, cancellation proceedings may be filed with the USPTO against our trademarks, once registered, which may not survive such proceedings. In foreign jurisdictions, opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names.

If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. In many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names, social media handles or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. 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 have a different scope and strength than those in the United States. Moreover, obtaining such protection in a timely manner, or at all, may be affected by factors or events beyond our control, such as a prolonged economic downturn, or global financial or political crises. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patents or patent applications in foreign jurisdictions could result in

substantial cost of defending our patent rights, put our patent applications at risk of not issuing and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. In addition, certain countries outside of the United States 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. In addition, many countries limit the enforceability of patents against government authorities or government contractors. This could limit our potential revenue opportunities. 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.

Risks Related to Government Regulation

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could adversely affect our business, results of operations, and financial condition.

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 activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our future commercialization efforts, research and development efforts and business operations, and/or environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not be the case and we may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state, federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes or our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. Although we have environmental liability insurance for our California facility as required by the related lease agreement, we do not currently carry specific biological waste or hazardous waste insurance coverage, and our workers' compensation, property and casualty and general liability insurance policies do not include coverage for criminal damages and fines arising from biological or hazardous waste exposure or contamination.

We have conducted, are currently conducting, and may in the future conduct clinical trials for our product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted, are currently conducting, and may in the future conduct one or more clinical trials of our current or future product candidates outside of the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. Many foreign regulatory authorities have similar approval

requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we would need to conduct additional trials, which could be costly and time-consuming.

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

We plan to seek regulatory approval of our current or future product candidates outside of the United States and are currently conducting certain clinical trials internationally, including in Europe, Brazil and Saudi Arabia. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of any of our product candidates in certain countries. Regulatory and marketing approval in one country does not ensure regulatory and marketing approval in another, but a failure or delay in obtaining regulatory and marketing approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

****The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

Any of our product candidates and any future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies, clinical trials, and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain, and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. 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. We have not obtained regulatory approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of our product candidates through an NDA or BLA from the FDA. The FDA and other regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA or other regulatory authorities that any of our product candidates are safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or other regulatory authorities for approval;
- the FDA or other regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the benefits of any of our product candidates outweigh their safety risks;

- the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials, or may not accept data generated at our clinical trial sites;
- the data collected from preclinical studies and clinical trials of any of our product candidates may not be sufficient to support the submission of an IND or other application for regulatory approval;
- the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- the FDA may require development of a REMS and other regulatory authorities may require a risk management plan, or RMP, as a condition of approval for new products, among other additional requirements;
- the FDA or other regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA or other regulatory authorities may change their approval policies or adopt new regulations; and
- the FDA or other regulatory authorities may require simultaneous approval for both adults and for children and adolescents, which may delay approval, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory authorities may require that we conduct additional clinical, preclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA or other regulatory authorities for obtaining approval. If any of these outcomes occur, we may be forced to abandon one or more of our applications for approval, which might significantly harm our business and prospects.

In addition, the FDA or other regulatory authorities may approve a product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements, such as the implementation of a REMS or comparable foreign risk management approaches. The FDA or other regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Further, the FDA and its foreign counterparts may respond to any BLA or NDA that we may submit, including our BLA submission for miv-cel in SPS in the fourth quarter of 2026, by defining requirements that we do not anticipate. Such responses could delay clinical development of any of our product candidates or any future product candidates.

On November 28, 2023, the FDA issued a statement that it was investigating a serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous chimeric antigen receptor, or CAR, T cell immunotherapies . While the FDA noted that it believed that the overall benefits of these products continue to outweigh their potential risks for their approved uses, the FDA stated that it was investigating the identified risk of T-cell malignancy with serious outcomes, including hospitalization and death, and was evaluating the need for regulatory action. In January 2024, the FDA notified the manufacturers of the six FDA-approved BCMA-directed and CD19-directed CAR genetically modified autologous T-cell therapies that their products' safety information must be updated to include a boxed warning that T-cell malignancies have occurred following treatment with BCMA-directed and CD19-directed genetically modified autologous T-cell immunotherapies. In April 2024, the FDA issued a public safety statement announcing its initiation of the class labeling changes and noting that patients and clinical trial participants receiving treatment with these products should be monitored life-long for secondary malignancies. Because all currently approved CAR T-cell immunotherapies are in oncology indications, there can be no assurance that the FDA will reach the same risk-benefit analysis in other indications, such as autoimmune diseases. Given that the autoimmune diseases we are seeking to treat are different indications from the approved oncology indications, the FDA and other regulatory authorities may apply a different benefit-risk assessment threshold such that even if our product candidate demonstrated a similar safety profile as current CAR T-cell therapies, the FDA could ultimately determine that the harmful side effects outweigh the benefits and require us to cease clinical trials or deny approval of our product candidates. The FDA's investigation may impact the FDA's review of product candidates that we are

developing, or that we may seek to develop in the future, which may, among other things, result in additional regulatory scrutiny of our product candidates, delay the timing for receiving any regulatory approvals, require us to include a boxed warning on any of our product candidates that receive regulatory approval or impose additional post-approval requirements on any of our product candidates that receive regulatory approval.

Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we commercialize any product candidates, alone or with our partners, such product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

****Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.***

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be certain that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will continue to be available for any product that we may develop that receives coverage and adequate reimbursement from one or more third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Accordingly, coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. These groups have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and

- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

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. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several U.S. presidential executive orders, U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reform government program reimbursement methodologies for pharmaceutical products, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In addition, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations, the prices of which will be effective starting January 1, 2027. On January 27, 2026, HHS announced its selection of 15 additional drugs covered by Part D and, for the first time, Part B for the third cycle of negotiations, as well as one previously negotiated drug for renegotiation. Negotiated prices for the third cycle will be effective starting January 1, 2028. Each year thereafter, more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain whether that will continue under the new framework. It is unclear whether or how much such rights may be exercised.

Several pharmaceutical companies, as well as the U.S. Chamber of Commerce, and the Pharmaceutical Research and Manufacturers of America have filed lawsuits against HHS and the Centers for Medicare & Medicaid Services, or CMS, asserting that, among other things, the IRA's drug price negotiation program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the U.S. Constitution and is otherwise unlawful. HHS has generally won the substantive disputes in these cases. Certain of these cases continue to be appealed.

The current U.S. administration has indicated that it is pursuing policies to reduce regulations and expenditures across government, including at HHS, the FDA, CMS and related agencies. These actions, frequently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions and proposals may, for example, include directives: (1) reducing agency workforce and cutting programs; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation, or CMMI, to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration's executive order that directed HHS to establish an AI task force and develop a strategic plan; (4) directing HHS and other

agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs on imported pharmaceutical products; and (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and to standardize prices across hospitals and health plans. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. This could lower the price that we receive for any approved 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 addition, on July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law, which reduced funding to federal healthcare programs and imposed additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs.

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, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for any of our current and future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Additionally, there may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services.

We expect to experience pricing pressures in connection with the sale of all of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Our relationships with healthcare providers and physicians and third-party payors may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research and, if approved, sell, market and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales, marketing and business arrangements of our product candidates, is subject to extensive laws designed to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of

information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;
- the federal civil and criminal false claims laws, including the federal False Claims Act, or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the healthcare fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;
- the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biological products and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage, tracking and tracing and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies have continued to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties and settlements in the healthcare industry. Ensuring that business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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 civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment of or restriction on our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, results of operations and financial condition.

We may attempt to seek approval from the FDA for one or more of our product candidates through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval pathway, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified time period after the date accelerated approval is granted. The FDA has issued draft guidance that proposes criteria it will use to determine if a trial is underway, including whether enrollment in the trial has been initiated. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. In addition, FDORA gives the FDA increased authority to withdraw accelerated approval on an expedited basis if, for example, the sponsor fails to conduct such studies in a timely manner, such studies fail to confirm the drug's clinical benefit or the sponsor fails to send the necessary updates to the FDA. The FDA is empowered to take action against companies that fail to conduct any post-approval confirmatory study with due diligence or submit timely reports to the agency on their progress. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA seeking accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated

approval for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may not be successful in pursuing or maintaining Fast Track or other regulatory designations for our product candidates, and such designations may not actually lead to a faster development or regulatory approval process.

Although we received Fast Track designation for miv-cel for the treatment of patients with refractory lupus nephritis in May 2023, for miv-cel for the treatment of patients with myasthenia gravis, or MG, in December 2023 and for miv-cel for the treatment of patients with multiple sclerosis in January 2024 and RMAT designation for miv-cel for the treatment of SPS in July 2024, for the treatment of MG in August 2024 and for the treatment of naSPMS in August 2026, these designations do not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures. In addition, the FDA may withdraw a Fast Track or other accelerated review designation if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate. Access to an expedited program may expedite the development or approval process, but it does not change the standards for approval.

Furthermore, although we may pursue additional opportunities to accelerate the development of certain of our product candidates through one or more of the FDA's expedited program designations, we cannot be assured that any of our product candidates will qualify for such programs. The FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program.

We may not be able to maintain or obtain additional orphan drug designation or orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation 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. We received orphan drug designation from the FDA for miv-cel for the treatment of MG in April 2024 as well as from the EMA, for the treatment of SPS in August 2024, and for the treatment of systemic sclerosis in September 2024, but we may not be granted orphan drug designations for our product candidates in other indications in the U.S. or in other jurisdictions.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain orphan drug exclusivity for that product candidate. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity on the basis of greater effectiveness or safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Finally, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because the FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

We have received RMAT designation for miv-cel for the treatment of SPS, MG and naSPMS. These designations may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval.

We received RMAT designation for miv-cel for the treatment of SPS in July 2024 and for the treatment of MG in August 2024. We also received RMAT designation for miv-cel in non-active secondary progressive multiple sclerosis, or naSPMS in August 2026.

A company may request RMAT designation of its product candidate, which designation may be granted if the product meets the following criteria: (i) it is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and potential eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites post-approval, if appropriate. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

RMAT designation does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program, or MDRP, are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and established a new Medicare Part D coverage gap discount program. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA, which have resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, former President Biden signed the IRA into law, which, among other things, eliminated the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges

or legislative modifications in the future. It is unclear how other such challenges or modifications, and any healthcare reform measures of the current U.S. administration, will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional congressional action is taken. In addition, in certain countries outside the United States, reimbursement for products that have not yet received marketing authorization may be provided through national managed access programs.

Additionally, on July 4, 2025, the One Big Beautiful Bill Act was signed into law, which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding and limiting provider taxes used to fund the program. The One Big Beautiful Bill Act also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. Moreover, the American Rescue Plan Act of 2021, effective January 1, 2024, eliminated the statutory cap on rebate amounts owed by drug manufacturers under the MDRP, previously capped at 100% of the average manufacturer price for a covered outpatient drug.

We expect that the ACA, the IRA, and any other healthcare reform measures that may be adopted or implemented in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Changing regulatory environments could negatively impact our business.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess the therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No. 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the European Union. This Regulation, which entered into force in January 2022 and became applicable as of January 2025, is intended to

boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at European Union level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the European Union may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

The U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rule-making process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, 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 business could be materially harmed.

Our business may be impacted by actions of the current U.S. administration, including executive orders, policies, new legislation and judicial decisions.

Actions of the current U.S. administration may cause us to change our business operations, with an unknown impact to our stakeholders, including patients, healthcare providers and employees. Failure to comply with new administration actions could expose us to litigation or other government actions. There can be no assurance that our compliance with new administration actions will provide sufficient mitigation.

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities, and other organizations.

We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate and other related

parties for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Disruptions at the FDA, the SEC and other government agencies, including government shutdowns, funding changes, or other disruptions to these agencies' operations, could negatively impact our business, operations, regulatory interactions and access to capital.

Significant disruptions to the operations of government agencies, including from prolonged or repeated shutdown of the federal government, could adversely affect our business, financial condition and results of operations. For example, on October 1, 2025, the U.S. government shut down for 43 days, during which time certain regulatory agencies, such as the FDA and the SEC, furloughed certain employees and stopped critical activities. On October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. The ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, reductions in workforce, ability to hire and retain key personnel and accept the payment of user fees, substantial changes in leadership and shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory, and policy changes. In the past, average review times at the agency have fluctuated, and this may continue in the future. In addition, government funding of other agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. In addition, government shutdowns, if prolonged, could significantly impact the ability of government agencies upon which we rely (such as the FDA and SEC) to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Disruptions at the FDA and other agencies, including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes, may slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the U.S. administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Additionally, over the past decade, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. The U.S. administration has taken steps to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. If funding for the FDA is reduced, if the FDA workforce is reduced, or if government shutdowns reoccur, any of these factors could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Further, a future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, during the most recent U.S. federal government shutdown, the SEC announced that it would not declare registration statements effective. In the event of a future shutdown, the SEC may operate with limited staff or suspend certain functions

altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

In addition, future government shutdowns or funding freezes could negatively affect broader business operations and economic conditions and cause delays in or suspension of manufacturing facility and shipping operations, which could adversely affect our clinical trials and supply of product candidates. If these disruptions reoccur or worsen, our business, financial condition, results of operations and ability to execute our strategic plans could be materially and adversely affected.

There remains substantial uncertainty as to how the current administration will seek to or continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. State governments may also attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. This uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. If we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

Risks Related to Data and Privacy

If our internal information technology systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including, but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related to our business, and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data and, as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause security incidents.

Our internal information technology systems and those of our CROs, CMOs, clinical sites and other contractors and consultants upon which we rely are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware (including as a result of advanced persistent threat intrusions), and other attacks by computer hackers, cracking, application security attacks, social engineering (including through phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

Some actors also now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products, if approved. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Furthermore, future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Additionally, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. As such, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Furthermore, because the technologies used to obtain unauthorized access to, or to sabotage or disrupt, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. A security breach or privacy violation that leads to disclosure or modification of or prevents access to personal data or other protected information could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of data and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. Similarly, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, a security breach that exposes our confidential intellectual property could compromise our patent portfolio. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Regulators have also increased their focus on companies' cybersecurity vulnerabilities and risks.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services including clinical trials.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

While we do not believe that we have experienced any material system failures, accidents or security breaches, we have experienced cybersecurity incidents in the past and expect that we will experience cybersecurity incidents in the future. The procedures and controls we use to monitor these threats and mitigate our exposure may not be sufficient to prevent cybersecurity incidents. If any such incidents were to occur and cause interruptions in our operations, it could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident were to result in the loss of or

damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

Failure to comply with data privacy and security laws, regulations and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, negative publicity, and/or other adverse consequences that could negatively affect our operating results and business.

We and our partners and vendors may be subject to federal, state, and foreign privacy and data protection laws and regulations that impose broad compliance obligations on the collection, possession, use, storage, access, disclosure, transfer, deletion and protection of personal data. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal data, could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to criminal and civil penalties if we violate HIPAA. HIPAA mandates the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Requirements for compliance under HIPAA are also subject to change, as the U.S. Department of Health and Human Services Office for Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates.

Even when HIPAA does not apply, according to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal data secure may constitute unfair acts or practices in or affecting commerce in violation of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of personal data it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. Additionally, the FTC's Health Breach Notification Rule applies to health applications and other similar technologies and has expanded breach notification requirements, which may add additional complexity to compliance obligations. Further, the SEC implemented rules around incident reporting, requiring cybersecurity incidents to be reported within four business days after determining that an incident is material.

The U.S. Department of Justice issued a final rule entitled, "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202, or the Bulk Transfer Rule. The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia, and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act, or the CCPA, as revised and amended by the California Privacy Rights Act, created new individual privacy rights for California residents, including the right to opt out of certain disclosures of their data, the right to limit the use and disclosure of sensitive personal information (including health information). The CCPA places increased privacy and security obligations on entities handling certain personal data of California residents or households, limits data use and mandates audit requirements for higher risk data. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, as currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. The CCPA is enforced by the California Privacy Protection Agency, a data protection authority, which has the power to issue substantive regulations resulting in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required.

While California was the first among the states to adopt comprehensive data privacy legislation similar to the GDPR, many other states are following suit, which could increase our potential liability and adversely affect our business. Many states have adopted statewide comprehensive privacy laws and many other states have privacy legislation that is pending. Many of these new state laws contain some type of exemption for information collected under HIPAA and some data processed in the context of clinical trials, either at the entity level or the data level, so the impact might be limited particularly as it relates to protected health information. Some states also have laws that specifically focus on the processing of personal data related to individuals' health, including California's Confidentiality of Medical Information Act and Washington's My Health My Data Act. Changes to federal and state privacy laws may add complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

In addition, all 50 U.S. states and territories and international jurisdictions have varying breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential data experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify patients or other counterparties of a security breach. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards.

Foreign data protection laws, including the European Union's General Data Protection Regulation, or the EEA GDPR, and the UK equivalent of the same, or UK GDPR, may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out.

The GDPR in the EEA and the UK GDPR in the United Kingdom, together the GDPR, impose stringent requirements for controllers and processors of personal data of individuals within the European Economic Area, or EEA, or the United Kingdom. The GDPR applies to any company established in the EEA or United Kingdom as well as to those outside the EEA or United Kingdom if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or United Kingdom or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom governing the processing of personal data, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting and access to certain data under frameworks such as the European Health Data Space Regulation. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million (£17.5 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater. Such requirements may be subject to change in the near future as the European Commission announced

proposed amendments to the GDPR in November 2025. In addition, on June 19, 2025, the UK's Data (Use and Access) Act 2025, or the DUAA, was granted Royal Assent, implementing various measures concerning data usage in the UK and reforming data protection laws. It remains too soon to tell how the DUAA will be implemented and what impact it will have on our international activities. Further, other EU and member state laws and regulations may impose further obligations or restrictions on processing health information in the EEA, such as the European Health Data Space Regulation.

In the EEA, the NIS 2 Directive, or NIS 2, is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. To the extent that we become subject to NIS 2 in the future, we may require additional investment of our resources in compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the United Kingdom may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class-action-type litigation. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures, engaging data protection personnel, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Certain jurisdictions, including the EEA, have enacted laws and regulations governing cross-border personal information transfer and providing for data localization in certain cases. For example, absent appropriate safeguards or other circumstances, the GDPR and laws in the UK generally restrict the transfer of personal information to countries outside the EEA and the UK, such as the United States. Such safeguards include the use of standard contractual clauses approved by the European Commission and the UK Data Protection Authority as well as the EU-U.S. Data Privacy Framework. If we are unable to implement a valid solution to transfer personal data from the EEA to the United States or other countries that have not been deemed to provide an essentially equivalent level of data protection, we may face increased exposure to regulatory action, substantial fines, or injunction orders to stop processing personal data from EEA or UK residents. Any inability to import personal data to the United States may also restrict our clinical trials activities in the EU, limit our ability to collaborate with contract research organizations as well as other service providers, contractors and other companies subject to EU data privacy and security laws, and require us to increase our data processing capabilities in the EU and the UK at a significant expense. Additionally, other countries outside of the EU have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The types of challenges we face in the EEA and the UK will likely also arise in other jurisdictions that adopt laws similar to the GDPR or regulatory frameworks of equivalent complexity.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

Issues in the development and use of artificial intelligence, or AI, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. We may adopt and integrate generative AI tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and have a material adverse effect on our business, financial condition and results of operations.

