

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

- (Mark One)
- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2025
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE
TRANSITION PERIOD FROM** _____ **TO** _____

Commission File Number: 001-39980

Sensei Biotherapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
1405 Research Blvd, Suite 125
Rockville, MD
(Address of principal executive offices)

83-1863385
(I.R.S. Employer
Identification No.)

20850
(Zip Code)

Registrant's telephone number, including area code: (240) 243-8000

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, \$0.0001 par value per share	SNSE	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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

The number of shares of Registrant's Common Stock outstanding as of November 10, 2025 was 1,261,290.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

SENSEI BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,562	\$ 9,994
Marketable securities	14,479	31,341
Prepaid expenses	496	474
Other current assets	248	120
Total current assets	<u>25,785</u>	<u>41,929</u>
Right-of-use assets - operating leases, net	1,668	2,804
Right-of-use assets - financing leases, net	6	163
Property and equipment, net	112	417
Other non-current assets	18	48
Total assets	<u>\$ 27,589</u>	<u>\$ 45,361</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 1,405	\$ 1,248
Compensation and employee benefits liabilities	1,156	1,882
Operating lease liabilities, current	1,682	1,586
Financing lease liabilities, current	193	732
Total current liabilities	<u>4,436</u>	<u>5,448</u>
Operating lease liabilities, non-current	146	1,429
Financing lease liabilities, non-current	—	98
Total liabilities	<u>\$ 4,582</u>	<u>\$ 6,975</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value and 10,000,000 shares authorized as of September 30, 2025 and December 31, 2024; zero shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	—	—
Common stock, \$0.0001 par value and 12,500,000 shares authorized as of September 30, 2025 and December 31, 2024; 1,261,290 and 1,258,940 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	301,431	300,451
Accumulated deficit	(278,421)	(262,052)
Accumulated other comprehensive loss	(3)	(13)
Total stockholders' equity	<u>23,007</u>	<u>38,386</u>
Total liabilities and stockholders' equity	<u>\$ 27,589</u>	<u>\$ 45,361</u>

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

SENSEI BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 2,536	\$ 4,637	\$ 8,794	\$ 14,138
General and administrative	2,315	3,186	8,537	10,202
Total operating expenses	4,851	7,823	17,331	24,340
Loss from operations	(4,851)	(7,823)	(17,331)	(24,340)
Other income (expense):				
Interest income	289	591	1,016	2,028
Interest expense	(6)	(21)	(29)	(73)
Loss on asset disposal	(1)	—	(21)	—
Other expense, net	—	—	(3)	(2)
Net loss	(4,569)	(7,253)	(16,368)	(22,387)
Net loss per common share, basic and diluted	\$ (3.62)	\$ (5.77)	\$ (12.98)	\$ (17.84)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,261,290	1,257,299	1,260,569	1,254,953
Comprehensive loss:				
Net loss	\$ (4,569)	\$ (7,253)	\$ (16,368)	\$ (22,387)
Other comprehensive items:				
Unrealized gain on marketable securities	8	107	10	223
Total other comprehensive income	8	107	10	223
Total comprehensive loss	\$ (4,561)	\$ (7,146)	\$ (16,358)	\$ (22,164)

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

SENSEI BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMMON STOCK AND STOCKHOLDERS' EQUITY
(Unaudited)