Additionally, ineffective or inadequate AI development or deployment practices could result in unintended consequences. For example, AI algorithms we may use in connection with our operations may be flawed or based on datasets that are biased or insufficient, potentially leading to errors in our business processes. Disruption or failure in AI functionality could adversely affect our business, cause delays or inaccuracies in our offerings, or harm our reputation. Conversely, if we are unable to adopt and deploy AI effectively as quickly as our competitors, it may cause us to be relatively less productive or innovative, adversely impacting our competitiveness and requiring additional investments that increase our costs. Laws and regulations regarding AI technologies are rapidly evolving as well, including in the areas of intellectual property, cybersecurity, privacy, and data protection. Compliance with new or changing laws, regulations, or industry standards relating to AI may impose significant operational and financial burdens and may limit our ability to develop, deploy, or use AI technologies in our business.

Risks Related to Our Reliance on Third Parties

****We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, or become more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.***

We rely and intend to rely in the future on third-party clinical investigators, CROs, and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. In addition, third parties are conducting and we expect will continue to conduct investigator-initiated trials with our product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

We completed our first BLA submission in the fourth quarter of 2026 and have limited experience as a company in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety or efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities in our product registrations. Further, our third-party clinical manufacturers may not be

able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies is conducted in accordance with good laboratory practices, or GLPs, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and well-being of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA or BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminated entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

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

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers to manufacture drug substances, drug products, raw materials, samples, components, and other materials for our product candidates. For example, under the MAT Agreement, MAT provides us with certain customized cell manufacturing, release and testing services for our miv-cel product candidate; under the Elevate CCSA, Elevate provides us with development and manufacturing services for the clinical and commercial supply of miv-cel; and pursuant to the Oxford Agreement, we engaged Oxford to undertake lentiviral

vector process development services, with the intention for Oxford to ultimately manufacture and supply to us lentiviral vectors for research and development purposes and for use in connection with our clinical trials.

Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted or terminated, or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

The manufacturing process for our product candidates is subject to the FDA, EMA and foreign regulatory authority review. We and our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs, and, in certain cases, current good tissue practice, or cGTP, requirements. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and foreign regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Moreover, we do not conduct the manufacturing process ourselves and are dependent on our CMOs for manufacturing in compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, delayed, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us to manufacture, or to have another third party manufacture, our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

Under recent legislation, certain third-party manufacturers and other third parties (frequently China-based companies) may be considered a "biotechnology company of concern." If a third-party manufacturer receives such a designation, it may restrict the ability of U.S. companies like us to purchase services or products from, collaborate with, or otherwise work with such manufacturers. For example, it may delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Such disruption could have adverse effects on the development of our product candidates.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs and cGTPs, or maintain a compliance status acceptable to the FDA, EMA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products; and

- regulatory enforcement actions against our manufacturers or us, including fines and civil, criminal and administrative penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, requirements to cease distribution of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants if approved, would be jeopardized. For example, the current U.S. administration has substantially altered prior U.S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the current U.S. administration has initiated and continues to consider imposing additional tariffs on certain foreign goods. Related to this action, certain foreign governments, including Canada and China, have instituted or are considering imposing tariffs on certain U.S. goods. It remains unclear what the current U.S. administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers and increase the cost of materials purchased to manufacture our product candidates.

We depend on limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. For example, MAT and Elevate are currently our only providers of customized cell manufacturing, release and testing services for our mivcel product candidate. We do not currently have long-term supply contracts with all of our CMOs and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our CMOs in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, produce insufficient quantities of our supplies or otherwise fail to meet contractual requirements, experience financial difficulties, cease operations, face business disruptions or be acquired by, or enter into exclusive arrangements with, our competitors. In addition, geopolitical tensions may impact our CMOs.

Establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The operations of our suppliers, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, some of our suppliers are located outside of the United States. As a result, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or cGTPs or status acceptable to the FDA, EMA or foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, which may be important to our business. If we are unable to enter into new collaborations, or if these or any of our current collaborations are not successful and we fail to realize the benefits of such collaborations or licensing arrangements, our business, results of operations and financial condition could be adversely affected.

A part of our strategy is to strategically evaluate and, as we deem appropriate, enter into additional partnerships in the future, including potentially with major biotechnology or pharmaceutical companies. Although we are progressing launch readiness activities in anticipation of a potential FDA approval of mivcel in SPS, we have limited capabilities for product development and do not yet have full capabilities for commercialization. Accordingly, we may continue to enter into collaborations with other companies in the future to provide us with important technologies and funding for our programs and technology. Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators.

Our current collaborations and any future collaborations we enter into may pose a number of risks, including the following:

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

- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates, if approved;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing, manufacturing and distribution rights to one or more of our product candidates that achieve regulatory approval, if any, may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out the marketing and distribution of such product or products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or future commercialization of product candidates, if approved, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may seek to amend or modify the terms of any collaboration;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in such a way as to invite actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or future commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or future commercialization of the applicable product candidates.

If our collaborations do not result in the successful discovery, development and future commercialization of product candidates, if approved, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and future commercialization described in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q also apply to the activities of our therapeutic collaborators. Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner with our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies.

Collaborations are complex, expensive 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. Our ability to 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. Additionally, our collaboration agreements may contain non-competition provisions that could limit our ability to enter into strategic collaborations with future collaborators or restrict our ability to commercialize products on our own, if approved.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, if approved, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or future commercialization activities at our own expense. If we elect to increase our expenditures to fund development or future commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and future commercialization activities, we may not be able to further develop our product candidates, bring them to market, if approved, and generate revenue from sales of drugs or continue to develop our technology, and our business, results of operations and financial condition could be adversely affected. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of any approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could delay the development and future commercialization of our product candidates, if approved, and reduce their competitiveness even if they reach the market.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile.

The market price of our common stock is volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- expiration of market standoff or lock-up agreements;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States that may impact the operation of our business, including changes in the structure of healthcare payment systems;
- litigation or arbitration;
- pandemics, natural disasters or major catastrophic events;
- general economic, political and market conditions and other factors; and

- the occurrence of any of the risks described in this section titled "Risk Factors."

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

We have experienced volatility in our stock price. For example, from January 1, 2025 to December 31, 2025, our closing stock price ranged from $1.83 to $10.82 per share, and from January 1, 2026 to September 30, 2026, our closing stock price ranged from $6.80 to $11.25 per share. When the market price of a stock has been volatile, as our stock price has been, holders of that stock have occasionally brought securities class action litigation claims against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit were without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management. See the risk factor under the heading "We or our directors or officers may be subject to securities litigation, which is expensive and could divert management attention" above for a discussion of a securities class action complaint in which we are currently named as a defendant.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, 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. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market opportunities for our product candidates and forecasts of market growth may not be accurate, and the actual market for our products may be smaller than we estimate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

The precise incidence and prevalence for all of the conditions we aim to address with our product candidates are unknown. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States, other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

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

We have never declared or paid dividends on our capital stock. Under the Loan and Security Agreement, we are prohibited from paying any dividends without the prior written consent of Oxford Finance. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

****The future issuance of equity or of debt securities that are convertible into equity would dilute our stockholders' ownership.***

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or other equity securities or the availability of common stock for future sales will have on the trading price of our common stock.

Pursuant to our 2024 Equity Incentive Plan, or our 2024 Plan, our management is authorized to grant stock options to our employees, directors and consultants. As of September 30, 2026, we had 4,241,250 shares of common stock available for future issuance under our 2024 Plan. Additionally, the number of shares of our common stock reserved for issuance under the 2024 Plan will automatically increase on January 1st of each year, continuing through and including January 1, 2034, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In accordance with the foregoing, on January 1, 2026, an aggregate of 3,019,494 shares of our common stock were added to the reserve of shares available for future issuance under the 2024 Plan. Additionally, pursuant to our Amended and Restated 2024 Inducement Equity Incentive Plan, or our Inducement Plan, our management is authorized to grant equity-based awards in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance shares solely to our prospective employees provided that certain criteria are met. As of September 30, 2026, we had 338,866 shares of common stock available for future issuance under our Inducement Plan. Unless our board of directors or a committee thereof elects not to increase the number of shares available for future grant each year under the 2024 Plan or Inducement Plan, our stockholders may experience additional dilution, which could cause our stock price to fall.

Our board of directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations.

Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness, contractual obligations or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant amortization expense. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to the Company, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

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

On March 26, 2026, we filed a shelf Registration Statement on Form S-3 (File No. 333-294645), or the 2026 Shelf Registration Statement, that became effective on April 2, 2026 and allows us to undertake various equity and debt offerings for an aggregate amount of up to $300.0 million. In addition, on March 27, 2025, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or the Agent, pursuant to which we may offer and sell from time to time through the Agent up to $100.0 million in shares of our common stock pursuant to the 2026 Shelf Registration Statement, or the ATM Prospectus. As of September 30, 2026, $200.0 million remains available under the 2026 Shelf Registration Statement and $90.7 million remains available and allocated for sale under the ATM Prospectus.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

In addition, the shares of our common stock that are subject to outstanding options under our equity incentive plans are eligible for sale in the public market, to the extent permitted by the provisions of various vesting schedules, the lock-up agreements (and the exceptions thereto) and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

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

As of November 6, 2026, our executive officers, directors and holders of 5% or more of our capital stock beneficially owned approximately 35.6% of our outstanding common stock. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in our Annual Reports on Form 10-K and our other periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. We could be an emerging growth company for up to five years following the completion of our IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required

to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our Annual Reports on Form 10-K and our other periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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

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

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- authorize our board of directors to issue one or more new series of preferred stock without stockholder approval and create, subject to applicable law, one or more series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our amended and restated bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66-2/3% of all outstanding shares of our capital stock;
- require the approval of not less than 66-2/3% of all outstanding shares of our capital stock to amend our amended and restated bylaws and specific provisions of our amended and restated certificate of incorporation; and

- specify the jurisdictions in which certain stockholder litigation may be brought.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

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

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction) shall be the sole and exclusive forum, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants, for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed to us or our stockholders by any director, officer or other employee; (iii) any action asserting a claim against us or any director, officer or other employee arising pursuant to the DGCL; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws; or (v) any other action asserting a claim that is governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the exclusive forum provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

Techniques employed by short sellers may drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be

costly and time-consuming, and could be distracting for our management team. Additionally, such allegations against us could negatively impact our business operations and stockholders' equity, and the value of any investment in our stock could be reduced.

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

(a) Unregistered Sales of Equity Securities

None.

(b) Use of Proceeds from Initial Public Offering

On February 12, 2024, we closed the IPO, pursuant to which we issued and sold 16,675,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 2,175,000 additional shares, at an initial public offering price of $22.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-276523), which was declared effective by the SEC on February 7, 2024. Following the sale of the above shares, the offering terminated. J.P. Morgan, Morgan Stanley, Leerink Partners and Wells Fargo Securities acted as joint book-running managers.

We received aggregate gross proceeds from the IPO of $366.9 million, or aggregate net proceeds of $336.2 million, inclusive of the full exercise by the underwriters of their option to purchase additional shares, after deducting underwriting discounts and commissions and estimated other offering costs totaling $30.7 million. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to (i) our directors or officers or their associates, (ii) persons owning 10% or more of our common stock or (iii) any of our affiliates.

As of September 30, 2026, we estimate that we have used all of the proceeds from the IPO, and such proceeds have been used for general corporate purposes, including to fund the clinical development of miv-cel and our other clinical and preclinical activities, as well as operating expenses.

(c) Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the fiscal quarter ended September 30, 2026, none of our directors or officers (as defined in Section 16 of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Kyverna Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 12, 2024).
3.2	Amended and Restated Bylaws of Kyverna Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on February 12, 2024).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-276523) filed with the SEC on January 16, 2024).
10.1†	First Amendment to Loan and Security Agreement, entered into as of July 8, 2026 and made effective as of June 30, 2026, by and among Kyverna Therapeutics, Inc., Oxford Finance LLC, as collateral agent, and the lenders named therein or otherwise a party thereto from time to time (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 11, 2026).
10.2*†	Clinical and Commercial Supply Agreement, dated July 23, 2026, between Kyverna Therapeutics, Inc. and ElevateBio Basecamp, Inc.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

** Furnished herewith.

† Portions of this exhibit (indicated by […***…]) have been omitted because the Registrant has determined that the information is both (i) not material and (ii) of the type that the Registrant treats as private or confidential.

SIGNATURES

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

KYVERNA THERAPEUTICS, INC.

Date: November 12, 2026

By: /s/ Warner Biddle

Warner Biddle
Chief Executive Officer
(*Principal Executive Officer*)

Date: November 12, 2026

By: /s/ Gregory Martini

Gregory Martini
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 10.2

*****Certain identified information has been omitted from this exhibit because it is both (i) not material and (ii) of the type that the Registrant treats as private or confidential. Such omitted information is indicated by brackets ("[…***…]") in this exhibit.*****

CLINICAL AND COMMERCIAL SUPPLY AGREEMENT

THIS CLINICAL AND COMMERCIAL SUPPLY AGREEMENT (this "**Agreement**") is made as of the last date of signature below (the "**Effective Date**") by and between **ELEVATEBIO BASECAMP, INC.**, a Delaware corporation with an office at 200 Smith Street, Suite 301, Waltham, MA 02451 ("**ElevateBio**") and **KYVERNA THERAPEUTICS, INC.**, with an office at 5980 Horton St., Suite 200, Emeryville, CA 94608 ("**Client**").

RECITALS:

WHEREAS, ElevateBio and Client previously executed a Development and Manufacturing Services Agreement effective July 22, 2023 (the "**Original Effective Date**"), as subsequently amended by Amendment #1 effective July 24, 2023 (together, the "**Original Agreement**"); and

WHEREAS, ElevateBio and Client now desire to enter into this Agreement with the intent for it to replace the Original Agreement and to allow Client to engage ElevateBio to perform certain Development or Manufacturing (as those terms are defined below) services for clinical and commercial supply, on the terms and conditions set forth herein, and ElevateBio desires to perform such services for Client.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants of the Parties set forth in this Agreement, the Parties hereto agree as follows:

1. **Definitions.** Unless this Agreement expressly provides to the contrary, the following terms, whether used in the singular or plural, have the respective meanings set forth below.

1.1 "**Accepted Purchase Orders**" has the meaning set forth in Section 4.4.

1.2 "**Affiliate**" means, with respect to either Client or ElevateBio, any corporation, company, partnership, joint venture or other entity which controls, is controlled by or is under common control with Client or ElevateBio, as the case may be, for so long as such control exists. As used in the definition of Affiliate, "**control**" means (a) ownership of fifty percent (50%) or more of the voting shares or equity interests of such entity or (b) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of equity, by contract, by board of director representation or otherwise.

1.3 "**Applicable Law**" means all applicable ordinances, rules, regulations, laws, statutes, guidelines, guidances, requirements, judgments, and court orders of any kind whatsoever of any Authority as amended from time to time, including GMP (if applicable).

1.4 "**Authority**" means any government regulatory authority responsible for granting approvals for the performance of Services under this Agreement or for issuing regulations pertaining to the Development, Manufacture, use, or sale of any Product in the intended country of Development, Manufacture, use, or sale including the FDA.

1.5 "**Bankruptcy Code**" means the United States Bankruptcy Code.

1.6 "**Batch**" means a specific quantity of a Product that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture. Batches may include GMP validation, clinical, and/or commercial batches.

1.7 "**Batch Fee**" has the meaning set forth in Section 9.2.

1.8 "**Batch Documentation**" has the meaning set forth in Section 7.2.

1.9 "**Binding Forecast**" means such quantity of Batches of Product set forth in the Binding portion for the then-current Forecast.

1.10 "**Certificate of Analysis**" means a document signed by an authorized representative of ElevateBio's Quality Assurance department, describing the Specification for, and testing methods applied to, a Product, and the results of testing.

1.11 "**Change Order**" has the meaning set forth in Section 6.3(a).

1.12 "**Client Background Improvement Invention**" means any Invention that (a) is Created by or on behalf of either Party or its Affiliates or both Parties in connection with the performance of activities under this Agreement, (b) constitutes an improvement, modification, or enhancement to Client Background Technology and does not constitute an improvement, modification, or enhancement to ElevateBio Background Technology, and (c) does not incorporate ElevateBio's Confidential Information.

1.13 "**Client Background Technology**" means any Invention or any Patent Right that Client or any of its Affiliates Controls as of the effective date of the applicable Statement of Work or that comes into the Control of Client or any of its Affiliates independently of this Agreement during the term of this Agreement. Client Background Technology, if provided to ElevateBio, will be identified and described in the applicable Statement of Work prior to being provided to ElevateBio.

1.14 "**Client Equipment**" means the Equipment, if any, identified on the applicable Statement of Work as being provided by Client or purchased or otherwise acquired by ElevateBio at Client's expense.

1.15 "**Client Foreground Patent Rights**" means Patent Rights that claim or cover any Client Invention.

1.16 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.17 "**Client Invention**" means any (a) Client Background Improvement Inventions, or (b) Client Product Inventions.

1.18 "**Client Materials**" means the materials identified in the applicable Statement of Work as being provided by Client, including labels (if any) for a Product.

1.19 "**Client Product Inventions**" means all Inventions (other than Client Background Improvement Inventions) that (a) are Created by or on behalf of either Party or its Affiliates or both Parties in connection with the performance of activities under this Agreement, and (b) incorporate or necessarily rely on (i) a Product, (ii) Client's Confidential Information, or (iii) Client Materials. For clarity, to the extent any of ElevateBio's Confidential Information is incorporated in Client Product Inventions, such ElevateBio's Confidential Information shall remain owned solely and exclusively by ElevateBio. For further clarity, Client Product Inventions do not include any ElevateBio Inventions.

1.20 "**CMO**" means any contract manufacturing organization.

1.21 "**Confidential Information**" has the meaning set forth in Section 11.1.

1.22 "**Control**" or "**Controlled**" means, with respect to any Inventions or Patent Rights, the possession (whether by ownership or license, but other than pursuant to this Agreement) by a Party of the ability to grant to the other Party a license or access as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party, in existence as of the time such Party would first be required hereunder to grant the other Party such license or access.

1.23 "**Created**" means created, made, developed, invented, generated, conceived, or reduced to practice. "**Create**" and "**Creating**" have their correlative meanings.

1.24 "**Deliverables**" has the meaning set forth in Section 6.4(a).

1.25 "**Delivery**" has the meaning set forth in Section 7.3.

1.26 "**Develop**" or "**Development**" means the studies and other activities conducted by or on behalf of ElevateBio under this Agreement to develop or validate all or any part of a Manufacturing Process, including analytical tests and methods, formulations and dosage forms, and stability.

1.27 "**Development Batches**" has the meaning set forth in Section 7.8.

1.28 "**Discloser**" has the meaning set forth in Section 11.1.

1.29 "**Dispute**" has the meaning set forth in Section 16.10.

1.30 "**Dispute Notice**" has the meaning set forth in Section 16.10.

1.31 "**ElevateBio Background Improvement Invention**" means any Invention that (a) is Created by or on behalf of either Party or both Parties in connection with the performance of activities under this Agreement, (b) constitutes an improvement, modification or enhancement to ElevateBio Background Technology, and (c) does not incorporate or necessarily rely on Client's Confidential Information, Client Materials, or Product.

1.32 "**ElevateBio Background Technology**" means any Invention or any Patent Right that ElevateBio Controls as of the effective date of the applicable Statement of Work or that comes into the Control of ElevateBio independently of this Agreement during the term of this Agreement. ElevateBio Background Technology, if provided to Client, will be identified and described in the applicable Statement of Work prior to being provided to Client.

1.33 "**ElevateBio Foreground Patent Rights**" means Patent Rights that claim or cover any ElevateBio Invention.

1.34 "**ElevateBio Indemnitees**" has the meaning set forth in Section 13.2.

1.35 "**ElevateBio Invention**" means any (a) ElevateBio Background Improvement Inventions, or (b) ElevateBio Manufacturing Inventions.

1.36 "**ElevateBio Manufacturing Inventions**" means all Inventions (other than ElevateBio Background Improvement Inventions) that (a) are Created solely by or on behalf of ElevateBio or jointly by or on behalf of both Parties in connection with the performance of activities under this Agreement, (b) constitute generally applicable processes for formulating, manufacturing, filling, processing, packaging, analyzing, testing, releasing, storing, labeling, or supplying biological materials, and (c) do not incorporate Client's Confidential Information, Client Materials, or Product. For clarity, ElevateBio Manufacturing Inventions do not include any Client Inventions.

1.37 "**ElevateBio Technology**" means ElevateBio Background Technology and ElevateBio Inventions.

1.38 "**Equipment**" means any equipment or machinery, including Client Equipment, used by ElevateBio in the performance of Services under this Agreement, including in the Development or Manufacturing of a Product, or the holding, processing, testing, or release of Product.

1.39 "**Facility**" means any of the facility(ies) of ElevateBio or subcontractors identified in the applicable Statement of Work or otherwise approved by Client, in advance in writing, in accordance with the terms hereof.

1.40 "**Facility Master Files**" means any master files relating to the Facility controlled by ElevateBio that are necessary for obtaining or maintaining regulatory and governmental approvals and permits to use any Product Developed or Manufactured under this Agreement.

1.41 "**FDA**" means the United States Food and Drug Administration, and any successor agency having substantially the same functions.

1.42 "**Force Majeure**" has the meaning set forth in Section 16.2.

1.43 "**GMP**" means then current good manufacturing practices and regulations applicable to the Manufacture of a Product that are promulgated by any Authority.

1.44 "**Included ElevateBio Technology**" has the meaning set forth in Section 10.6(b).

1.45 "**Initial Term**" has the meaning set forth in Section 15.1.

1.46 "**Intellectual Property**" means all intellectual property and proprietary rights, however denominated, throughout the world, including rights in copyrights, copyright registrations, and copyright applications; trademarks, service marks, trade dress, trade names, trademark registrations, and trademark applications; rights in inventions and discoveries (whether patentable or not), and Patent Rights; trade secret rights; rights in know-how; and all other rights and interests existing, created, or protectable under any intellectual property law of any jurisdiction.

1.47 "**Invention**" means any invention, discovery, development, data, information, know-how, process, method, technique, trade secret, composition of matter, formulation, article of manufacture or work of authorship, and any physical embodiments of any of the foregoing and all related Intellectual Property.

1.48 "**Joint Foreground Patent Rights**" means Patent Rights that claim or cover Joint Inventions.

1.49 "**Joint Inventions**" means all Inventions that are Created by or on behalf of either Party or both Parties in connection with the performance of activities under this Agreement, other than ElevateBio Inventions and Client Inventions.

1.50 "**Latent Defect**" means, with respect to a Product, a failure to comply with the applicable Specification, applicable Statement of Work, applicable Quality Agreement or Applicable Law that is existing at the time of Delivery but which could not reasonably be discovered by inspection by Client or its designee pursuant to Section 7.3, and is discovered by the earlier of (a) [...***...], or (b) [...***...].

1.51 "**Losses**" has the meaning set forth in Section 13.1.

1.52 "**Manufacture**" and "**Manufacturing**" means any steps, processes, and activities necessary to produce any Product including as applicable, the manufacturing, processing, in-process testing, packaging, labeling, quality control testing, stability testing, release, storage, or supply of a Product.

1.53 "**Manufacturing License Agreement**" has the meaning set forth in Section 10.8(b).

1.54 "**Manufacturing Process**" means any and all processes and activities (or any step in any process or activity) used by or on behalf of ElevateBio to Manufacture a Product in connection with the performance of the Services by or on behalf of ElevateBio, as evidenced in the Batch Documentation.

1.55 "**Non-Conforming Batch**" has the meaning set forth in Section 7.5(a).

1.56 "**Parties**" means Client and ElevateBio together.

1.57 "**Party**" means either Client or ElevateBio, as the context requires.

1.58 "**Patent Right**" means the rights and interests in and to any and all issued patents and pending patent applications (including inventor's certificates, applications for inventor's certificates, statutory invention registrations, applications for statutory invention registrations, utility models and any foreign counterparts thereof) in any country or jurisdiction, including any and all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals and other continuing applications, extensions or restorations by existing or future extension or restoration mechanisms, including patent term extension, supplementary protection certificates or the equivalent, renewals, and all letters patent on any of the foregoing, and any and all reissues, reexaminations, extensions, confirmations, registrations and patents of addition on any of the foregoing.

1.59 "**Personnel**" has the meaning set forth in Section 3.2.

1.60 "**PLI**" has the meaning set forth in Section 6.2(e).

1.61 "**Processing Fee**" means the specific fee or percentage fee added to a pass-through cost by ElevateBio as reimbursement for any and all associated overhead costs, markup, administrative fee, or any other associated fee for such pass-through costs.

1.62 "**Product**" means Client's product(s) to be Manufactured by ElevateBio under this Agreement, as described in the applicable Statement(s) of Work.

1.63 "**Project**" has the meaning set forth in Section 2.1.

1.64 "**QP**" has the meaning set forth in Section 6.2(e).

1.65 "**Quality Agreement**" or "**QAA**" has the meaning set forth in Section 2.3.

1.66 "**Raw Materials**" means the materials to be consumed during Batch production as expressly set forth in the bill of materials and explicitly excludes reagents used during any testing.

1.67 "**Recipient**" has the meaning set forth in Section 11.1.

1.68 "**Records**" has the meaning set forth in Section 6.4(a).

1.69 "**Regulatory Approval**" means all required applications, filings, approvals, clearances, exemptions or other requirements of any Authority necessary for the Manufacture, distribution or other commercialization of the Product under this Agreement, in any country or regulatory jurisdiction anywhere in the world, excluding any pricing and reimbursement approvals and satisfaction of all applicable regulatory and notification requirements.

1.70 "**Representative**" has the meaning set forth in Section 3.1.

1.71 "**Senior Officer**" means, with respect to each Party, Vice President or above of such Party.

1.72 "**Services**" means the Development, Manufacturing, or other services described in a Statement of Work entered into by the Parties.

1.73 "**Specification**" means the specifications for a Product, including any list of tests, references to any analytical procedures and appropriate acceptance criteria which are numerical limits, or ranges or other criteria for tests or for attributes of a Product, which are described in order to establish a set of criteria to which a Product at any stage of Manufacture should conform, that are provided by or approved by Client, as such specification is amended or supplemented from time to time in accordance with the terms of this Agreement. Client will not release Product if these parameters are not met, and the investigation shows the non-complying parameter to be a valid test result, without approval from the Authority of the intended country of use.

1.74 "**Statement of Work**" has the meaning set forth in Section 2.1.

1.75 "**Technology Transfer**" has the meaning set forth in Section 10.8(a).

1.76 "**Technology Transfer Notice**" has the meaning set forth in Section 10.8(a).

1.77 "**Testing Materials**" means the reagents, consumables, and other materials used by ElevateBio in performing testing activities under this Agreement that are not Raw Materials or Client Materials.

1.78 "**Third Party**" means any individual, entity, or organization other than the Parties and their respective Affiliates.

1.79 "**Third Party Infringement**" has the meaning set forth in Section 10.6(d).

2. **Engagement of ElevateBio**.

2.1 Statements of Work. From time to time, Client may wish to engage ElevateBio to perform Services for Client. The specific details of the Services for each project under this Agreement (each, a "**Project**") will be set forth in a mutually agreed work order signed by the Parties or their respective Affiliate and substantially in the form attached hereto as Appendix A (each, a "**Statement of Work**"). Each Statement of Work will include the material terms for the applicable Project, and may include the scope of work, specified Services, Specification, Deliverables, timelines, milestones (if any), quantity, budget, payment schedule and such other details and special arrangements as are agreed to by the Parties with respect to the activities to be performed under such Statement of Work. No Statement of Work will be effective unless and until it has been agreed to and signed by authorized representatives of both Parties or their Affiliates. Except as set forth in this Agreement or otherwise agreed by the Parties, documents relating to the relevant Project, including Specifications, proposals, quotations, and any other relevant documentation, will only be effective if mutually agreed and attached to the applicable Statement of Work and incorporated in the Statement of Work by reference (or if impracticable to physically or digitally attach to the applicable Statement of Work, then clearly referred to in such Statement of Work and

incorporated in such Statement of Work by reference). Each Statement of Work will be subject to the terms of this Agreement and will be incorporated herein and form part of this Agreement. ElevateBio will perform the Services specified in each fully executed Statement of Work, as amended by any applicable Change Order(s) (as defined below), and in accordance with the terms and conditions of such Statement of Work and this Agreement. Nothing in this Agreement will obligate either Party to enter into any Statement of Work under this Agreement, and, subject to each Party's obligations under this Agreement, including under Section 2.2 and Article 11, this Agreement shall not limit in any way either Party's right to contract for any goods or services (including Product) with any other person or entity, including sources operated by such Party, such Party's Affiliates, or any Third Party.

2.2 Client hereby agrees that (a) [...***...] and (b) [...***...]; provided, however, that Client's obligation shall be conditional on the following: (A) ElevateBio delivers Product in accordance with Client's monthly Forecast for the Product; (B) ElevateBio's performance of the Services continues to meet monthly performance metrics, as defined by the JSC; and (C) ElevateBio has not materially breached this Agreement or otherwise failed to meet its obligations hereunder, which material breach or failure remains uncured [...***...] calendar days after the receipt of the corresponding notice from Client.

2.3 Quality Agreement. The Parties will negotiate in good faith and enter into a Quality Technical Agreement containing quality assurance provisions for the Manufacture of Products ("**Quality Agreement**") as soon as possible and in all cases no later than [...***...] calendar days prior to the initiation of the first GMP Manufacturing activities under this Agreement.

2.4 Conflict Between Documents. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and any Statement of Work, Quality Agreement, Purchase Order, or other document or form used by the Parties, (a) the terms of this Agreement will control, except solely to the extent that a Statement of Work, the Quality Agreement, Purchase Order or other document executed by both Parties explicitly modifies the terms of this Agreement by reference to this Agreement and the specific section or sections of this Agreement so modified and (b) the Quality Agreement will control with respect to any quality matters.

3. **Project Performance.**

3.1 Representatives. Each Party will appoint a representative having primary responsibility for day-to-day interactions with the other Party for a Project (each, a "**Representative**"), who will be identified in the applicable Statement of Work, Quality Agreement, or other binding agreement associated with this Project. Each Party may change any of its Representatives by providing written notice to the other Party in accordance with Section 16.4. Except for notices or communications required or permitted under this Agreement, which will be subject to Section 16.4, or unless otherwise mutually agreed by the Parties in writing, the relevant receiving Party Representative will receive a written copy of all formal communications between ElevateBio and Client (or their respective Affiliates), such as meeting minutes, requests for data or materials, transfer documents, new Statements of Work, Change Orders, Purchase Orders, issue escalations, progress reports, or other reporting communications as agreed to by the Parties regarding the conduct of a Project.

3.2 Personnel. ElevateBio's employees, the employees of its Affiliates, and all Third Party subcontractors of ElevateBio or its Affiliates are deemed "**Personnel.**" ElevateBio shall assign Personnel in such numbers and with such expertise as is necessary to provide the Services to Client in accordance with the terms and conditions described in each Statement of Work and in this Agreement. ElevateBio shall, in its sole discretion, designate which Personnel shall perform the Services and may change such Personnel at its sole discretion and ElevateBio may, at its sole expense, subcontract with Third Parties and Affiliates of ElevateBio to perform any of its obligations under this Agreement and any Statement of Work, provided that ElevateBio may not subcontract any of its obligations relating specifically to the Manufacture of the Product to any Third Parties or Affiliates without Client's express prior written approval, which shall not be unreasonably withheld, conditioned, or delayed; provided, however, Client may reasonably withhold approval of a subcontractor in the case that use of such subcontractor could cause a change to the cost of services and/or could impact any related regulatory filings under the applicable Statement of Work. Such approval may be provided via email. ElevateBio will remain fully responsible and liable for the performance of any subcontractor, including any Affiliate of ElevateBio, as if such performance had been provided by ElevateBio itself under this Agreement and fully guarantees and warrants the related performance (in accordance with this Agreement) of any responsibilities so subcontracted. Without limiting the foregoing, ElevateBio shall cause any and all such subcontractors (whether Affiliates or Third Parties) to comply with the terms and conditions of this Agreement, and such subcontractor shall be so bound in writing. All Personnel shall possess the training, education, experience, and skill levels necessary to provide the Services to be provided to Client hereunder competently and effectively. Before providing the Services, all Personnel must have agreed in writing to: (a) confidentiality obligations consistent with the terms of this Agreement and (b) assign or otherwise effectively vest in ElevateBio any and all rights that such Personnel might otherwise have in the results of their work which would arise from the Services to permit ElevateBio to comply with the ownership provisions of Article 10. Notwithstanding any delegation or subcontracting by ElevateBio to any Third Party, Affiliate, or other Personnel, (1) ElevateBio remains responsible for compliance with this Agreement and full satisfaction of the terms and conditions hereof, and (2) any breach of the terms and conditions of this Agreement by any Third Party, Affiliate, or other Personnel shall be deemed a breach by ElevateBio of such terms or conditions.

3.3 Joint Steering Committee.

(a) Joint Steering Committee. Within [...***...] calendar days after the Effective Date, unless a JSC has already been established by the Parties, the Parties shall establish a joint steering committee (the "**JSC**") by each Party designating and notifying the other Party of its initial members to serve on the JSC. The JSC will remain in place until the termination or expiry of this Agreement and, unless otherwise agreed in writing between the Parties, will be disbanded at the end of such period.

(b) Role of Joint Steering Committee. The JSC shall lead and oversee the performance of the Parties under this Agreement and shall be responsible for and have authority for:

i) providing a forum for strategic decision-making;

ii) resolving any disputes and acting on any escalation topics referred to it by the Joint Project Team; and

iii) making such other determinations as are expressly delegated to it under the terms of this Agreement.

(c) Membership. The JSC shall consist of at least two senior personnel of ElevateBio and at least two senior personnel of Client, in each case with authority to make decisions for the appointing Party on issues within the mandate of the JSC. Each member shall have the appropriate background and expertise to contribute to the JSC. Each Party may change its members on the JSC from time to time by providing notice in writing to the other Party. Either Party may, from time to time, invite additional representatives or consultants, who are not JSC members to attend JSC meetings. Prior to attendance of any JSC meeting all attendees must be bound by confidentiality obligations at least as protective to the other Party's Confidential Information as the terms set out in Article 11.

(d) Co-Chairpersons. Each Party shall appoint one of its members to co-chair JSC meetings (each a "**Co-Chairperson**"). The Co-Chairpersons shall attend meetings, ensure the orderly conduct of meetings, and ensure that written minutes of each meeting are taken and issued to each of the Parties.

(e) Meetings. The JSC shall meet as often as agreed by the Co-Chairpersons, but in no event less than twice annually. Such meetings may be conducted by telephone, videoconference or in person as determined by the Co-Chairpersons. Each Party may also call for special meetings of the JSC with reasonable prior notice (it being agreed that at least [...***...] business days shall constitute reasonable notice), to resolve particular matters within the decision-making responsibility of the JSC. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present and participating as a Co-Chairperson.

(f) Decision-Making. The JSC will endeavor to make decisions by consensus of the Co-Chairpersons with each Party having one (1) vote. If a dispute or failure to agree arises which cannot be resolved within the JSC, the JSC shall cause such dispute or failure to agree to be referred to the Senior Officers (or their respective delegates) for resolution. The Senior Officers (or their respective delegates) shall attempt in good faith to resolve such dispute or failure to agree. In the event that the Senior Officers (or their respective delegates) have been unable to resolve such dispute within [...***...] calendar days of the dispute being referred to them, then either Party may escalate such dispute to the chief executive officers of the Parties. If the chief executive officers of the Parties cannot resolve such dispute within [...***...] calendar days, either Party may seek resolution of the dispute in accordance with clauses 6.4, 6.5, and 16.10.

(g) Limits. The JSC shall only have the powers assigned expressly to it in this Agreement. Notwithstanding any provision to the contrary, the JSC shall not have any power to amend or modify the provisions of this Agreement, or to waive compliance with this Agreement and each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JSC.

3.4 Joint Project Teams.

(a) Within [...***...] calendar days after the effective date of a Statement of Work, the Parties will establish a project team ("**Joint Project Team**") which shall consist of each Party's Project Manager (or his/her delegate) and such other employees, or, subject to the approval of the other Party, representatives or consultants of a Party as considered necessary to attend by such Party's Project Manager (or his/her delegate), or assign such Statement of Work to an existing Joint Project Team. The Project Manager (or his/her delegate) role is to track performance under the relevant Statement of Work, provide meeting minutes and coordinate meetings, ensure information is communicated efficiently across the working teams and to initiate any escalations that may be necessary. Prior to attendance of any Joint Project Team meeting all such employees, representatives and consultants of a Party must be bound by confidentiality obligations at least as protective to the other Party's Confidential Information as the terms set out in Article 11. The Joint Project Team shall:

(i). provide a forum for, and facilitate, communications between the Parties with respect to the activities of the Parties under a Statement of Work;

(ii). review, define, monitor, and track metrics associated with performance under a Statement of Work and implement necessary corrections or improvement actions;

(iii). have operational responsibility for coordinating the performance of the Statements of Work, including planning day-to-day operations, managing the addition of markets and/or regions added in accordance with this Agreement, and managing supply priority;

(iv). discuss existing Statements of Work or Change Orders, and discuss new Statements of Work or Change Orders; provided however that any new or amended Statements of Work or Change Orders or any termination of a Statement of Work or Change Order must be mutually agreed to in a written document executed by an authorized representative of each Party in order to become effective;

(v). resolve any disputes between the working groups; provided, that, in the event that the Joint Project Team is unable to resolve any dispute within [...***...] calendar days, either Project Manager (or his/her delegate) may refer such dispute to the JSC for resolution; and

(vi). reporting and escalating (i) - (v) above, as needed, to the JSC.