(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	1,251,432	\$ —	\$ 296,999	\$ (231,895)	\$ (209)	\$ 64,895
Stock-based compensation expense	—	—	1,216	—	—	1,216
Issuance of equity in exchange for compensation	—	—	293	—	—	293
Surrender of shares for tax withholding	(616)	—	(10)	—	—	(10)
Vesting of restricted stock shares	2,798	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	72	72
Net loss	—	—	—	(7,992)	—	(7,992)
Balance at March 31, 2024	1,253,614	—	298,498	(239,887)	(137)	58,474
Stock-based compensation expense	—	—	795	—	—	795
Employee stock purchase plan expense	2,166	—	21	—	—	21
Vesting of restricted stock shares	350	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	44	44
Net loss	—	—	—	(7,142)	—	(7,142)
Balance at June 30, 2024	1,256,130	—	299,311	(247,029)	(93)	52,192
Stock-based compensation expense	—	—	733	—	—	733
Vesting of restricted stock shares	1,351	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	107	107
Net loss	—	—	—	(7,253)	—	(7,253)
Balance at September 30, 2024	1,257,481	\$ —	\$ 300,044	\$ (254,282)	\$ 14	\$ 45,779
Balance at December 31, 2024	1,258,940	\$ —	\$ 300,451	\$ (262,052)	\$ (13)	\$ 38,386
Stock-based compensation expense	—	—	461	—	—	461
Surrender of shares for tax withholding	(390)	—	(3)	—	—	(3)
Vesting of restricted stock shares	1,768	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	7	7
Net loss	—	—	—	(6,864)	—	(6,864)
Balance at March 31, 2025	1,260,318	—	300,909	(268,916)	(6)	31,987
Stock-based compensation expense	—	—	264	—	—	264
Employee stock purchase plan expense	1,004	—	5	—	—	5
Cash-in-lieu of fractional shares for reverse stock split	(32)	—	(1)	—	—	(1)
Unrealized loss on marketable securities	—	—	—	—	(5)	(5)
Net loss	—	—	—	(4,936)	—	(4,936)
Balance at June 30, 2025	1,261,290	—	301,177	(273,852)	(11)	27,314
Stock-based compensation expense	—	—	254	—	—	254
Unrealized gain on marketable securities	—	—	—	—	8	8
Net loss	—	—	—	(4,569)	—	(4,569)
Balance at September 30, 2025	1,261,290	\$ —	\$ 301,431	\$ (278,421)	\$ (3)	\$ 23,007

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

SENSEI BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	For the Nine Months Ended September 30,	
	2025	2024
Operating activities		
Net loss	\$ (16,368)	\$ (22,387)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	979	2,744
Depreciation and amortization	92	412
Accretion on marketable securities	(584)	(638)
Non-cash lease expense	1,136	1,151
Amortization of financing lease right-of-use assets	13	579
Loss on asset disposal	21	—
Changes in operating assets and liabilities:		
Prepaid expenses	(23)	152
Other assets	(98)	244
Accounts payable and accrued liabilities	156	(18)
Compensation and employee benefits	(726)	114
Operating lease liabilities	(1,187)	(1,164)
Other liabilities	—	(67)
Net cash used in operating activities	<u>(16,589)</u>	<u>(18,878)</u>
Investing activities		
Purchases of property and equipment	(16)	(146)
Purchases of short-term investments	(18,633)	(26,829)
Maturities of short-term investments	36,090	52,566
Proceeds from sale of property and equipment	250	—
Net cash provided by investing activities	<u>17,691</u>	<u>25,591</u>
Financing activities		
Principal payments for financing leases	(677)	(604)
Proceeds from the sale of financing lease assets	142	—
Payment of employee restricted stock tax withholdings	(3)	(10)
Employee stock purchase plan proceeds	5	21
Cash in lieu of fractional shares for reverse stock split	(1)	—
Net cash used in financing activities	<u>(534)</u>	<u>(593)</u>
Net increase in cash and cash equivalents	568	6,120
Cash and cash equivalents at beginning of period	9,994	13,011
Cash and cash equivalents at end of period	<u>\$ 10,562</u>	<u>\$ 19,131</u>
Supplemental disclosure of noncash financing information:		
Issuance of equity in exchange for compensation included in compensation and employee benefits	\$ —	\$ 293
Initial measurement of operating lease right-of-use assets	\$ —	\$ 28
Initial measurement of operating lease liabilities	\$ —	\$ 28
Initial measurement of finance lease right-of-use assets	\$ —	\$ 1

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

SENSEI BIOTHERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. ORGANIZATION AND OPERATIONS

Business

Sensei Biotherapeutics, Inc. (the “Company” or “Sensei”), a clinical-stage biotechnology company, was incorporated in 1999 as a Maryland corporation until being incorporated in Delaware on December 1, 2017. The Company is focused on the discovery and development of next-generation therapeutics for cancer patients.

Liquidity and capital resources

Since its inception, the Company has devoted substantially all of its resources to advancing development of its portfolio of programs, establishing and protecting its intellectual property, conducting research and development activities, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. As a result, the Company has incurred substantial losses and had a net loss of \$16.4 million for the nine months ended September 30, 2025. As of September 30, 2025, the Company had an accumulated deficit of \$278.4 million. The Company expects to generate operating losses and negative operating cash flows for the foreseeable future, and as a result the Company’s liquidity position continues to tighten with the passage of time. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations.