(b) The Joint Project Team shall hold meetings as often as the Project Managers (or their respective delegates) agree is necessary during the term of this Agreement. Joint Project Team meetings may be held face to face, or by tele- or video-conference, at such times and places as are agreed to by the Parties. All decisions of the Joint Project Team will be made by consensus, and any failure to agree will be referred to the JSC for resolution.

3.5 Performance. ElevateBio shall use commercially reasonable efforts to meet the timelines in each Statement of Work. Each Party, however, acknowledges that there may arise situations that are unavoidable and are likely to impact the timeline. ElevateBio will communicate progress and issues using the agreed governance, project team structure, and communication channels. Where decisions made negatively impact the timeline, the newly proposed timeline will be set as the base case with the agreement of both Parties.

3.6 In the case of an unplanned event that causes a delay, ElevateBio will promptly notify Client within [...***...] business days of becoming aware of the event and will work diligently with the Client to propose the new timeline; provided however, if such event will impact delivery of Product, ElevateBio shall notify Client in accordance with the time period set forth in the Quality Agreement. Either Party may determine that the overall impact of the timeline makes it unlikely to complete the applicable Project. If this is determined, the two Parties may jointly agree on mitigation steps or to terminate the applicable Statement of Work. If a joint decision to terminate a Statement of Work is made, the termination will occur per Section 15.4(d) of this Agreement.

4. **Forecasts; Ordering**.

4.1 Forecasts.

(a) The executed Statement of Work for the Product will provide an initial [...***...] month forecast ("**Forecast**") of the amount of Product that Client will require each month of such [...***...] month period. Thereafter, for the remainder of the term of this Agreement, no later than the [...***...] business day of each month, Client will provide, in writing, rolling monthly updated Forecasts, in which Client will update the Forecast each month for the [...***...] month period following the updated Forecast. Within [...***...] business days after receipt of an updated monthly Forecast, ElevateBio will inform Client, in writing, if it is able to meet the [...***...] binding portion of the forecast, and will provide estimated delivery dates for the first month of the Binding Forecast. If accepted by ElevateBio, each such updated Forecast will be deemed incorporated into the Statement of Work. Client will use commercially reasonable efforts to provide accurate and consistent updated Forecasts based on the information then available to Client at the time.

(b) The first [...***...] months of each Forecast shall be Binding. For purposes of this Agreement, "**Binding**" means ElevateBio has agreed to the Forecast for such [...***...] month period, and there is a financial obligation of Client to pay the Batch Fees for the number of Batches forecasted within such [...***...] month period. Forecasts beyond the [...***...] month Binding period will be non-binding and serve only as good-faith estimates.

4.2 Tiered Capacity.

(a) As part of the rolling Forecast process, Client shall indicate the range of Batch capacity expected for such forecast in accordance with the capacity tiers set forth in the relevant Statement of Work (the "**Capacity Tiers**"). Each Capacity Tier shall include a minimum and maximum number of Batches for each monthly Forecast within such Capacity Tier.

(b) Other Capacity Tiers.

(i). Client may increase Forecasted production by one Tier to a higher Capacity Tier (e.g., Tier 1 to Tier 2; Tier 3 to Tier 4) or any higher Tier (e.g., Tier 1 to Tier 3; Tier 1 to Tier 4) with ElevateBio's prior written consent upon [...***...] months' prior written notice to ElevateBio. In such event, the first [...***...] months of the next monthly Forecast delivered pursuant to Section 4.1 shall remain under then-current Capacity Tier and the increase to the next Capacity Tier shall only take effect for the [...***...] month of such Forecast, provided that any succeeding months shall remain non-Binding until such point that these succeeding months fall into the [...***...]-month Binding window. Notwithstanding the foregoing, ElevateBio shall use commercially reasonable efforts to increase production to the next Capacity Tier earlier if so required by Client's then current Forecast. Client shall not increase Forecasted production beyond the next consecutive Capacity Tier without ElevateBio's prior written consent.

(ii). Client may decrease Forecasted production to an adjacent lower Capacity Tier (e.g., Tier 3 to Tier 2) upon [...***...] months' prior written notice to ElevateBio. In such event, the first [...***...] months of the next monthly Forecast delivered pursuant to Section 4.1 shall remain under then-current Capacity Tier and the decrease to the prior Capacity Tier shall only take effect for the [...***...] month of such Forecast, provided that any succeeding months shall remain non-Binding until such point that these succeeding months fall into the [...***...] month Binding window.

4.3 Production Lot Maximum. During the term of this Agreement, ElevateBio shall accommodate Client's Manufacturing needs for the Product as set forth in a Binding Forecast (inclusive of training, demonstration, engineering runs plus clinical and/or commercial Batches) up to the maximum number of monthly Batches in the highest Capacity Tier in the then-current Forecast (the "**Production Lot Maximum**"). ElevateBio shall be required to supply the quantity of Product specified in the applicable Binding Forecast, subject to the Production Lot Maximum. In the event that ElevateBio fails to meet the Binding Forecast production needs in a month due to factors under ElevateBio's reasonable control (and for the avoidance of doubt not due to Force Majeure event), ElevateBio shall, at Client's request, meet a previous month minimum Batch deficit by Manufacturing the amount of such deficit in the following months (in addition to the requirement for such months set forth in the Binding Forecast). If Client requests additional Batch production beyond the Production Lot Maximum in any given month, ElevateBio will use commercially reasonable efforts to accommodate such needs, provided that additional Batch fees will be charged for the additional lot(s), additional fees may apply (as specified in the SOW, as applicable) and ElevateBio will not have any liability if it cannot supply such additional lot(s).

4.4 Purchase Orders. Client shall issue purchase orders (each, a "**Purchase Order**") that are consistent with Client's Forecast in order to satisfy the Binding Requirement for each Product. Any such Purchase Order at the time of issuance may be submitted by Client to ElevateBio as a blanket Purchase Order sufficient to cover the total obligations of the then-current Binding Forecast (i.e., the next [...***...] months) and amounts anticipated to cover Raw Materials during such time period, as may be updated from time to time. The final Purchase Order shall specify the Product and (a) the country of intended use or sale (b) an order number, (c) the Product form (*i.e.*, drug product or finished product), (d) the intended use (e.g., clinical or commercial), (e) the quantity of Product, and (f) the desired delivery dates (consistent with the estimated delivery dates provided by ElevateBio). Client will submit all Purchase Orders for the initial Binding Forecast upon execution of the Statement of Work and additional Purchase Orders for new Binding Forecast along with its updates to the Forecast. All Purchase Orders for Product submitted by Client to ElevateBio meeting the requirements of this Section 4.4 that (x) are for quantities of Product not exceeding the Binding Forecast or (y) are otherwise accepted by ElevateBio in writing shall be deemed accepted by ElevateBio ("**Accepted Purchase Orders**"). Notwithstanding ElevateBio's acceptance of any Accepted Purchase Order, (A) ElevateBio shall not be obligated to supply, and shall not be in breach of this Agreement for failure to supply, quantities of Product in excess of the Binding Forecast, and (B) in the event that Client fails to submit Accepted Purchase Orders for at least the Binding Forecast in accordance with this Section 4.4 or for at least the minimum requirements in the then-current Capacity Tier, then, without limiting any rights or remedies available to ElevateBio, ElevateBio shall be permitted to invoice Client, and Client shall pay such invoice in accordance with Article 9 below, with respect to such remaining quantity of Product not ordered.

4.5 Packaging. The requirements for the packaging of the Product for delivery to Client shall be set forth in the applicable Specification and the applicable SOW, and such requirements shall: (a) provide for packaging customary for similar items that are designed to protect the Products during shipment, (b) comply with any applicable environmental regulations; and (c) contain the proper labeling as reasonably instructed by Client pursuant to this Agreement in addition to ElevateBio's requirements based on its Regulatory Approvals for such Product.

5. Materials and Equipment.

5.1 Supply of Raw Materials. Unless the Parties otherwise agree in a Statement of Work, ElevateBio will procure, in accordance with the relevant approved Raw Material specifications and bill of materials (in the case of Manufacturing Services) per the safety stock targets, which shall be mutually agreed by the Parties, all Raw Materials and Testing Materials to be used by ElevateBio in the performance of Services under a Statement of Work other than the Client Materials specified in such Statement of Work. With regard to Raw Materials, ElevateBio shall, in accordance with the terms of such Statement of Work, pass through to Client the cost of Raw Materials and related Third Party shipping, handling, brokerage, storage, and other fees plus a Processing Fee of (a) [...***...], and (b) [...***...], as specified in the applicable Statement of Work. ElevateBio may charge Client for any additional Raw Materials that are required as a result of a change to a Statement of Work, provided that in each case the cost of such Raw Materials (or commensurate change in fees if not billed on a time and materials basis) will be agreed to in advance in the applicable Change Order. ElevateBio may not charge Client for any additional Raw Materials that are required as a result of any loss, damage, or theft of prior Raw Materials caused

by or due to ElevateBio's negligence, willful misconduct, or breach of this Agreement. ElevateBio will work in good faith to obtain a reduction in price on Raw Materials from the applicable suppliers based on the estimated volume of Raw Materials expected to be used by ElevateBio for the then-current Forecast, at a minimum on [...***...] basis, and to pass on such price reduction to Client. For avoidance of doubt, [...***...] will be included in the Batch Fee.

5.2 Supply of Client Materials. Client or its designees will, at Client's expense, provide ElevateBio with the Client Materials. ElevateBio agrees (a) to account for all Client Materials and to handle, use, and store Client Materials under suitable conditions at the Facility in accordance with the applicable handling and storage requirements, if any, set forth on the applicable Statement of Work or the Quality Agreement, as well as GMPs, all Applicable Law, and any applicable specifications for such Client Materials provided by Client to ElevateBio; (b) not to use Client Materials for any purpose other than conducting the Services; (c) without limiting the generality of the foregoing, not to analyze, characterize, modify, or reverse engineer any Client Materials or take any action to determine the structure or composition of any Client Materials unless required pursuant to conducting the Services; and (d) to destroy or return to Client, at Client's expense, all unused quantities of Client Materials according to Client's written directions. Client will at all times retain title to and ownership of the Client Materials and ElevateBio shall ensure that no pledges, liens, restrictions, claims, charges, security interests, or other encumbrance are placed on such Client Materials, other than by the Client or its Affiliates.

5.3 Protection of Client Materials from Loss, Damage, and Theft; Replacement of Client Materials. ElevateBio will at all times use commercially reasonable efforts to protect the Client Materials from loss, damage, and theft at all stages of the Manufacturing Process. ElevateBio will promptly notify Client if at any time it believes any Product or Client Materials have been damaged, lost, or stolen. ElevateBio will be responsible for the replacement costs of all Client Materials to the extent caused by or due to ElevateBio's negligence, willful misconduct or breach of this Agreement; provided that, in such event the replacement cost shall be calculated using the follow formula: as relates to [...***...] multiplied by [...***...] cost per [...***...], plus (b) Client's [...***...] cost per [...***...], [...***...], based on Client's [...***...]. Client will promptly provide ElevateBio with documentation evidencing the [...***...] of [...***...] and [...***...] following any such loss or damage. ElevateBio shall prepare and maintain documents showing receipt, inventory, location, handling, and storage of Client Materials at the Facility, including but not limited to, the quantities of all Client Materials on hand and utilized to Manufacture Product or perform Services hereunder (in each case, broken down on a material-by-material basis), and shall provide copies thereof to Client upon request. For clarity, Product replacement for Non-Conformance and Latent Defects is covered in Section 7.5 hereof.

5.4 Supply of Client Equipment.

(a) Client Equipment Generally. The Parties shall set forth the Client Equipment necessary to perform the Services in each applicable Statement of Work.

(b) Requirements for Client Equipment. Client shall ensure that any Client Equipment meets all applicable criteria for use in Development or Manufacturing, including GMP Manufacturing as required in connection with the Services under the applicable Statement of Work. Client will be responsible for ensuring that all Client Equipment complies with its applicable specifications, and delivery of the Client Equipment to ElevateBio will not be deemed to have been completed unless and until the Client Equipment complies with its specifications. ElevateBio will notify Client if ElevateBio identifies any issues with the Client Equipment at the time of its delivery. The Parties will work together to resolve any issues that are identified. ElevateBio shall use and maintain Client Equipment in accordance with all Applicable Law.

(c) Purchase of Client Equipment. Prior to purchasing any Client Equipment, ElevateBio will provide to Client for written approval (including via email) a quotation for the purchase of the Client Equipment, which will include a quotation for installation and qualification package, an extended warranty, and/or maintenance plan as appropriate. After Client approval of the quotation (including via email), ElevateBio will invoice Client for the purchase of the Client Equipment including the installation and qualification fees according to the terms agreed to between the Parties via written approval. In consideration for the purchase, installation, qualification, and maintenance of the Client Equipment, Client agrees to reimburse ElevateBio (i) the Client Equipment purchase price, (ii) the shipping and handling fees, (iii) the installation and qualification package fees, (iv) associated software (including software upgrades and/or required re-qualifications driven by equipment needs), (v) Processing Fee of [...***...] on the purchase price and other pass-through costs unless otherwise agreed in the applicable Statement of Work and (vi) any other fees or costs that Client has provided written approval for (including via email). Client also agrees to reimburse ElevateBio for the extended warranty fees, and any associated taxes. For clarity, re-qualification requirements beyond initial qualification shall be subject to a Change Order.

(d) Title to Client Equipment. ElevateBio will not use the Client Equipment except in the performance of Services under the applicable Statement of Work. As between the Parties, title to the Client Equipment will remain with Client, and ElevateBio will ensure that the Client Equipment is labeled in such a way so as to allow it to be identified as the property of Client and remains free and clear of any liens or encumbrances. At Client's written request and Client's expense, the Client Equipment will be returned to Client, or to Client's designee.

(e) Location and Maintenance of Client Equipment. ElevateBio shall at all times use commercially reasonable efforts to maintain a suitable environment for the Client Equipment and furnish all necessary and appropriate utilities for its operation and maintenance. ElevateBio shall not move the Client Equipment from the Facility without the prior written consent of Client. ElevateBio shall use commercially reasonable efforts to maintain the Client Equipment in a clean and orderly condition and protect the Client Equipment from deterioration other than normal wear and tear. ElevateBio shall use, operate, and maintain the Client Equipment in the regular course of business only, within its normal capacity, without abuse, and in a manner consistent with any instructions provided by the manufacturer of the Client Equipment and all Applicable Law. ElevateBio

will be responsible, at Client's cost (except as set forth in the last sentence of this Section 5.4(d)), for maintenance of the Client Equipment. To the extent Client provides spare parts for the Client Equipment, such spare parts will remain the property of Client and will be used by ElevateBio only for maintenance of the Client Equipment. ElevateBio will at all times use commercially reasonable efforts to protect the Client Equipment from loss, damage, and theft. ElevateBio will promptly notify Client if at any time it believes any Client Equipment has been damaged, lost, or stolen. ElevateBio will be responsible for the repair or replacement costs of all Client Equipment to the extent caused by ElevateBio's negligence, willful misconduct, or breach of this Agreement.

(f) Client Equipment Disclaimer. All Client Equipment is provided on an 'AS IS' basis. Other than as provided in this Agreement, Client makes no representations and extends no warranties of any kind, either express or implied, regarding the Client Equipment.

6. **Development and Manufacture of Product.**

6.1 Applicable Law. Each Party will comply with all Applicable Law in performing all activities under or in relation to this Agreement.

6.2 Facility.

(a) Performance of Services. ElevateBio will perform all Services at the Facility, provide all Personnel necessary to perform the Services in accordance with the terms of the applicable Statement of Work and this Agreement, and hold at such Facility all Equipment, Client Equipment, Client Materials, and other items used in the Services. ElevateBio will not change the location of such Facility that Manufactures Batches without at least [...***...] months' prior written notice to, and prior written consent (including via email) from Client, which consent will not be unreasonably withheld or delayed; provided, however, Client may reasonably withhold approval of a change to the location of such Facility in the case that such change could cause a change to the cost of services and/or impact any related regulatory filings under the applicable Statement of Work. In the event Client does not consent to the proposed location change in (or addition of) such Facility, the Parties shall resolve the dispute in accordance with Section 16.10. For clarity, upon prior written notice to Client, ElevateBio may subcontract the performance of all non-Manufacturing Services to its Affiliates or Third Parties in accordance with Section 3.2, provided that any such non-Manufacturing Services have no impact on related regulatory filings. ElevateBio will maintain, at its own expense (other than expenses for Client Equipment, subject to Section 5.4) the Facility and all Equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of GMP (if applicable) and all Applicable Law.

(b) Validation. ElevateBio will be responsible for performing all qualification or validation of the Facility, Equipment (including conducting installation, operational, and performance qualification, as applicable), and maintenance processes employed in the Manufacturing Process in accordance with GMP (if applicable), ElevateBio's standard operating procedures ("**SOPs**"), the applicable Quality Agreement, Applicable Law, any other validation procedures established mutually by Client and ElevateBio, and in accordance

with any validation procedures required by any Authority in a country in which Client will use or sell the Product as set forth in the Quality Agreement or applicable Statement of Work; provided, however, that the cost of validation of Client Equipment will be the responsibility of Client.

(c) Licenses and Permits. ElevateBio will be responsible for obtaining and maintaining, at its own expense, any Facility or other licenses or permits, and any regulatory and government approvals necessary for the performance of Services by ElevateBio under this Agreement. Notwithstanding the foregoing, as articulated in a Statement of Work, or Change Order thereto as necessary, if certain licenses or permits specific to the Product are required for ElevateBio to perform the Services, the cost of such licenses or permits shall be at Client's expense.

(d) Noncontravention. ElevateBio will not enter into any agreements, licenses, or other arrangements of any kind with any Third Parties or Affiliates that are in contravention of the provisions of this Agreement.

(e) Audit. ElevateBio will, upon reasonable advance notice, permit authorized personnel of Client's quality group (or Third Party consultants engaged by Client) to have access, during operational hours, upon reasonable notice, and subject to confidentiality terms, to inspect the Facility and Manufacturing Process to ascertain compliance by ElevateBio with the terms of this Agreement, any Statement of Work, any Quality Agreement, and Applicable Law, including inspection of (i) the Equipment and materials used in the performance of Services; (ii) the holding facilities for such materials and Equipment; and (iii) all Records relating to such Services and the Facility. Client is allowed an additional audit when market authorizations are expected for the Product. The additional audit will be requested to be scheduled at least [...***...] months in advance of any Product Licensure Inspection ("**PLI**") or facility inspection from Authorities related to Product licensure and will be for the purpose of the Client ensuring facility readiness. Other than "for-cause" inspections, Client may not conduct inspections under this Section 6.2(e) (x) more than [...***...] during any [...***...] period, except as required in support of a new manufacturing authorization or manufacturing license required to supply product in a new region; (y) for a duration greater than [...***...] business days; or (z) using more than [...***...] Client employees or representatives, except where a Qualified Person ("**QP**") declaration is the intended outcome, in which case a [...***...] employee (the QP) can attend. For the avoidance of doubt, each Party shall be responsible for its own costs and expenses incurred for the audit activities outlined in this Section 6.2(e).