The Company has discontinued development of solnerstotug and initiated a comprehensive review of strategic alternatives aimed at maximizing shareholder value. The Company is exploring a range of strategic alternatives that may include, among other options, a sale of assets, licensing arrangements, collaborations, a sale of the Company, a business combination, a merger, or an orderly wind-down of operations.

As part of the cash preservation associated with the strategic review process, the Company expects to implement a reduction in force of approximately 65% of its workforce. The Company estimates that it will incur cash expenditures of \$1.6 million, primarily consisting of severance payments and other employee termination-related expenses, which the Company expects to recognize the majority of such costs in the fourth quarter of 2025, with the remaining employees forming a small team to assist in exploring strategic alternatives and managing compliance with regulatory and financial reporting requirements. The Company expects to incur additional losses in the future to fund its operations during the exploration of strategic alternatives. Failure to manage discretionary spending or execute on a strategic alternative, may adversely impact the Company’s ability to achieve its intended business objectives.

Based on the Company’s available cash, cash equivalents and marketable securities and current operating plans excluding any financing, and consideration of the above factors, it is not probable that the Company will have sufficient cash and cash equivalents to fund its operating expenses and capital requirements within one year from the issuance of these condensed consolidated financial statements, and therefore, the Company has concluded that there is substantial doubt about its ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on the basis that the Company will continue to operate as a going concern, which contemplates it will be able to realize assets and settle liabilities and commitments in the normal course of business for the foreseeable future. Accordingly, the accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

Reverse stock split

On June 16, 2025, at 5:00 p.m. Eastern Time, the Company effected a 1-for-20 reverse stock split of the Company’s issued and outstanding shares of common stock (the “Reverse Stock Split”) and a corresponding reduction in the total number of authorized shares of its common stock from 250,000,000 shares to 12,500,000 shares, as authorized at the Company’s 2025 annual meeting of stockholders held on May 21, 2025 and approved by the Company’s board of directors on June 3, 2025. As a result of the Reverse Stock Split, every 20 shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value of \$0.0001 per share. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders entitled to a fractional share received a cash payment based on the average closing sales price of the Company’s common stock on The Nasdaq Stock Market for the five trading days immediately preceding the filing date of the Certificate of Amendment. All historical share and per share amounts reflected throughout the financial statements have been adjusted to reflect the Reverse Stock Split. Proportionate adjustments were made to the per share exercise price and the number of shares of

common stock that may be purchased upon exercise of outstanding stock options and warrants, the number of shares of common stock reserved for future issuance under the 2021 Equity Incentive Plan (the “2021 Plan”) and the 2021 Employee Stock Purchase Plan (the “2021 ESPP”).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The Company has prepared the accompanying condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States (“US GAAP”). The condensed consolidated financial statements include those accounts of the Company and its subsidiaries after elimination of all intercompany accounts and transactions.

Unaudited Interim Financial Information

The condensed consolidated financial statements of the Company included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”). The accompanying condensed consolidated financial statements reflect all adjustments, consisting of normal, recurring adjustments, that are necessary for a fair presentation of the financial position, results of operations, statement of stockholders’ equity, and cash flows for the interim periods presented. Certain information and note disclosures normally included in financial statements prepared in accordance with US GAAP have been condensed or omitted from these condensed consolidated financial statements, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company’s Annual Report on Form 10-K. The results for any interim period are not necessarily indicative of results for any future period.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods presented. Estimates are used for, but are not limited to, stock-based compensation, accrued research and development expenses, depreciation of equipment, fair value of financial instruments, the Company’s ability to continue as a going concern and contingencies. Actual results may differ from those estimates.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with an original maturity of 90 days or less at the date of purchase and consist of time deposits, commercial paper, and investments in money market funds with commercial banks and financial institutions. As of September 30, 2025, cash and cash equivalents included cash on deposit at commercial banks, commercial paper, and a money market fund that invests in U.S. Government securities.

Marketable Securities

Investments consist of marketable securities with original maturities greater than 90 days at the date of purchase. The Company has classified its investments with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. The Company considers its investment portfolio of marketable securities to be available-for-sale. Accordingly, these investments are recorded at fair value (Level 2). Unrealized gains and losses are reported as the accumulated other comprehensive items in stockholders’ equity. Amortization and accretion of premiums and discounts are recorded in other income (expense). Realized gains or losses on debt securities are included in interest income or interest expense, respectively. If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is other than temporary and, if so, marks the investment to market on the Company’s statement of operations and comprehensive loss.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized over the estimated useful lives of the assets. Repairs or maintenance costs are expensed as incurred. Depreciation is computed using the straight-line method over the following estimated useful lives:

Office equipment and furniture	3—7 years
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Research equipment

1—7 years

Leasehold improvements are depreciated over the shorter of their useful life or the life of the lease.

Segments

The Company manages its operations as a single segment, dedicated to discovering, developing, and advancing innovative, next-generation immunotherapies for cancer patients through its TMAb™ (Tumor Microenvironment Activated Biologics) platform. The Company's Chief Operating Decision Maker ("CODM"), the Chief Executive Officer, reviews the operating results on an aggregate basis and manages the operations as a single operating segment. The CODM oversees performance assessment and resource allocation by reviewing net loss from our condensed consolidated statement of operations to guide operational decisions, strategic planning, and forecasting for future periods. To support this oversight, operating expenses are closely tracked to compare budget against actual results. As a single reporting segment, the significant operating expense categories regularly provided to the CODM include research and development and general and administrative expenses. These expense categories are reported as separate line items in our condensed consolidated statements of operations. All segment assets are reflected as 'total assets' in the condensed consolidated balance sheet. All equipment, leasehold improvements, and fixed assets are located in the United States, and agreements with partners are denominated in U.S. dollars, unless otherwise noted.

Leases

At lease inception, the Company determines if an arrangement is or contains a lease, and if so, assesses the lease for classification as either an operating or finance lease. A lease is classified as a finance lease if any one of the following criteria are met: (i) the lease transfers ownership of the asset by the end of the lease term, (ii) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (iii) the lease term is for a major part of the remaining useful life of the asset, (iv) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset, or (v) the leased asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease. A lease is classified as an operating lease if it does not meet any of these criteria.

Leases with a term greater than one year are recognized on the balance sheet as right-of-use ("ROU") assets and current and non-current lease liabilities, as applicable. Leases with a term of one year or less are expensed as rent in the period incurred. The Company elected not to separate lease and non-lease components for all underlying assets. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment. Lease terms include options to extend or terminate the lease when it is reasonably certain that the Company will exercise the options. For leases that existed prior to the adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842) ("ASC 842"), the Company used the remaining lease term to determine the appropriate incremental borrowing rate.

Recently Issued Accounting Standards

In November 2024, the Financial Accounting Standards Board ("FASB") issued ASU 2024-03, "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses." The standard is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU 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. The amendments may be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to all prior periods presented in the financial statements. The Company is currently assessing the impact this standard will have on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures". ASU 2023-09 is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. A public entity should apply the amendments in ASU 2023-09 prospectively to all annual periods beginning after December 15, 2024. The Company does not expect adoption of this new guidance to have a material impact on its results of operations, financial condition, and financial statement disclosures.

3. MARKETABLE SECURITIES

Marketable securities consist of the following as of September 30, 2025 and December 31, 2024 (in thousands):

	As of September 30, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	\$ 14,482	\$ —	\$ (3)	\$ 14,479
Total	\$ 14,482	\$ —	\$ (3)	\$ 14,479

	As of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	\$ 25,875	\$ 2	\$ (16)	\$ 25,861
Corporate bonds	5,479	2	(1)	5,480
Total	\$ 31,354	\$ 4	\$ (17)	\$ 31,341

As of September 30, 2025, all marketable securities held by the Company had remaining contractual maturities of one year or less.

There were no impairments of the Company's assets measured and carried at fair value during the nine months ended September 30, 2025.

As of September 30, 2025, an immaterial amount of unrealized losses were associated with marketable securities with contractual maturities of one year or less.