6.3 Changes to Statements of Work; Manufacturing Process and Specification.

(a) Changes to Statements of Work. If the scope of work of a Statement of Work changes, then the applicable Statement of Work may be amended as provided in this Section 6.3(a). If a required modification to a Statement of Work is identified by Client or by ElevateBio, the identifying Party will notify the other Party in writing as soon as reasonably possible. ElevateBio will provide the Client Representative named in the relevant SOW and the Project Manager with a change order containing a description of the required modifications and their effect on the scope, fees, and timelines specified in the Statement of Work,

substantially in the form attached hereto as Appendix B ("**Change Order**"), and will use reasonable efforts to do so within [...***...] business days of receiving or providing such notice, as the case may be. No Change Order will be effective, and ElevateBio will not perform any work under the requested Change Order, unless and until it has been signed by authorized representatives of both Parties.

(b) Process/Specification Changes. Any change or modification to the Manufacturing Process or Specification for any Product proposed by ElevateBio must be approved in advance by Client and will be made in accordance with the change control provisions of the applicable Quality Agreement.

6.4 Records; Sample Retention.

(a) Records. ElevateBio will keep complete and accurate records of all work done by it under this Agreement, in form and substance as specified in the applicable Statement of Work, the applicable Quality Agreement, this Agreement, and Applicable Law (collectively, the "**Records**"). All Records will be retained by ElevateBio as required by the applicable Quality Agreement or by Applicable Law. "**Deliverables**" means all Records and any other work product, tangible or intangible, that ElevateBio or its Personnel are required to deliver to Client under a Statement of Work or the applicable Quality Agreement. Deliverables will be the sole property of and are hereby assigned to Client, provided that, if any information of ElevateBio Technology is included in the Deliverables, such ElevateBio Technology shall not be deemed to be Deliverables and ElevateBio shall retain the sole and exclusive ownership of such ElevateBio Technology. All other Records not included in the Deliverables will be the property of ElevateBio. ElevateBio will not transfer, deliver, or otherwise provide Records to any Third Party other than Third Party subcontractors, without the prior written approval of Client. All Records, including original records of the Development and Manufacture of Product under this Agreement, will be retained and archived by ElevateBio in accordance with GMP (if applicable) and Applicable Law. Upon Client's request, upon reasonable notice, ElevateBio will provide Client with copies of such Records, at Client's expense. Client may use such copies that relate to Records other than Deliverables solely for the purpose of fulfilling its obligations and exercising its rights under this Agreement and provided that, except as provided in Section 10.8 or Section 11.3, in no event will Client disclose Records (excluding Deliverables) to any Third Party without obtaining ElevateBio's prior written consent. For clarity, except as expressly provided in Section 10.8, or to the extent expressly identified in a Statement of Work to be delivered to Client, ElevateBio will not be required to provide confidential or trade secret information regarding its proprietary methods or technologies constituting ElevateBio Background Technology, ElevateBio Inventions, or ElevateBio's Confidential Information to Client except to fulfill any Authority documentation requirements with respect to a Product.

(b) Sample Retention. ElevateBio will take and retain, for such period and in such quantities as may be required by GMP (if applicable), Applicable Law, the applicable Statement of Work, and the applicable Quality Agreement, samples of Product from the Manufacturing Process produced under this Agreement. ElevateBio shall be responsible for any and all losses and casualties to such samples and quantities resulting from ElevateBio's

negligence, willful misconduct, or breach of this Agreement unless and until either delivered to Client or destroyed or disposed of at Client's direction. All such samples and quantities shall be used by ElevateBio solely for the purposes of this Agreement and for no other purpose. Further, upon Client's written request, ElevateBio will transfer such samples to Client, at Client's expense. ElevateBio will notify Client upon completion of the retention period for any such samples required under GMP and the applicable Quality Agreement, and if Client does not request shipment of such samples at Client's expense within [...***...] calendar days of such notification, then ElevateBio may destroy any such samples remaining in its possession at Client's expense. ElevateBio shall perform any such destruction in compliance with Applicable Law.

6.5 Regulatory Matters.

(a) Regulatory Approvals. Client will be responsible for obtaining, at its expense, all regulatory and governmental approvals and permits necessary for Client's use of any Product Developed or Manufactured under this Agreement, including investigational new drug application, biologics license application, new drug application, and abbreviated new drug application submissions and any analogous submissions filed with the appropriate Authority of a country other than the United States. As between the Parties, Client shall have the sole right to prepare and file for the health registrations for the Product with the applicable Authorities, provided that ElevateBio will have the right to communicate with all applicable Authorities in connection with its Facility or Manufacturing Process or as otherwise required by Applicable Law. ElevateBio will provide Client, at Client's expense, with supporting data and information, other than Facility Master File contents, relating to the Development or Manufacture of any Product necessary for obtaining and maintaining such approvals and permits, which activities shall be performed by ElevateBio in compliance with all Applicable Law. To the extent any information relating to the Facility Master Files is required by the Authorities, Client shall promptly notify ElevateBio in writing and authorize ElevateBio to submit or otherwise communicate directly with the Authorities regarding such information. If determined by Client (in its sole discretion), Client shall have the right to include a designation of ElevateBio and the approved facility as a Manufacturer and Manufacturing site of Product in the applicable health registrations. Client will provide ElevateBio with copies of any written communication received from any Authority relating to any Product (if it relates to or affects the Services) or ElevateBio Technology and will consult with ElevateBio with respect to any responses thereto, in each case according to the processes or procedures set forth in the Quality Agreement.

(b) Regulatory Inspections. Client or its agents have the right to be present in any visit or inspection by any Authority of the Facility to the extent it relates in any way to any Product or Client Background Technology or Client Invention used in the Manufacturing Process. The Client may, with ElevateBio's prior consent, participate in the Product relevant inspection (such as a pre-license inspection or a foreign equivalent) to the extent that the Client's knowledge of the Product can facilitate the conduct of the inspection. At no time can the Client interact with the inspector(s) during such inspection of the Facility without the representatives of ElevateBio being present and leading the discussions. ElevateBio will give notice to Client of any such visit or inspection, and to the extent reasonably possible will give advance notice to Client of such visit or inspection. ElevateBio will

provide Client with a copy of any report or other written communication received from such Authority in connection with such visit or inspection, and any written communication received from any Authority relating to any Product, the Facility (if it relates to or affects the Development or Manufacture of Product) or Client Background Technology or Client Invention used in the Manufacturing Process, within [...***...] business days after receipt, and will consult with Client before responding to any such communication. ElevateBio will provide Client with a copy of its final responses within [...***...] business days after submission.

(c) Client will provide timely notice to ElevateBio of Client's intent to add additional regions to the approved markets list, as articulated in the Quality Agreement, and planned timing of such addition(s). Any such additional regions will require the prior written approval of ElevateBio, not to be unreasonably withheld. The Parties will negotiate in good faith a Change Order. ElevateBio will use commercially reasonable efforts to upgrade any of their applicable operations in accordance with the Change Order corresponding to such additional region in order to come into compliance with the applicable laws and regulations of such new proposed region(s) that have been approved by ElevateBio. Client will reimburse ElevateBio for all reasonable costs and expenses incurred by ElevateBio in connection with such upgrade.

6.6 Waste Disposal. The generation, collection, storage, handling, transportation, movement, and release of hazardous materials and waste generated in connection with the Services will be the responsibility of ElevateBio at ElevateBio's sole cost and expense. Without limiting other applicable requirements, ElevateBio will prepare, execute, and maintain, as the generator of waste, all licenses, registrations, approvals, authorizations, notices, shipping documents, and waste manifests required under Applicable Law. Client must notify ElevateBio of any hazardous conditions or wastes known to Client that may exist or be produced in the course of performing the Services contemplated by this Agreement or any Statement of Work prior to ElevateBio's performance of such Services.

6.7 Safety Procedures. ElevateBio will be solely responsible for implementing and maintaining health and safety procedures for the performance of Services and for the handling of any materials or hazardous waste used in or generated by the Services. ElevateBio, in consultation with Client, will develop safety and handling procedures for Product; *provided, however*, that Client will have no responsibility for ElevateBio's health and safety program. For each Product, Client shall provide ElevateBio with all relevant information in Client's possession or control concerning any health hazards or potential health hazards associated with exposure to or the handling, storage, use, or disposal of such Product or the Raw Materials used in the Manufacturing Process or in the course of performing the Services contemplated by this Agreement or any Statement of Work prior to ElevateBio's performance of such Services. Without limiting the foregoing, Client shall provide to ElevateBio a copy of all applicable material safety data sheets, safe handling instructions, health and environmental information, and any regulatory certifications or authorizations that may be required under Applicable Law or necessary or useful in the performance of the Services and shall promptly provide any updates thereto.

6.8 Delays by Client.

(a) Delays due to Client Preparedness. ElevateBio reserves the right to cancel or postpone, in its sole discretion, any part or all of the Services to be completed under a Statement of Work upon written notice to Client, if, for a period of not less than [...***...] months, Client fails to timely supply conforming Client Materials, Client Equipment, Client Background Technology or other information or approvals in accordance with the requirements set forth in this Agreement or the applicable Statement of Work and such failure would result in a material delay or inability of ElevateBio to perform the applicable Services. Such cancellation shall be deemed, solely for purposes of Section 15.5(b), a termination of the applicable Statement of Work pursuant to Section 15.4(b), in which case all of the terms under this Agreement applicable to termination pursuant to Section 15.4(b), and ElevateBio shall have no further obligations with respect to such Statement of Work. In the event of postponement, ElevateBio shall use commercially reasonable efforts to reschedule the Services to the next available slot following receipt of all conforming Client Materials, Client Equipment, Client Background Technology, information and approvals (which, for clarity, imposes no obligations on ElevateBio to reschedule slots that have already been filled by other clients), subject to Section 6.8(c).

(b) Delays due to Client Request.

(i). With respect to Batches subject to the Binding portion of a Forecast, upon written notice delivered to ElevateBio at least [...***...] business days prior to the planned manufacturing start date of such Batches, Client may reschedule Batches within the [...***...] binding period without incurring any delay or cancellation fees, so long as such rescheduling does not result in the tier maximum for any month being exceeded. Additionally, [...***...] per calendar month as part of the monthly Forecast process, Client may reschedule Batches to a period outside the [...***...] month binding period without incurring any delay or cancellation fees, so long as such rescheduling does not result in the tier maximum for any month being exceeded. For the avoidance of doubt, rescheduled Batches shall count towards the batch minimum set forth in the applicable Statement of Work or towards any minimum batch requirement within a Tier Capacity, in either case, for the original month to which such Batches were scheduled. With respect to any rescheduled Batches, Client will be invoiced for [...***...] of the fees and expenses for such delayed binding Batches during the month in which the original initiation date occurs. The remaining [...***...] will be invoiced upon Delivery of the Batches.

(ii) With respect to other Services not covered in (b)(i) above, upon written notice delivered to ElevateBio at least [...***...] calendar days prior to the scheduled start date for such Services, Client may reschedule such Services to a mutually agreed date no more than [...***...] calendar days following the original start date without incurring any delay or cancellation fee.

(iii) The Parties hereby agree that if Client requests to delay part or all of the Services for a period of greater than [...***...] months, ElevateBio may elect, at its sole discretion, to terminate the entirety of the Statement of Work applicable to the effected Services pursuant to Section 15.4(b), and all of the terms under this Agreement applicable to termination by

ElevateBio pursuant to Section 15.4(b) shall apply to such termination; provided, however, that this Section 6.8(b)(iii) shall not apply to delays requested by Client in accordance with Section 6.8(b)(i).

(c) Effects of Delays.

(i). If Manufacturing Services are delayed or cancelled, and, in each case, such delay is not directly due to a breach, default, or delay on the part of ElevateBio, then, subject to Section 6.8(b)(i), Client shall pay the fees and expenses for any delayed Batches in the Binding portion of the Forecast as if the Batches had been manufactured on their originally scheduled dates; provided, however, that such payment shall not excuse Client from payment for such delayed Batches when the Batches are actually Manufactured and delivered. In addition, if the payment terms under a Statement of Work include any applicable batch minimum fee, such fees shall continue to apply during any delay of the Services under a Statement of Work or any portion thereof.

(ii). If non-Manufacturing Services are delayed or cancelled, and, in each case, such delay is not directly due to a breach, default, or delay on the part of ElevateBio, then, subject to Section 6.8(b)(ii), Client agrees to pay ElevateBio a delay fee equal to the [...***...] for [...***...] by such delay under the applicable Statement of Work that cannot be mitigated by reasonable efforts, including any non-cancellable third party costs.

(d) Batch Minimum Fees. If the payment terms under a Statement of Work include any applicable Batch Fee minimum, such fees shall continue to apply during any delay pursuant to Section 6.8(a) or Section 6.8(b) of the Services under a Statement of Work or any portion thereof.

6.9 Delays by ElevateBio. In the event of any delay by ElevateBio in performing Services other than pursuant to Section 16.2, or caused by Client as set forth in Section 6.8(a) or Section 6.8(b), then (i) ElevateBio will promptly inform Client, within [...***...] hours as relates to Manufacturing and within [...***...] business days as relates to other Services, and the Parties will promptly discuss next steps with respect to the impacted Services, (ii) ElevateBio will use commercially reasonable efforts to remediate the situation, and (iii) if ElevateBio is unable to remediate the situation within [...***...] calendar days following the onset of the delay, Client may, in its sole discretion, (x) allow ElevateBio additional time to continue their remediation efforts, or (y) elect to cancel the impacted Services and, if Client already paid the fees in relation to such impacted Services, ElevateBio shall issue to Client a credit in an amount equal to such fees, unless otherwise specified in the applicable SOW.

Notwithstanding the foregoing, with respect to commercial supply of the Product, in the event of any delay by ElevateBio in performing (a) the Batch start (per the original slot date forecast) and/or (b) completion of the Batch record documentation (within [...***...] calendar days of conclusion of batch manufacturing)) in accordance with the timelines set forth in Section 14.4 of the Quality Agreement), where such delay does not result from (i) any Client request to delay such Services or (ii) Client's refusal or failure to timely supply relevant conforming Client Materials, Client Equipment, or other information or approvals in accordance with the requirements set forth in this Agreement and the Statement of Work, or (iii) Force Majeure, then ElevateBio shall supply the

delayed Batch at the rates reflected in the table below as Client's exclusive remedy for such Batch delay; provided that the foregoing shall not apply to delays in the commercial supply of the Product in excess of the Production Lot Maximum. For the avoidance of doubt, nothing in this Section 6.9 shall preclude Client from asserting that repeated delays by ElevateBio constitute a material breach, and from exercising any remedies available under this Agreement with respect to such repeated delays.

Batch Start/Release Date (Calendar Days)	**Batch Fee Adjustment**
[...***...] Days late	[...***...] reduction in Batch Fee
[...***...] Days late	[...***...] reduction in Batch Fee
[...***...] Days late	[...***...] reduction in Batch Fee

7. **Testing and Acceptance Process**.

7.1 Testing by ElevateBio. Prior to Delivery to Client, each Batch of Product will be sampled and tested by ElevateBio against the applicable Specification and in accordance with the applicable Quality Agreement and Applicable Law, and ElevateBio will review the documentation relating to the Manufacture of the Batch and will assess if the Manufacture has taken place in compliance with the Manufacturing Process and GMP. ElevateBio will complete their review and disposition the Batch in accordance with the Quality Agreement. For the avoidance of doubt, Client takes full responsibility for the suitability of the Specification for obtaining a Product that possesses Client's desired characteristics and is suitable for Client's intended purposes, and ElevateBio assumes no responsibility for any deficiency of the Specification in this regard.

7.2 Provision of Records. Following the tests and documentation review described in Section 7.1, ElevateBio shall provide Client with a copy of the applicable Batch Documentation. For purposes of this Agreement, "**Batch Documentation**" means (a) with respect to Product that is Manufactured using a proprietary Manufacturing Process of ElevateBio, a Certificate of Analysis, the applicable Specification, the Batch record (redacted as necessary), and a Batch manufacturing summary that includes in-process control results, any applicable deviations, and any other information specified in the applicable Statement of Work, or (b) with respect to a Product that is Manufactured using Client's own Manufacturing Process, the production record pertaining to the Batch, a Certificate of Analysis, the applicable Specification, and a complete and accurate copy of such other documents specified in the applicable Statement of Work. Batch Documentation shall also include any other data and records as agreed to in the Quality Agreement.

7.3 Review of Batch Documentation; Acceptance. Client will review the Batch Documentation for each Batch of Product. Client may reject a Batch of Product only if such Batch is a Non-Conforming Batch. Client will notify ElevateBio in writing of its acceptance or rejection of such Batch in accordance with the processes or procedures set forth in the Quality Agreement. For clarity, "**Delivery**" of a Batch Product shall mean the earliest of (a) Client's notification of its acceptance of such Batch in accordance with this Section 7.3, (b) shipment of the Batch Product to Client from the Facility or (c) if mutually agreed in writing by the Parties, storage of such Batch of Product after release at the Facility in accordance with the applicable Statement of Work.

7.4 Disputes. In case of any disagreement between the Parties as to whether Product conforms to the applicable Specification or GMP or was Manufactured in accordance with the Manufacturing Process, the quality assurance representatives of the Parties will endeavor in good faith to resolve any such disagreement and Client and ElevateBio will follow the applicable Quality Agreement and their respective SOPs to determine the conformity of the Product to the applicable Specification and GMP and whether such Product was Manufactured in compliance with the Manufacturing Process. In the event that the Parties do not resolve such disagreement within [...***...] calendar days of such disagreement being brought before the Parties, the Parties will appoint an independent Third Party expert mutually agreed to by the Parties to resolve such disagreement based on a review of the relevant data. In the absence of fraud or manifest error, the Third Party expert's determination will be binding on the Parties, and the fees of such Third Party expert shall be borne by the Party that is not the prevailing Party.

7.5 Product Non-Compliance and Latent Defects; Product Loss, Damage, or Theft; Remedies.

(a) Non-Conforming Batches and Latent Defects. If (i) a Batch of Product is lost, stolen, or damaged, or fails to comply with the applicable Specification, applicable Statement of Work, applicable Quality Agreement, or Applicable Law at the time of release (as relates to a Batch, a "**Non-Conforming Batch**" or otherwise a "**Non-Conformance**"), or (ii) a Latent Defect is identified, then ElevateBio will use commercially reasonable efforts to Manufacture a replacement Batch of Product as soon as possible. For clarity, use of a component, intermediary or Raw Material, other than in compliance with the bill of materials or the Quality Agreement, shall cause the affected Batch of Product to be Non-Conforming to the extent such use causes the Batch of Product to fail to comply with the Specifications or Applicable Law at the time of release.