4. FAIR VALUE MEASUREMENTS

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair value measurements at September 30, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Commercial paper	\$ —	\$ 999	\$ —	\$ 999
Money market funds	\$ 8,791	\$ —	\$ —	\$ 8,791
Investments:				
Commercial paper	—	14,479	—	14,479
Total	\$ 8,791	\$ 15,478	\$ —	\$ 23,270

	Fair value measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 9,220	\$ —	\$ —	\$ 9,220
Investments:				
Commercial paper	—	25,861	—	25,861
Corporate bonds	—	5,480	—	5,480
Total	\$ 9,220	\$ 31,341	\$ —	\$ 40,561

When developing fair value estimates, the Company maximizes the use of observable inputs and minimizes the use of unobservable inputs. When available, the Company uses quoted market prices to measure fair value. The valuation technique used to measure fair value for the Company's Level 1 and Level 2 assets is a market approach, using prices and other relevant information generated by market transactions involving identical or comparable assets. If market prices are not available, the fair value measurement is based on models that use primarily market-based parameters including yield curves, volatilities, credit ratings and

currency rates. In certain cases where market rate assumptions are not available, the Company is required to make judgments about assumptions market participants would use to estimate the fair value of a financial instrument.

There were no transfers among Level 1, Level 2 or Level 3 categories in the nine months ended September 30, 2025 and 2024.

5. PROPERTY AND EQUIPMENT, NET

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

	September 30, 2025	December 31, 2024
Research equipment	\$ —	\$ 1,306
Office equipment and furniture	369	354
Leasehold improvement	253	253
Total property and equipment	622	1,913
Less accumulated depreciation and amortization	(510)	(1,496)
Property and equipment, net	\$ 112	\$ 417

Depreciation and amortization expense for the nine months ended September 30, 2025 and 2024 was \$92 thousand and \$412 thousand, respectively.

During the nine months ended September 30, 2025, the Company disposed of all research equipment through the sale of fixed assets, resulting in a reduction of the gross carrying amount to zero. The related accumulated depreciation of \$1,078 thousand was written off in connection with this disposal. A gain of \$22 thousand was recognized on the sale and is included in the other expense line in the condensed consolidated statements of operations and comprehensive loss for the period.

6. COMMITMENTS AND CONTINGENCIES

Operating Leases

As of September 30, 2025, the Company leases office and laboratory facilities under operating leases, which expire at various dates through 2027. The Company has \$678 thousand in letters of credit outstanding as security on certain of these leases. As part of its adoption of ASC 842, the Company recorded operating ROU assets and operating lease liabilities for these leases as of January 1, 2022.

The Company entered into an operating sublease agreement on January 18, 2023 (the "Sublease") with respect to part of its existing Boston office and laboratory facilities (the "Head Lease"). The Company accounted for the Head Lease and the Sublease as separate contracts and there was no effect on the ROU asset or lease liability associated with the Head Lease. The Sublease ended on December 31, 2024. The Head Lease rent expense is presented separately from income related to the Sublease and both are reported as components of operating expenses on the condensed consolidated statements of operations and comprehensive loss. The Company recorded \$288 thousand of income related to the Sublease for the nine months ended September 30, 2024.

Finance Leases

The Company leases research equipment and furniture under finance leases.

The following table contains a summary of the lease costs recognized under ASC 842 pertaining to the Company's finance and operating leases for the nine months ended September 30, 2025 and 2024 (in thousands):

	For the Nine Months Ended September 30,	
	2025	2024
Lease Cost:		
Amortization of finance ROU assets	\$ 13	\$ 579
Interest on finance lease liabilities	29	73
Operating lease cost	1,269	1,386
Variable lease cost	640	491
Total lease costs	1,951	2,529
Operating Sublease income	—	(288)
Total lease costs, net	\$ 1,951	\$ 2,241

During the nine months ended September 30, 2025, the Company disposed of research equipment classified as a ROU asset under a lease agreement. The ROU asset was sold, resulting in a loss of \$43 thousand, which is included in the other expense line in the condensed consolidated statements of operations and comprehensive loss for the period.

The following table contains a summary of other information pertaining to the Company's finance and operating leases for the nine months ended September 30, 2025 and 2024 (in thousands, except lease term and discount rate):

	For the Nine Months Ended September 30,	
	2025	2024
Other Operating Lease Information:		
Operating cash outflows for operating leases	\$ 1,320	\$ 1,400
Operating cash inflows for operating subleases	\$ —	\$ (300)
Operating cash outflows for finance leases	\$ 29	\$ 73
Financing cash outflows from finance leases	\$ 677	\$ 604
Weighted average remaining lease term		
Operating leases	1.1 years	2.0 years
Financing leases	0.6 years	1.4 years
Weighted average discount rate		
Operating leases	7.6%	7.7%
Financing leases	10.1%	8.4%

The following table presents the maturity of the Company's operating and finance lease liabilities as of September 30, 2025 (in thousands):

	Operating	Financing
2025	\$ 428	\$ 116
2026	1,413	81
2027	59	—
Total future minimum lease payments	1,900	197
Less amount representing interest	72	4
Total lease liabilities	<u>\$ 1,828</u>	<u>\$ 193</u>

License Agreements

In the normal course of business, the Company enters into licensing agreements with various parties to obtain the right to make, use, and sell licensed products currently in development.

Litigation

The Company records estimated losses from loss contingencies, such as a loss arising from a litigation, when it determines that it is probable a liability has been incurred and the amount of loss can be reasonably estimated. Litigation is subject to many factors that are difficult to predict so that there can be no assurance, in the event of a material unfavorable result in one or more claims, the Company will not incur material costs.

7. ACCOUNTS PAYABLE AND CURRENT ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Accounts payable	\$ 306	\$ 244
Accrued expenses	1,019	847
Accrued restructuring (Note 14)	—	31
Other current liabilities	80	126
Total	<u>\$ 1,405</u>	<u>\$ 1,248</u>

8. EQUITY

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

Common Stock Warrants

The following is a summary of the common stock warrant activity for the nine months ended September 30, 2025, related to common stock warrants issued in conjunction with equity and debt fundraising events:

	Number of Common Stock Warrants	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	20,609	\$ 195.80	2.70	\$ —
Expired	(19,466)	\$ 79.00	—	—
Outstanding at September 30, 2025	<u>1,143</u>	<u>\$ 2,185.04</u>	3.41	<u>\$ —</u>

9. STOCK-BASED COMPENSATION

2018 Equity Incentive Plan

The Company's 2018 Stock Incentive Plan (the "2018 Plan") provided for the Company to grant qualified incentive options, nonqualified options, stock grants and other stock-based awards to employees and non-employees to purchase the Company's common stock. Upon the effectiveness of the 2021 Plan, the Company ceased issuing new awards under the 2018 Plan.

2021 Equity Incentive Plan

The 2021 Plan became effective in February 2021. The 2021 Plan provides for the grant of incentive stock options to employees, including employees of any parent or subsidiary corporations, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of the Company's affiliates. The number of shares initially reserved for issuance under the 2021 Plan was 250,000 (5,000,000 prior to Reverse Stock Split), which began automatically increasing on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to 4.0% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the board of directors. As of September 30, 2025, 81,275 shares remained available for issuance pursuant to the 2021 Plan.

2021 Employee Stock Purchase Plan

The 2021 ESPP became effective in February 2021. A total of 16,666 shares (333,333 prior to Reverse Stock Split) of common stock were initially reserved for issuance under the 2021 ESPP, which will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 through January 1, 2031, by an amount equal to 1.0% of the total shares of common stock outstanding on December 31st of the preceding calendar year. The purchase price of the shares under the 2021 ESPP are at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the purchase date. As of September 30, 2025, the Company had issued 12,220 shares under the 2021 ESPP, and 60,237 shares were available to be issued under the same plan.

Stock Options

The Company has granted options to purchase shares of common stock to employees pursuant to the 2021 Plan at a weighted average grant date fair value of \$7.17 per share during the nine months ended September 30, 2025. The Company uses the Black-Scholes option-pricing model to estimate the fair value of the stock options on the applicable grant dates.

The following is a summary of the stock option award activity during the nine months ended September 30, 2025:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	264,741	\$ 95.96	7.22	\$ 41
Granted	47,224	\$ 9.21		
Forfeited	(3,155)	\$ 18.28		
Expired	(15,760)	\$ 117.87		
Outstanding at September 30, 2025	293,050	\$ 81.64	7.24	\$ 37
Vested or expected to vest as of September 30, 2025	293,050	\$ 81.64	7.24	\$ 37
Exercisable at September 30, 2025	164,204	\$ 136.28	5.85	\$ 5

The aggregate intrinsic value of the outstanding stock option awards is calculated as the difference between the exercise price and the market price of the Company's common stock at September 30, 2025. There were no stock options exercised in the nine months ended September 30, 2025.

The grant date fair value of options vested during the nine months ended September 30, 2025 and 2024 was \$0.8 million and \$2.7 million, respectively.

At September 30, 2025, there was \$0.8 million of unrecognized stock-based compensation expense associated with the stock options, which is expected to be recognized over a weighted-average period of 2.17 years.