(b) Non-Conforming Batches and Latent Defects Caused by ElevateBio Negligence, Willful Misconduct, or Breach. To the extent that the Non-Conformance, Non-Conforming Batch, or Latent Defect is due to ElevateBio's negligence, willful misconduct, or breach of this Agreement, and does not arise or result from a defect in the Client Materials that was present at the time such Client Materials were delivered to ElevateBio, the Parties shall engage in a good faith discussion and, subsequently, at Client's sole discretion, (i) replace the Non-Conforming Batch or the Batch impacted by the Non-Conformance or Latent Defect [...***...] to Client and at its own cost and expense, including Client Materials used in the replacement Batch (with the cost of Client Materials calculated in accordance with Section 5.3) on a timeline to be mutually agreed by the Parties, or (ii) issue to Client a credit in the amount of (A) any monies paid to ElevateBio, as set forth in the applicable Statement of Work, toward the cost of the Non-Conforming Batch or Batch impacted by the Non-Conformance or Latent Defect, and (B) the cost associated with the Client Materials used in the Manufacturing of the Non-Conformance or Latent Defect, using the calculation method articulated in Section 5.3. For the avoidance of doubt, [...***...] as determined by [...***...], shall, for the purposes of this Section 7.5(b) be deemed "negligence."

(c) Non-Conforming Batches and Latent Defects Caused by Other. ElevateBio shall, when Section 7.5(b) is not applicable, use commercially reasonable efforts to replace any Non-Conforming Batch or Batch impacted by a Latent Defect at Client's expense for the replacement Batch, subject to Section 7.7, on a timeline to be mutually agreed by the Parties.

(d) Evaluation. In the event a Batch of Product is a Non-Conforming Batch, the Parties will meet to discuss, evaluate, and analyze the reasons for and implications of such failure and will decide whether to proceed with or to amend the applicable Statement of Work via a Change Order, or to terminate such Statement of Work pursuant to Section 15.4(d).

7.6 Product Recalls. In the event Client shall be required to recall any Product, or elects to institute a voluntary recall, Client shall be responsible for coordinating such recall. Client shall promptly notify ElevateBio if any Product is the subject of a recall and provide ElevateBio with a copy of all documents relating to such recall. ElevateBio shall fully cooperate with Client in connection with any recall, at Client's cost. Client shall be responsible for all of the costs and expenses related to any such recall. Notwithstanding the foregoing, to the extent such Product recall results directly from a Non-Conforming Batch or a Latent Defect caused by (i) ElevateBio's gross negligence, fraud, or willful misconduct, and does not arise or result from a defect in the Client Materials that was present at the time such Client Materials were delivered to ElevateBio, ElevateBio shall be responsible for reimbursing all documented, out-of-pocket third party costs for the recall of such affected Product Batch(es), or (ii) ElevateBio's negligence or breach of this Agreement and does not arise or result from a defect in the Client Materials that was present at the time such Client Materials were delivered to ElevateBio, ElevateBio shall be responsible for reimbursing all documented, out-of-pocket third party costs for the recall of such affected Product Batch(es) subject to the limitations set forth in Section 13.5(a) and (b).

7.7 No ElevateBio Responsibility for Genetic Alterations. ElevateBio will not be responsible for genetic alterations that occur during Manufacturing of any Product except for any genetic alterations specifically required under the applicable Statement of Work and except for any genetic alterations that result from ElevateBio's negligence or willful misconduct. Without limiting the foregoing sentence, such genetic alterations will not be the basis for any claim by Client under this Agreement, including any claim under this Section 7.

7.8 Development Batches. Notwithstanding anything to the contrary in this Section 7, if a Statement of Work specifies the performance of training, demonstration, or engineering runs, ElevateBio shall perform one or more such runs to manufacture Batches (in any such case, "**Development Batches**") in accordance with the applicable Statement of Work and Applicable Law. There will be no specifications for acceptance of Development Batches, but the Parties may agree upon certain target quality attributes to aim for, as set forth in the applicable Statement of Work. ElevateBio shall provide analytical testing of Development Batches as agreed by the Parties in the applicable Statement of Work and will report the results to Client. Client shall have the right to make any use of such Development Batches as it shall determine in its discretion; provided that such use does not violate Applicable Law; and, provided further, that ElevateBio shall in no way be responsible for any claims, demands, losses, liabilities, expenses, or damages arising out of or in any way related to Client's use of such Development Batches.

7.9 Environmental Monitoring Performance Qualification. For deviations involving environmental monitoring test results that impact the Batch release, when, as a result, it is necessary to repeat the Environmental Monitoring Performance Qualification, if the root cause analysis indicates that the deviation is due to ElevateBio's negligence, willful misconduct, or breach of this Agreement, then ElevateBio shall repeat the Environmental Monitoring Performance Qualification at no cost to Client.

8. **Shipping and Delivery.** ElevateBio will ensure that each Batch will be delivered to Client or Client's designee in accordance with the instructions for shipping and packaging specified by Client in the applicable Statement of Work and/or QAA, or as otherwise agreed to by the Parties in writing. For the avoidance of doubt, in no event shall ElevateBio ship Product to Client from the Facility without Client's written approval. Delivery terms will be [...***...] the Facility and Client assumes all risk of loss and title of such Product upon Delivery (including any applicable Storage Period thereafter) and subject to Section 10.6(b), Product will be solely owned by Client. ElevateBio may invoice Client, and, if so invoiced, Client will pay, reasonable storage fees for long term storage in excess of [...***...] calendar days after Delivery of any Product in accordance with the Statement of Work, after ElevateBio has provided to Client the

Batch Documentation corresponding to such Product under Section 7.3 above (the "**Storage Period**").

9. **Fees and Payments.**

9.1 Price. The price of Product or the fees and expenses for the performance of Services will be set forth in the applicable Statement of Work. These prices, fees, and expenses are subject to an annual adjustment equal to an amount calculated in [...***...] of each year, based on [...***...], up to a maximum percentage amount calculated using [...***...] using the following calculation: the sum of [...***...] divided by the sum of [...***...], minus [...***...], and shown as a [...***...]. ElevateBio will promptly provide notice to Client of any such price adjustments. In the event any such [...***...] adjustment is in excess of [...***...] the Parties shall engage in a good faith discussion regarding actual cost increases at ElevateBio and the final adjustment for Client. Client shall only be responsible for up to [...***...] [...***...] of the portion, as agreed between the Parties, that exceeds the [...***...] adjustment. Such fees may include, if expressly set forth in a Statement of Work, non-refundable reservation fees due and payable by Client prior to ElevateBio's performance of corresponding Services. All dollar ($) amounts specified in this Agreement are United States dollar amounts, and all payments to be made under this Agreement will be made in United States dollars.

9.2 Batch Fees. During the term of this Agreement, Client will pay ElevateBio a Batch fee per Batch to be specified in the applicable Statement of Work (the "**Batch Fee**") based on then-current understanding of the Manufacturing Process and Facility requirements and as set forth in the applicable Statement of Work, as subject to change. It is understood that material differences from present process understanding and/or anticipated Batch maximums/minimums may impact the Batch Fee.

9.3 Invoice; Late Payments.

(a) Except as expressly provided in this Agreement, ElevateBio will invoice Client according to the invoice schedule in the applicable Statement of Work, referencing in each such invoice the Statement of Work(s) to which such invoice relates.

(b) Raw Materials charges will be invoiced [...***...] months in advance based on the Binding Forecast. ElevateBio will perform a quarterly true-up of actual Raw Material costs against amounts paid. If actual costs exceed amounts paid, ElevateBio will invoice Client for the difference; if actual costs are lower, ElevateBio will issue Client a credit for the difference. ElevateBio will provide a report at [...***...] setting forth Raw Material costs (if applicable), including any associated Processing Fee, broken down by applicable manufacturing batch number. Furthermore, the Parties agree that each year, based on the estimated volume of Raw Materials anticipated to be used at ElevateBio facilities, ElevateBio will use commercially reasonable efforts to obtain price reductions on Raw Materials from the applicable suppliers and any such price reductions achieved shall be passed on to Client.

(c) For invoices containing pass-through fees other than Raw Materials invoiced on a pass-through basis (if applicable), reasonably detailed information on the item or Services provided must be included in the report provided pursuant to Section 9.3(b) for Raw Materials or the invoice for other Services or materials.

(d) Payment of undisputed portions of invoices that provide complete and accurate information and are supported by appropriate detail will be due within [...***...] calendar days following receipt of the applicable invoice. In the event Client fails to pay undisputed invoice amounts when due, ElevateBio reserves the right to assess a late-pay penalty of the lesser of (a) [...***...] per month; and (b) the maximum amount permissible under Applicable Law, on the past-due balance. In the event Client fails to pay undisputed invoice amounts when due, ElevateBio reserves the right to suspend performance under the applicable Statement of Work pending ElevateBio's receipt of payment. Any dispute regarding any invoice or any portion thereof shall be subject to the dispute resolution procedures in Section 16.10. No late-pay penalties will be assessed on portions of invoices disputed in good faith; provided, however, that the late-pay penalty will be assessed to Client in the event that Client disputes a payment amount, and it is determined, pursuant to the terms of this Agreement, that ElevateBio was owed such payment amount, but in such case the penalty period shall commence [...***...] calendar days after the date the payment was due. The Parties will work in good faith to resolve any such payment dispute and any disputes that remain unresolved after [...***...] calendar days shall be escalated in accordance with Section 3.4(a)(v).

9.4 Payments. Client will make all payments pursuant to this Agreement by ACH, or wire transfer to the bank account provided by ElevateBio in the invoice.

9.5 Taxes. Duty, sales, use, or excise taxes imposed by any governmental entity that apply to the provision of Services will be borne by Client (other than taxes based upon the income of ElevateBio). Upon request, Client will provide ElevateBio with a completed Massachusetts Department of Revenue Form ST-12.

10. **Intellectual Property Rights.**

10.1 Background Technology and Third Party Licenses for Materials.

(a) Background Technology. Client will own and retain all of its right, title, and interest in, to, and under the Client Background Technology, and ElevateBio will own and retain all of its right, title, and interest in, to, and under the ElevateBio Background Technology.

(b) Third Party Licenses for Materials. Client is responsible for ensuring all intellectual property licenses have been obtained and that permissions have been granted for ElevateBio's use of third party materials on Client's behalf, including Lentiviral vector cell lines and plasmids. Third party materials include, but are not limited to, cell lines used in the vector production process, and will require a license agreement between Client and such third party associated with its use for clinical or commercial production. Client will ensure that it has obtained permissions for ElevateBio's use of such third-party materials on Client's behalf.

10.2 Inventions.

(a) ElevateBio Inventions. ElevateBio will own all right, title, and interest in, to, and under all ElevateBio Inventions. Subject to the following sentence, Client hereby assigns and agrees to assign, and shall ensure that its employees, agents, representatives, Affiliates, and subcontractors assign, to ElevateBio all of its right, title and interest in, to and under the ElevateBio Inventions. The foregoing assignment shall not apply to any ElevateBio Background Improvement Inventions solely Created by or on behalf of Client with respect to any ElevateBio Background Technology that is not specifically identified and described in the applicable Statement of Work.

(b) Client Inventions. Client will own all right, title, and interest in and to all Client Inventions. Subject to the following sentence, ElevateBio hereby assigns and agrees to assign, and shall ensure that its employees, agents, representatives, Affiliates, and subcontractors assign, to Client all of its right, title, and interest in, to, and under the Client Inventions. The foregoing assignment shall not apply to any Client Background Improvement Inventions solely Created by or on behalf of ElevateBio with respect to any Client Background Technology that is not specifically identified and described in the applicable Statement of Work.

(c) Joint Inventions. The Parties will jointly own all rights, title and interests in and to all Joint Inventions. Each Party hereby assigns and agrees to assign, and shall ensure that its employees, agents, representatives, Affiliates and subcontractors assign, to the other Party all rights, title and interest in any Joint Inventions as is necessary to fully effect the ownership provisions set forth in Section 10.2(c). Joint Inventions shall be owned jointly by the Parties without an obligation of accounting to or consent from the other Party. Joint Inventions shall be deemed the Confidential Information of neither Party, provided that

either Party may disclose and use Joint Inventions in the same manner as it would disclose and use its own like Confidential Information. Notwithstanding the foregoing, Client shall not disclose or otherwise grant a license under the Joint Inventions to any Third Party CMO other than to a Third Party CMO with respect to whom Client has elected a Technology Transfer pursuant to Section 10.8(a).

10.3 Inventorship. All determinations of inventorship under this Agreement will be made in accordance with U.S. patent law.

10.4 Disclosure. (a) Client will promptly disclose to ElevateBio all ElevateBio Inventions and all Joint Inventions Created by or on behalf of Client or its Affiliates and (b) ElevateBio will promptly disclose to Client all Client Inventions and Joint Inventions Created by or on behalf of ElevateBio or its Affiliates, in each case ((a)-(b)), that it Creates, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such Invention), including all invention disclosures or other similar documents submitted to the applicable Party by its employees, agents, or independent contractors relating thereto. Each Party will also promptly respond to reasonable requests from the other Party for additional information relating thereto.

10.5 Further Actions. Upon request by the assignee under Section 10.2(a), Section 10.2(b), or Section 10.2(c), as applicable, the assigning Party shall promptly execute or cause to be executed any and all applications, assignments, or other instruments, and shall take all reasonable actions, in each case that the assignee deems reasonably appropriate or necessary to permit and assist the assignee, at the assignee's expense, in obtaining, perfecting, and enforcing the full benefits, enjoyment, rights, and title throughout the world in the relevant assigned Intellectual Property rights.

10.6 License Grants.

(a) License Grant from Client. During the term of this Agreement, Client hereby grants to ElevateBio a fully paid, non-exclusive, non-transferable, non-sublicensable (except to subcontractors in accordance with this Agreement) license under any and all Client Background Technology and Client Inventions that are necessary or reasonably useful for ElevateBio to perform its obligations under this Agreement for the sole and limited purpose to permit ElevateBio to perform its obligations under this Agreement, including, without limitation, the manufacture of Product for Client.

(b) Included ElevateBio Technology. If, in the performance of its obligations under this Agreement, ElevateBio identifies a need or benefit to incorporate any ElevateBio Background Technology into any Product, or use any ElevateBio Background Technology in the manufacture of any Product, then ElevateBio will promptly notify Client thereof. Following receipt of such written notice, Client will determine whether it wants to include such ElevateBio Background Technology in its Products or their manufacture and will notify ElevateBio of its decision in writing, and if Client so determines, such ElevateBio Background Technology will be specified in the applicable Statement of Work, and the Parties will negotiate and agree on any licenses fees, milestone payments, royalties, and any other payments (collectively, "**License Fees**") charged by ElevateBio on a license to such ElevateBio Background Technology in the event of a Technology Transfer requested

by Client pursuant to Section 10.8. Upon such agreement by the Parties, any such ElevateBio Background Technology that Client elects to include in its Products or their manufacture, together with ElevateBio Invention incorporated into or used in the Manufacture of such Product shall be referred to herein as "**Included ElevateBio Technology**." If, ElevateBio fails to notify Client of any ElevateBio Background Technology before it incorporates such ElevateBio Background Technology in any Product or the Manufacture thereof, then, (i) such ElevateBio Background Technology shall not be deemed to be Included ElevateBio Technology for purposes of Section 10.8, and (ii) Client is granted a non-exclusive, royalty-free, irrevocable, perpetual, worldwide, fully-paid up, transferable, sublicensable (through multiple tiers) license under such ElevateBio Background Technology for the sole purposes of making, having made, using, selling, offering to sell or importing such Product and not for any other purposes.

(c) On a Product-by-Product basis, subject to Client's payments of all applicable fees pursuant to Section 10.9 (if any), ElevateBio hereby grants to Client a non-exclusive, royalty-free, irrevocable, perpetual, worldwide, fully paid-up, transferable (only in connection with transfer of the applicable Product Manufactured hereunder), sublicensable (through multiple tiers) license under the Included ElevateBio Technology to the extent reasonably necessary to use, sell, offer for sale and import each Product Manufactured hereunder and for no other purpose whatsoever; provided, that with respect to any such Included ElevateBio Technology in-licensed or acquired by ElevateBio from a Third Party, the foregoing license is subject to the terms and conditions of the applicable agreement between ElevateBio or its Affiliate with such Third Party. For the avoidance of doubt, in no event will such license grant to Client include the right to render services to a Third Party that are similar or identical to the Services, to Manufacture or have Manufactured any Product, or to use ElevateBio Technology in connection with products that are not the Product.

(d) Patents. Client will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain, enforce and defend, at its sole expense, any Client Foreground Patent Rights. ElevateBio will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain, enforce and defend at its sole expense, any ElevateBio Foreground Patent Rights. ElevateBio, by counsel it so chooses, shall have the first right, but not the obligation, to prepare, file and prosecute any Joint Foreground Patent Rights. ElevateBio shall keep Client advised as to material developments and steps to be taken with respect to prosecuting any such Joint Foreground Patent Rights and shall furnish Client with copies of applications for such Joint Foreground Patent Rights, amendments thereto, and other related correspondence to and from patent offices, and permit Client a reasonable opportunity (in all cases not less than [...***...] calendar days) to review and offer comments prior to submitting such applications and correspondence to the applicable governmental authority. ElevateBio shall incorporate any reasonable comments of Client into such applications and correspondence. Client shall reasonably assist and cooperate in obtaining, prosecuting, and maintaining the Joint Foreground Patent Rights, as reasonably requested by ElevateBio. ElevateBio shall be reimbursed for any reasonable costs and expenses actually incurred in prosecuting Joint Foreground Patent Rights and the subsequent maintenance of Joint Foreground Patent Rights by ElevateBio such that Client shall be responsible for [...***...] of such costs. If ElevateBio decides not to file, prosecute,

or maintain any Joint Foreground Patent Rights in a given country then ElevateBio will promptly notify Client of the same (in all cases at least [...***...] calendar days prior to any applicable deadline) and, if requested by Client, ElevateBio will promptly assign to Client all of ElevateBio's right, title, and interest in and to such Joint Foreground Patent Rights in such country and, following such assignment, (1) ElevateBio shall reasonably assist Client and cooperate with Client in obtaining, prosecuting, and maintaining such assigned Joint Foreground Patent Rights, as reasonably requested by Client and at Client's sole expense, (2) such assigned Joint Foreground Patent Rights shall thereafter be deemed to be Client Foreground Patent Rights for purposes of this Agreement, and (3) ElevateBio is hereby granted a non-exclusive, royalty-free, irrevocable, perpetual, worldwide, fully-paid up, transferable, sublicensable (through multiple tiers to its Affiliates and bona fide (sub)licensees) license under such assigned Joint Foreground Patent Rights for any and all purposes. Each Party shall promptly provide the other Party with written notice reasonably detailing any actual, threatened, known or alleged infringement or misappropriation by a third party of Joint Foreground Patent Rights, as well as any declaratory judgment or similar actions alleging the invalidity or unenforceability of such Joint Foreground Patent Rights of which it becomes aware ("**Third Party Infringement**"). ElevateBio shall have the first right to initiate legal action to enforce any Joint Foreground Patent Rights against Third Party Infringement, or to defend any declaratory judgment or similar action relating thereto. In the event such course of action includes litigation, Client may choose, at its own expense, to be represented in such action by counsel of its own choice. If Client is required to be joined as a party to such action, each Party shall pay its respective expenses associated therewith. In the event that ElevateBio fails to initiate or defend such action within [...***...] calendar days after being first notified of such infringement, misappropriation or declaratory judgment or similar action, Client shall have the right to do so. The Parties will negotiate in good faith a cost-sharing arrangement for any legal action to enforce any Joint Foreground Patent Rights, which cost-sharing arrangement will address the allocation of expenses and recoveries between the Parties for such legal action. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery realized as a result of any legal action to enforce any Joint Foreground Patent Rights will be shared as follows: (i) the amount of such recovery will first be applied to the Parties' reasonable out of pocket costs incurred in connection with such action; then (ii) any remaining proceeds shall be retained by the Party that brought and controlled such action.

10.7 Further Assurances. Each Party agrees to take all necessary and proper acts, and will cause its employees, Affiliates, contractors, and consultants to take such necessary and proper acts, to effectuate the ownership provisions set forth in this Article 10.

10.8 Technology Transfer.

(a) Client Request. Subject to Section 10.8(b), Client may request in writing that ElevateBio, on a Product-by-Product basis, transition the Manufacture of all or a portion of such Product to Client or an Affiliate thereof or a Third Party designated by Client (each, a "**Technology Transfer**" and each such notice, a "**Technology Transfer Notice**") and ElevateBio will promptly provide such Technology Transfer in accordance with the terms hereof; provided that Client may request a Technology Transfer a total of [...***...] times per Product (unless the Parties agree otherwise) as follows: [...***...] to Client or an

Affiliate of Client and [...***...] times to [...***...] [...***...] Third Parties. Each transfer shall be limited to one manufacturing site of Client's choice. Client shall bear the reasonable documented costs, mutually agreed upon in the applicable Statement of Work, incurred as a result of any Technology Transfer request assistance performed by Personnel under this Section 10.8.

(b) Manufacturing License Agreement. Upon receipt of a Technology Transfer Notice, if any such requested Technology Transfer would require a license under any Included ElevateBio Technology in order to Manufacture such Product, then the Parties will negotiate in good faith the terms (including the economics terms, and subject to Section 10.9) of a definitive technology transfer and license agreement ("**Manufacturing License Agreement**"), pursuant to which ElevateBio will transfer such Included ElevateBio Technology to Client and Client will be granted a license under such Included ElevateBio Technology, with the right to grant sublicenses (the specifics of which right to grant sublicenses will be determined at the time of negotiation, but with respect to any ElevateBio Inventions in such Included ElevateBio Technology, such sublicenses shall be sublicensable in multiple tiers, with a written notice to ElevateBio each time a sublicense is granted to a third party under such ElevateBio Inventions), to make, have made, use, sell, offer for sale and import the applicable Product and not for any other purposes. The Manufacturing License Agreement will include customary technology transfer fees for each Technology Transfer (which may contain different economic terms with respect to Technology Transfer to Client or its Affiliates compared to Technology Transfer to any Third Party CMO) and the License Fees for the applicable ElevateBio Background Technology included in the transferred Included ElevateBio Technology, but ElevateBio will not charge royalties, licenses fees or similar fees for the ElevateBio Inventions included in the transferred Included ElevateBio Technology under such license.

10.9 Third Party License Fees. Client shall reimburse ElevateBio for any payments that are owed and made by ElevateBio to any Third Party licensors of any Included ElevateBio Technology under the relevant license agreement(s) and are attributed to Client's, its Affiliates' or sublicensees' practice of the Intellectual Property rights sublicensed to Client under such Included ElevateBio Technology pursuant to Section 10.6(b) and, if Client elects a Technology Transfer under Section 10.8(a), pursuant to Section 10.8(b).

11. Confidentiality.

11.1 Definition. "**Confidential Information**" means any and all non-public scientific, technical, financial, regulatory or business information, or data or trade secrets in whatever form (written, oral or visual) that is (a) furnished or made available by or on behalf of one Party (the "**Discloser**") to the other (the "**Recipient**") or its designee or developed by either Party under this Agreement and (b) that is (i) if in tangible form, labeled in writing as proprietary or confidential;(ii) if in oral or visual form, identified as proprietary or confidential at the time of disclosure or within [...***...] calendar days after such disclosure; or (iii) information that by its nature and circumstances surrounding its disclosure would commonly be treated as confidential or proprietary by someone with experience in the life sciences industry. In addition, Confidential Information of Client includes (x) Client Materials, Deliverables and Client Inventions; (y) development and marketing plans, regulatory and business strategies, financial information, and forecasts of Client; and (z) all

information of Third Parties that Client has an obligation to keep confidential, in each case ((x)-(z)), regardless of the disclosing Party. Confidential Information of ElevateBio includes ElevateBio Technology, ElevateBio's pricing and business information and all information of Third Parties that ElevateBio has an obligation to keep confidential, in each case regardless of the disclosing Party. The existence and terms of this Agreement will be deemed to be the Confidential Information of both Parties, with each Party being deemed to be a Recipient thereof.

11.2 Confidentiality Obligations. During the term of the Agreement and for [...***...] years thereafter Recipient agrees to (a) hold in confidence all of Discloser's Confidential Information, and not disclose Discloser's Confidential Information except as expressly provided in Section 11.3, without the prior written consent of Discloser; (b) use Discloser's Confidential Information solely to carry out Recipient's obligations under this Agreement or in the reasonable exercise of Recipient's rights under this Agreement; (c) treat Discloser's Confidential Information with the same degree of care Recipient uses to protect Recipient's own confidential information but in no event with less than a reasonable degree of care; and (d) reproduce Discloser's Confidential Information solely to the extent necessary to carry out Recipient's rights or obligations under this Agreement, with all such reproductions being considered Discloser's Confidential Information.

11.3 Permitted Disclosure. Recipient may provide Discloser's Confidential Information to its Affiliates, and to its and their directors, employees, consultants, contractors, actual or potential investors or acquirers (and their consultants and advisors), and agents; *provided, however*, that (a) any such Affiliates, directors, employees, consultants, contractors, actual or potential investors or acquirers (and their consultants and advisors) and agents are bound by written obligations of confidentiality with respect to the Discloser's Confidential Information that are at least as restrictive as those set forth in this Agreement (provided that, solely in case of consultants, contractors, actual or potential investors or acquirers and such actual or potential investors' or acquirers' consultants and advisors, the term of such confidentiality obligations may be shorter than the confidentiality term set forth in this Agreement, provided such term is consistent with applicable industry standards); (b) Recipient remains liable for the compliance of such Affiliates, employees, consultants, contractors and agents with such obligations; and (c) such disclosure is only made to persons who in each case have a specific need to know such Confidential Information. Recipient may also disclose Discloser's Confidential Information to Third Parties only to the extent such disclosure is required to comply with Applicable Law, the rules of any stock exchange or listing entity, or to defend or prosecute litigation; *provided*, that Recipient provides prompt written notice (prior to disclosure, if legally permissible) of such disclosure to Discloser and cooperates reasonably with Discloser in any efforts to seek a protective order. Any provision of this Article 11 to the contrary notwithstanding, Client shall have the right to disclose and use Confidential Information of ElevateBio if it is (i) disclosed to Authorities to conduct clinical trials or to market Product (including health registrations), but such disclosures are permitted only to the extent reasonably necessary to obtain such authorizations; (ii) set forth in an audit report disclosed to an Authority, or (iii) in the reasonable exercise of the licenses granted to Client hereunder pursuant to a Technology Transfer, and further provided that, to the extent permitted by Applicable Law and practicable, Client will give ElevateBio reasonable advance notice of any disclosure made pursuant to clause (i) or (ii) hereof.

11.4 Exceptions. Recipient's obligations of non-disclosure and non-use under this Agreement will not apply to any portion of Discloser's Confidential Information that Recipient can demonstrate, by competent proof:

(a) is generally known to the public at the time of disclosure or becomes generally known through no breach of Article 11 by Recipient or its Affiliates;

(b) is already known or available to Recipient or its Affiliates on a non-confidential basis at the time of disclosure other than as a result of Recipient's or its Affiliate's breach of any legal obligation;

(c) becomes known to Recipient or its Affiliates on a non-confidential basis through disclosure by sources other than the Discloser having the legal right to disclose such Confidential Information; or

(d) is independently developed by Recipient or its Affiliates without reference to or reliance upon Discloser's Confidential Information.

If Recipient is required by a governmental authority or by order of a court of competent jurisdiction to disclose any Confidential Information, Recipient will, to the extent reasonably practicable given time constraints, give Discloser prompt written notice (prior to disclosure, if legally permissible) of such requirement or order and Recipient will cooperate reasonably with Discloser in any efforts of Discloser to seek a protective order.

12. **Representations of the Parties.**

12.1 ElevateBio Representations. ElevateBio represents to Client that, as of the Effective Date:

(a) it is a company, duly organized, validly existing, and in good standing under the Applicable Law of its place of incorporation, and is duly qualified to do business in each jurisdiction where the nature of the activities conducted by it or the character of the property owned by it make such qualification necessary;

(b) it has the full power and right to enter into this Agreement and it does not have any outstanding agreements, licenses, or other arrangements of any kind with Third Parties or Affiliates, that are in contravention of the provisions of this Agreement;

(c) the execution and delivery of this Agreement by ElevateBio has been authorized by all requisite corporate or company action and this Agreement is a valid and binding obligation of ElevateBio, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(d) there is no pending litigation which alleges that the use of any ElevateBio Technology relevant for the Services has infringed or misappropriated any Intellectual Property of any Third Party, and ElevateBio has not received any claim that the use of such ElevateBio Technology infringes or misappropriates the Intellectual Property of any Third Party;

(e) to ElevateBio's knowledge, the use of ElevateBio Technology in the performance of the Services will not violate any validly issued patent of any Third Party;

(f) all Services shall be performed with requisite care, skill and diligence, by individuals who are appropriately trained and qualified, and in accordance with all Applicable Law, this Agreement and relevant Statement of Work, and the Quality Agreement;

(g) unencumbered title to all Product and Client Inventions created by ElevateBio, its employees, agents, representatives, Affiliates and subcontractors will be conveyed to Client upon the delivery; and

(h) ElevateBio has not received notice that it, or any of its Personnel working on ElevateBio's behalf under this Agreement: (i) have been debarred or are subject to a pending debarment pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (ii) are ineligible to participate in any federal or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)); (iii) are disqualified by any government or regulatory Authorities from performing specific services, and are not subject to a pending disqualification proceeding; or (iv) have been convicted of a criminal offense related to the provision of healthcare items or services or are subject to any such pending action. ElevateBio will notify Client immediately if ElevateBio, its Affiliates, any Personnel or any of their respective officers or directors, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of ElevateBio's knowledge, is threatened.

12.2 Client Representations. Client represents to ElevateBio that, as of the Effective Date:

(a) it is a company, duly organized, validly existing, and in good standing under the Applicable Law of its place of incorporation, and is duly qualified to do business in each jurisdiction where the nature of the activities conducted by it or the character of the property owned by it make such qualification necessary;

(b) it has the full power and right to enter into this Agreement and it does not have any outstanding agreements, licenses, or other arrangements of any kind with Third Parties or Affiliates, that are in contravention of the provisions of this Agreement;

(c) the execution and delivery of this Agreement by Client has been authorized by all requisite corporate or company action and this Agreement is a valid and binding obligation of Client, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(d) there is no pending litigation which alleges that the use of any Client Background Technology or Client Invention as contemplated in the Services has infringed or

misappropriated any Intellectual Property of any Third Party, and Client has not received any claim that the use of such Client Background Technology or Client Invention infringes or misappropriates the Intellectual Property of any Third Party; and

(e) to Client's knowledge, the use of Client Background Technology, Client Invention and Client Materials as contemplated in the Services will not infringe the Intellectual Property rights of any Third Party and Client will promptly notify ElevateBio in writing should it become aware of any claims asserting such infringement.

12.3 Disclaimer of Other Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

13. **Indemnification**.

13.1 Indemnification by ElevateBio. ElevateBio will indemnify, defend and hold harmless Client, its Affiliates and its and their respective officers, directors, employees, subcontractors, and agents (collectively, the "**Client Indemnitees**") against any and all losses, damages, liabilities or expenses (including reasonable attorneys' fees and other costs of defense) (collectively, "**Losses**") in connection with any and all actions, suits, claims or demands that may be brought or instituted against any Client Indemnitee by any Third Party to the extent they arise out of or relate to (a) any material breach of this Agreement by ElevateBio; (b) any ElevateBio Indemnitee's (as defined below) gross negligence, willful misconduct, or violation of Applicable Law in performing obligations under this Agreement; or (c) infringement of any Intellectual Property rights arising from Client's use of the Deliverables (other than to the extent attributable to the Client Materials, Client Background Technology, or Client Inventions that are Created by Client) or any Included ElevateBio Technology or ElevateBio Technology incorporated into any Product in accordance with this Agreement, except, in each case, to the extent such Losses are within the scope of the indemnification obligation of Client under Section 13.2.

13.2 Indemnification by Client. Client will indemnify, defend and hold harmless ElevateBio, its Affiliates and its and their respective officers, directors, employees, subcontractors, and agents (collectively, the "**ElevateBio Indemnitees**") against any and all Losses in connection with any and all actions, suits, claims or demands that may be brought or instituted against any ElevateBio Indemnitee by any Third Party to the extent they arise out of or relate to(a) the research, development, manufacture, use, handling, storage, sale or other disposition of any Product by or on behalf of Client, its Affiliates, or their respective (sub)licensees; (b) ElevateBio's proper compliance with any instruction, specification, or direction given by Client (but excluding, for the avoidance of doubt, Losses arising out of or related to the general performance of the Services that are not attributable to the specific instructions, specifications, or directions given by Client); (c) any material breach of this Agreement by Client; (d) any Client Indemnitee's gross negligence or willful misconduct in performing obligations under this Agreement; or (e) infringement of any Intellectual Property rights relating to the Client Materials, Client Background Technology, Client Inventions that are Created by Client, or the Product, except, in each case, to the extent such Losses are within the scope of the indemnification obligation of ElevateBio under Section 13.1.

13.3 Indemnification Procedures. Each Party seeking indemnification must notify the indemnifying Party within [...***...] calendar days of receipt of any claims made for which the indemnifying Party might be liable under Section 13.1 or 13.2, as the case may be. Failure to provide such prompt notice shall limit the right of the Party seeking indemnification to indemnification solely to the extent that such failure adversely affects the indemnifying Party's ability to defend against the applicable action, suit, claim or demand. Subject to Section 13.4, the indemnifying Party will have the sole right to defend, negotiate, and settle such claims. The indemnified Party will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist in such defense; *provided, however*, that the indemnifying Party will have final decision-making authority regarding all aspects of the defense of any claim. The Party seeking indemnification will provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. The indemnified Party shall use commercially reasonable efforts to mitigate its Losses in respect of any claim for which it is seeking indemnification. Losses that may be recovered shall take account of and be reduced by (i) any amounts recovered and actually received by the indemnified Party pursuant to any indemnification agreement with any Third Party and (ii) the amount of any insurance proceeds actually received by the indemnified Party in respect thereof, in each case of clauses (i) and (ii) net of any out-of-pocket costs reasonably incurred for pursuing such amounts or insurance proceeds.

13.4 Settlement. Neither Party will be responsible nor bound by any settlement of any claim or suit made without its prior written consent; *provided, however*, that an indemnified Party will not unreasonably withhold or delay such consent; provided, further, if a settlement contains an absolute waiver of liability for the indemnified Party and provides for the payment by the indemnifying Party of money as the sole relief for claimant, then the indemnified Party's consent will not be required.

13.5 Limitation of Liability.

(a) CONSEQUENTIAL DAMAGES. SUBJECT TO SECTION 13.5(c), NEITHER PARTY WILL BE LIABLE UNDER ANY LEGAL THEORY (WHETHER TORT, CONTRACT OR OTHERWISE) FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, HOWEVER CAUSED, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

(b) DIRECT DAMAGES. SUBJECT TO SECTION 13.5(c), THE TOTAL LIABILITY OF EITHER PARTY ARISING OUT OF OR RELATED TO THIS AGREEMENT WILL NOT EXCEED THE GREATER OF [...***...] US DOLLARS OR THE TOTAL FEES PAID BY CLIENT TO ELEVATEBIO UNDER SUCH STATEMENT OF WORK AS IT MAY BE AMENDED BY CHANGE ORDER(S) IN THE PREVIOUS [...***...] PERIOD.

(c) NOTHING IN THIS SECTION 13.5 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY PURSUANT TO SECTION 13.1 OR SECTION 13.2, AS APPLICABLE; (B) A PARTY'S LIABILITY FOR BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 11; OR (C) A PARTY'S LIABILITY FOR GROSS NEGLIGENCE, FRAUD, OR WILLFUL MISCONDUCT, INCLUDING, AS RELATES TO SECTION 13.5(C), LIABILITY RELATING TO REPLACEMENT COSTS FOR CLIENT MATERIALS AND PRODUCT.

14. **Insurance.**

14.1 Insurance. Each Party will secure and maintain in full force and effect throughout the term of this Agreement (and for at least five (5) years thereafter for claims made coverage), the following respective minimum insurance coverage with financially sound and nationally reputable insurers with a minimum A. M. Best Rating of A-/VII:

(a) ElevateBio Insurance.

(i). *Workers' Compensation*, including coverage for occupational disease, with benefits determined by statute, and Employers' Liability of at [...***...];

(ii). *Commercial General Liability*, including personal/advertising injury, and contractual liability assumed by ElevateBio, with at least [...***...] combined single limit for bodily injury and property damage per occurrence, and a general aggregate limit of at least [...***...];

(iii). *Business Automobile Liability*, including owned (if applicable), non-owned and hired auto liability with at least [...***...] per accident;

(iv). *Errors and Omissions/Cyber Coverage*, covering actual or alleged acts, errors, or omissions committed by ElevateBio, its agents, subcontractors, or employees, arising out of the performance of this Agreement. ElevateBio will maintain a minimum limit of [...***...] per loss, and any combination of policies may be used to satisfy the coverage requirement. Such insurance will extend coverage for network risks (such as (1) system breach, (2) denial or loss of service, (3) introduction, implantation, or spread of malicious software code, and (4) unauthorized access to or use of computer systems), privacy breaches (loss, misuse, or disclosure of confidential information no matter how it occurs), media liability, and infringement of software copyrights and trademarks; and

(v). *Umbrella Liability Insurance* providing excess limits for Commercial General Liability, Employer's Liability and Auto Liability insurance with at least [...***...] per occurrence, and a general aggregate limit of at least [...***...].

(b) Client Insurance.

(i). *Workers' Compensation*, including coverage for occupational disease, with benefits determined by statute, and Employers' Liability of at least [...***...];

(ii). *Commercial General Liability*, including personal/advertising injury, coverage, and contractual liability assumed by Client, with at least [...***...] combined single limit for bodily injury and property damage per occurrence, and a general aggregate limit of at least [...***...];

(iii). *Products Liability*, exclusive of the coverage provided by the Commercial General Liability policy, with at least [...***...] per occurrence and an aggregate limit of at least [...***...].

(iv). *Business Automobile Liability*, including owned, non-owned and hired auto liability with at least [...***...] per accident;

(v). *Errors and Omissions/Cyber Coverage*, covering actual or alleged acts, errors, or omissions committed by Client, its agents, subcontractors, or employees, arising out of the performance of this Agreement. Client will maintain a minimum limit of [...***...] per loss, and any combination of policies may be used to satisfy the coverage requirement. Such insurance will extend coverage for network risks (such as (1) system breach, (2) denial or loss of service, (3) introduction, implantation, or spread of malicious software code, and (4) unauthorized access to or use of computer systems), privacy breaches (loss, misuse, or disclosure of confidential information no matter how it occurs), media liability, and infringement of software copyrights and trademarks; and

(vi). *Umbrella Liability Insurance* providing excess limits for Commercial General Liability, Employer's Liability and Auto Liability insurance with at least [...***...] per occurrence, and a general aggregate limit of at least [...***...].

14.2 Waiver. To the extent permitted by Applicable Law, Client waives all rights against ElevateBio Indemnitees and ElevateBio waives all rights against Client Indemnitees, in each case for recovery of damages to the extent the damages are covered by insurance obtained and maintained by the waiving Party including the insurance required above. All insurance policies will allow the applicable Party to waive subrogation as required in the foregoing sentence and endorse the policies, if necessary, to effect such waiver of subrogation.

14.3 Evidence of Insurance. Upon either Party's request, the other Party agrees to provide evidence of insurance coverage in compliance with Section 14.

15. Term and Termination.

15.1 Term. This Agreement will take effect as of the Original Effective Date and, unless earlier terminated pursuant to this Section 15, will continue for a period of [...***...] years (the "**Initial Term**"). This Agreement will automatically renew for successive [...***...] year periods thereafter, unless either Party notifies the other Party in writing at least [...***...] calendar days prior to the end of the Initial Term or each renewal period that the notifying Party does not intend to renew the Agreement or unless earlier terminated pursuant to this Section 15 (the Initial Term together with each renewal period, the "**Term**"). If any Statement of Work is ongoing as of the date of expiration of this Agreement, the terms of this Agreement will continue to apply to such Statement of Work as if the Agreement had not been terminated. In case of commercial supply of the Product, if any Accepted Purchase Order is open as of the date of expiration of this Agreement, the terms of this Agreement will continue to apply to such Accepted Purchase Order as if the Agreement had not been terminated.

15.2 Termination by Client.

(a) In the case of clinical or commercial supply of Product, Client will have the right, in its sole discretion, to terminate this Agreement and/or any Statement of Work, without cause, upon [...***...] months' prior written notice to ElevateBio.

(b) In the event that ElevateBio fails a Regulatory inspection by an Authority whereby such failure prevents Client from receiving Regulatory Approval for the Product, Client will have the right, in its sole discretion, to terminate this Agreement upon [...***...] calendar days' prior written notice to ElevateBio; provided that ElevateBio shall have [...***...] calendar days to remediate such deficiencies, at its sole expense (including any expenses related to remediation, qualifications, quality systems, training, equipment, or consultants), within the [...***...] calendar day period. Consequently, Client may elect to suspend its obligations with respect to any Binding Forecast during the [...***...] day notice period and such suspension shall remain in effect until ElevateBio remediates the deficiencies during such period. The suspension of Binding Forecast obligations pursuant to the foregoing shall not trigger any delay fees or cancellation obligations for Client.

(c) Client may terminate any Statement of Work upon [...***...] calendar days' prior written notice to ElevateBio, in the event ElevateBio fails to meet the Binding Forecast production need for [...***...] months within a [...***...] month period in accordance with the second sentence of Section 4.3.

15.3 Termination by ElevateBio. In the case of clinical supply of Product, ElevateBio will have the right, in its sole discretion, to terminate any Statement of Work, without cause, upon [...***...] months' prior written notice to Client. In case of commercial supply of the Product, ElevateBio will have the right, in its sole discretion, to terminate any Statement of Work, without cause, upon [...***...] months' prior written notice to Client and, in the event of any such termination, any outstanding Accepted Purchase Orders shall survive until such Accepted Purchase Order is completed or terminated.

15.4 Termination by Either Party. Either Party will have the right to terminate this Agreement or any Statements of Work that are pending by written notice to the other Party, upon the occurrence of any of the following:

(a) the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or becomes subject to involuntary proceedings under any bankruptcy or insolvency law (which proceedings remain undismissed for [...***...] calendar days);

(b) the other Party fails to start and diligently pursue the cure of a material breach of this Agreement within [...***...] calendar days after receiving written notice from the other Party of such breach;

(c) an event of Force Majeure that will, or continues to, prevent performance (in whole or substantial part) of this Agreement or any pending Statement of Work for a period of at least [...***...] calendar days. In the case of an event of Force Majeure relating solely to a pending Statement of Work, the right to terminate will be limited to such Statement of Work; or

(d) upon mutual agreement of the Parties.

15.5 Effect of Termination.

(a) ElevateBio will, on the effective date of termination, promptly cease performance of the applicable Services and will take reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith.

(b) In the event that Client terminates this Agreement or any Statement of Work pursuant to Section 15.2 or ElevateBio terminates this Agreement or a Statement of Work pursuant to Section 15.4(a) or Section 15.4(b), Client will pay to ElevateBio, with respect to the terminated Statement of Work (if a Statement of Work is terminated) or with respect to each then-current Statement of Work (if this Agreement is terminated): (i) all amounts already owing to ElevateBio at the time of such termination for Services (including Products) completed in accordance with applicable Quality Agreement; (ii) costs for all work-in-process (including any intermediates and components of Products); (iii) third party costs and expenses incurred or that are non-cancellable (including fees for Raw Materials and Client Equipment); (iv) the aggregate fees for the Services within the termination notice period; (v) the Batch Fees for Product set forth in the Binding Forecast during the termination notice period; and (vi) the Batch Fee Minimum for each month in the termination notice period to the extent not covered by the Binding Forecast.

(c) In the event that ElevateBio terminates this Agreement or any Statement of Work pursuant to Section 15.3, or Client terminates this Agreement or any Statement of Work pursuant to Section 15.4(a) or Section 15.4(b), Client will pay to ElevateBio all amounts already owing to ElevateBio at the time of such termination for work completed in accordance with applicable Quality Agreement. Furthermore, in the event that ElevateBio terminates this Agreement or any Statement of Work related to Manufacturing pursuant to Section 15.3,

ElevateBio will work with Client in good faith to help facilitate a timely Technology Transfer in accordance with Section 10.8.

(d) In the event of termination of this Agreement or a Statement of Work pursuant to Section 15.4(c), Client will pay to ElevateBio (i) all amounts already owing to ElevateBio at the time of such termination for work completed in accordance with applicable Quality Agreement; (ii) costs for all work-in-process; and (iii) third party costs and expenses incurred or that are non-cancellable (including fees for Raw Materials and Client Equipment). In cases (ii) and (iii) above, if ElevateBio is able to mitigate the costs with reasonable efforts, then ElevateBio shall reduce the associated costs accordingly.

(e) In the event of termination of this Agreement or a Statement of Work pursuant to Section 15.4(d), the Parties will agree to any additional fees or costs to be paid by either Party to the other Party.

15.6 Return of Confidential Information. Upon the expiration or termination of this Agreement for any reason, or upon request of Discloser at any time, Recipient agrees, except as otherwise provided in this Agreement, to return to Discloser or destroy all documentation or other tangible evidence or embodiment of Discloser's Confidential Information and not to use such Confidential Information, unless otherwise agreed. Notwithstanding the foregoing, Recipient may retain one archival copy of Discloser's Confidential Information in order to monitor Recipient's ongoing obligations of confidentiality and non-use under this Agreement or to comply with Applicable Law or regulatory requirements or to exercise any rights which survive termination of this Agreement; *provided*, that such retained copies must be kept confidential in accordance with Section 11. Upon written request, ElevateBio will also promptly return all Client Materials and Client Equipment to Client.

15.7 Inventories. Upon expiration or termination of this Agreement or a Statement of Work, other than (x) termination by Client pursuant to Section 15.2 or (y) termination by ElevateBio pursuant to Section 15.3, in each case (x) and (y) Client will have the right but not the obligation to do the following, Client (a) must purchase from ElevateBio any existing inventories of Product duly ordered under this Agreement and that is not a Non-Conforming Batch, at the price for such Product set forth in the applicable Statement of Work; and (b) must either (i) purchase any such Product in process held by ElevateBio as of the date of the termination, at a price [...***...]; or (ii) pay ElevateBio for [...***...] and direct ElevateBio to dispose of such material at Client's cost. In the event Client Equipment, Client Materials, and/or Raw Materials remain in ElevateBio's possession after the expiration or earlier termination of the applicable Statements of Work for which such Client Equipment, Client Material, and/or Raw Materials were provided or procured, then ElevateBio shall notify Client of such. In the event Client fails to remove or take possession of such Client Equipment, Client Materials, and/or Raw Materials remaining in ElevateBio's possession within [...***...] calendar days of the expiration or termination of the applicable Statements of Work, ElevateBio may invoice Client for, and Client will pay, reasonable storage fees for such Client Equipment, Client Materials, and/or Raw Materials beyond such [...***...]-day period following receipt of notice. If Client Materials are not removed by Client within [...***...] calendar days after receiving notice from ElevateBio, ElevateBio may return or destroy such Client Materials at Client's reasonable expense.

15.8 Payment Reconciliation. Within [...***...] calendar days after the termination of a Statement of Work, ElevateBio will provide to Client a written statement of all work performed by it in connection with the terminated Statement of Work, breakdown of the costs associated with that work, and a final invoice for that Statement of Work. If Client has pre-paid to ElevateBio more than the amount in a final invoice then ElevateBio agrees to, at Client's election (i) refund that money to Client within [...***...] calendar days after Client notifies ElevateBio of Client's election to receive a refund, or (ii) credit the excess payment toward another existing or future Statement of Work.

15.9 Intellectual Property Rights in Bankruptcy. The Parties agree that, for purposes of Section 365(n) of the Bankruptcy Code, all rights and licenses granted under this Agreement are rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties agree that the licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties agree that in the event of the commencement of a case by or against a Party under the Bankruptcy Code, then the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any Intellectual Property licensed to such other Party and all embodiments of such Intellectual Property, and the same, if not already in the other Party's possession, will be promptly delivered to the other Party (i) upon such other Party's written request therefor, unless and until this Agreement or any license of rights to Intellectual Property hereunder is rejected, and (ii) if not delivered under clause (i), upon the other Party's written request therefor, following (A) the rejection of this Agreement or any license of rights to Intellectual Property hereunder, and (b) such other Party's election to retain its rights under Section 365(n)(1)(B) of the Bankruptcy Code. The foregoing provisions of this Section 15.9 are without prejudice to any rights that either Party may have arising under the Bankruptcy Code or other Applicable Law.

15.10 Survival. Expiration or termination of this Agreement for any reason will not relieve either Party of any obligation accruing prior to such expiration or termination. Further, the provisions of Sections 1 (Definitions), 2.4 (Conflict Between Documents), 6.4 (Records; Sample Retention), 9 (Fees and Payments), 10 (Intellectual Property Rights), 11 (Confidentiality), 13 (Indemnification), 14 (Insurance), 15 (Term and Termination) and 16 (Miscellaneous), any other provisions of this Agreement that by their nature should survive, and the provisions of the applicable Quality Agreement will survive any termination or expiration of this Agreement.

16. **Miscellaneous.**

16.1 Independent Contractor. All Services will be rendered by ElevateBio as an independent contractor for federal, state and local income tax purposes and for all other purposes. ElevateBio will not in any way represent itself to be a partner or joint venturer of or with Client. This Agreement does not create an employer-employee relationship between Client on the one hand and ElevateBio or any Affiliate of ElevateBio, or any of its or their respective employees or subcontractors, on the other. ElevateBio is acting under this Agreement as an independent contractor with full power and authority to determine the means, manner and method of performance of ElevateBio's duties. ElevateBio will be responsible for and will withhold or pay any and all applicable federal, state or local taxes, payroll taxes, workers' compensation contributions, unemployment insurance contributions, or other payroll deductions from the compensation of ElevateBio's employees and other ElevateBio personnel.

16.2 Force Majeure. Except as otherwise expressly set forth in this Agreement, neither Party will have breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, acts of God or acts, omissions, or delays in acting, by any governmental authority ("**Force Majeure**"). The Party affected by any event of Force Majeure will promptly notify the other Party, explaining the nature and expected duration of the Force Majeure event. Such Party will also notify the other Party from time to time as to when the affected Party reasonably expects to resume performance in whole or in part of its obligations under this Agreement, and to notify the other Party of the cessation of any such event. A Party affected by an event of Force Majeure will use its commercially reasonable efforts to remedy, remove, or mitigate such event and the effects of it with all reasonable dispatch. Upon termination of the event of Force Majeure, the performance of any suspended obligation or duty will promptly recommence.

16.3 Public Statements. Except to the extent required by Applicable Law or regulation or the rules of any stock exchange or listing agency, neither ElevateBio nor Client will make any public statement or release concerning this Agreement or the transactions contemplated by this Agreement, or use the other Party's name or trademarks or the name or trademarks of any Affiliate of the other Party in any form of advertising, promotion or publicity, without obtaining the prior written consent of the other Party.

16.4 Notices. All notices must be in writing (including by email) and sent to the address for the recipient set forth in this Agreement below or at such other address as the recipient may specify in writing under this procedure. All notices must be given by (a) personal delivery, with receipt acknowledged; (b) prepaid certified or registered mail, return receipt requested with confirmation of delivery; (c) email with confirmation of receipt; or (d) prepaid recognized next business day or express delivery service with confirmation of delivery. Notices will be effective upon receipt or at a later date stated in the notice.

If to ElevateBio, to:

ElevateBio BaseCamp, Inc.
200 Smith Street, Suite 301
Waltham, MA 02451
Attention: Legal Department
Email: [...***...]

With a copy to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: [...***...]
Email: [...***...]

If to Client, to:

Kyverna Therapeutics, Inc.
5980 Horton St, Suite 200
Emeryville, CA 94608
Attention: Legal Department
Email: [...***...]

16.5 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; *provided, however*, that either Party may, without such consent, but with notice to the other Party, assign this Agreement, in whole or in part, (a) in connection with the transfer or sale of all or substantially all of its assets or the line of business or Product to which this Agreement relates; (b) to a successor entity or acquirer in the event of a merger, consolidation or change of control; or (c) to any Affiliate. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume the rights and obligations of its assignor under this Agreement.

16.6 Entire Agreement. This Agreement, together with the Quality Agreement, the attached Appendices, and Accepted Purchase Orders, each of which are incorporated into this Agreement, constitute the entire agreement between the Parties with respect to the specific subject matter of this Agreement and all prior agreements regarding such subject matter are superseded, including the Mutual Confidentiality and Non-Disclosure Agreement between the Parties, dated January 23, 2023 and the Original Agreement.

16.7 No Modification. This Agreement or any Statement of Work or Quality Agreement may be changed only by a writing signed by authorized representatives of each Party.

16.8 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

16.9 Severability; Reformation. Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the Parties, within the limits of Applicable Law.

16.10 Dispute Resolution. Unless otherwise expressly set forth under this Agreement, or as may be necessary for either Party to seek interim or provisional relief that may be necessary to protect the rights or property of that Party any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity hereof (each, a "**Dispute**"), shall be submitted for negotiation and resolution to the other Party, by delivery of written notice (including by email) (each, a "**Dispute Notice**"). The Parties shall negotiate in good faith to resolve the Dispute. If the Parties are unable to resolve any Dispute within [...***...] calendar days after delivery of the applicable Dispute Notice or such longer period as mutually agreed between the Parties, either Party may file suit in a court of competent jurisdiction in accordance with the provisions of Sections 16.11, 16.12 and 16.13.

16.11 Governing Law. This Agreement and any disputes arising out of or relating to this Agreement will be governed by, construed and interpreted in accordance with the internal laws of State of New York, without regard to any choice of law principle that would require the application of the law of another jurisdiction. The Parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods; and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980.

16.12 Jurisdiction; Venue. Any legal action or proceeding concerning the validity, interpretation and enforcement of this Agreement, matters arising out of or related to this Agreement or its making, performance or breach, or related matters will be brought exclusively in the state and federal courts in New York, New York. All Parties consent to the exclusive jurisdiction of those courts and waive any objection to the propriety or convenience of such venues.

16.13 Waiver of Jury Trial. Each Party acknowledges and agrees that any controversy that may arise under this Agreement or any Statement of Work, including exhibits, schedules, attachments, and appendices attached hereto or thereto, is likely to involve complicated and difficult issues and, therefore, each such Party irrevocably and unconditionally waives any right it may have to a trial by jury in respect of any legal action arising out of or relating to this Agreement or any Statement of Work, including any exhibits, schedules, attachments or appendices attached to hereto or thereto, or the transactions contemplated hereby or thereby.

16.14 Waiver. Any delay in enforcing a Party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable.

16.15 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons.

16.16 No Strict Construction; Headings. This Agreement has been prepared jointly and will not be strictly construed against either Party. The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement. Except where the context expressly requires otherwise: (a) the use of any gender herein will be deemed to encompass references to all genders, and the use of the singular will be deemed to include the plural (and vice versa); (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation" and will not be interpreted to limit the provision to which it relates; (c) the word "will" will be construed to have the same meaning and effect as the word "shall"; (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) any reference herein to any person will be construed to include the person's successors and assigns; (f) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in each of their entirety, as the context requires, and not to any particular provision hereof; (g) all references herein to Sections, Annexes, Schedules, Exhibits or Appendices will be construed to refer to Sections, Annexes, Schedules or Appendices of this Agreement, and references to this Agreement include all Annexes, Schedules, Exhibits or Appendices, hereto; (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (including email but excluding instant messaging); (j) references to any specific law, rule or regulation, article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

16.17 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature) or other electronic transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Remainder of page left blank intentionally]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

KYVERNA THERAPEUTICS, INC.		**ELEVATEBIO BASECAMP, INC.**	
By:	/s/ Warner Biddle	By:	/s/ Mike Paglia
Print Name:	Warner Biddle	Print Name:	Mike Paglia
Title:	CEO Kyverna	Title:	CTO ElevateBio
Date:	07/23/2026	Date:	7/23/2026

APPENDIX A

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, Warner Biddle, hereby certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Kyverna Therapeutics, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

By: /s/ Warner Biddle

Warner Biddle
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Gregory Martini, hereby certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Kyverna Therapeutics, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

By: /s/ Gregory Martini

Gregory Martini
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 on Form 10-Q of Kyverna Therapeutics, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

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

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

Date: November 12, 2026

By: /s/ Warner Biddle

Warner Biddle
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

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 on Form 10-Q of Kyverna Therapeutics, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

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

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

Date: November 12, 2026

By: /s/ Gregory Martini

Gregory Martini
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.