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions.

The following is a summary of the restricted stock unit activity during the nine months ended September 30, 2025:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2024	4,178	\$ 55.01
Vested	(1,768)	\$ 61.07
Forfeited	(136)	\$ 35.78
Unvested at September 30, 2025	2,274	\$ 51.44

Pursuant to the 2021 Plan, the Company has historically granted restricted stock units which vest annually over a period of one, two, three or four years. The Company granted no restricted stock units during the nine months ended September 30, 2025.

At September 30, 2025, there was approximately \$0.1 million of unrecognized stock-based compensation expense associated with the restricted stock units which is expected to be recognized over a weighted-average period of 0.86 years.

Common Stock Warrants

There was no common stock warrant activity related to common stock warrants for the nine months ended September 30, 2025. The following is a summary of the common stock warrants outstanding at September 30, 2025 and December 31, 2024:

	Number of Common Stock Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding and exercisable at December 31, 2024	229	\$ 217.49	2.98	\$ —
Outstanding and exercisable at September 30, 2025	229	\$ 217.49	2.23	\$ —

As of September 30, 2025 there was no unrecognized stock-based compensation expense associated with the common stock warrants.

For the nine months ended September 30, 2025 and 2024, respectively, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options and common stock warrants granted. The following table presents the assumptions and the Company's methodology for developing each of the assumptions used:

	For the Nine Months Ended September 30,	
	2025	2024
Volatility	94%-96%	91%-94%
Expected term (years)	5.5-6.0	5.0-6.0
Risk-free interest rate	4.2%-4.4%	3.8%-4.6%
Dividend rate	—%	—%

- Volatility—The Company lacks sufficient Company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies in addition to its own historical volatility and will continue to do so until it has adequate historical data regarding the volatility of its own traded stock price.
- Expected term—The Company calculates the expected term of options using the simplified method, as the Company lacks relevant historical data due to the Company's limited operating experience.
- Risk-free interest rate—The risk-free rate for periods within the estimated life of the stock award is based on the U.S. Treasury yield curve in effect at the time of grant.
- Dividend rate—The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

Stock-based compensation expense was recorded in the following line items in the condensed consolidated statements of operations for the three and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	\$ 78	\$ 223	\$ 286	\$ 788
General and administrative	176	510	693	1,956
Total stock-based compensation expense	\$ 254	\$ 733	\$ 979	\$ 2,744

10. EMPLOYEE RETIREMENT PLAN

The Company maintains a defined contribution 401(k) profit-sharing plan (the "Plan") for all employees. Under the Plan, participants may make voluntary contributions up to the maximum amount allowable by law. The Plan is based on employees' salary deferral, and the Company matches employees' contributions up to 4% of the employees' base salary. Employees are 100% vested in the Company's match contributions. During the three months ended September 30, 2025 and 2024, the Company's matching contributions were \$31 thousand and \$58 thousand, respectively. During the nine months ended September 30, 2025 and 2024, the Company's matching contributions were \$132 thousand and \$198 thousand, respectively.

11. COMPENSATION AND EMPLOYEE BENEFITS

Compensation and employee benefits consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Accrued incentive compensation	\$ 1,105	\$ 1,379
Accrued restructuring - compensation (Note 14)	—	445
Other compensation related liabilities	51	58
Total	\$ 1,156	\$ 1,882

12. INCOME TAXES

The Company recorded no provision for income taxes for the nine months ended September 30, 2025 and 2024.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards, equity-based compensation, research and development tax credit carryforwards, and capitalized research and development expenditures. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance has been established against the Company's otherwise recognizable net deferred tax assets.

On July 4, 2025, the United States Congress passed budget reconciliation bill H.R. 1, referred to as the One Big Beautiful Bill (OB BB). The OB BB contains several changes to corporate taxation, including modifications to the capitalization of research and development expenses, limitations on deductions for interest expense, and accelerated fixed asset depreciation. As the Company maintains a full valuation allowance on its U.S. deferred tax assets, the legislation did not have a material impact on the condensed consolidated financial statements for three months ended September 30, 2025, and the Company does not expect the legislation to have a material impact on its consolidated financial statements for the year ending December 31, 2025.

13. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands, except share and per share amounts):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	\$ (4,569)	\$ (7,253)	\$ (16,368)	\$ (22,387)
Net loss per share—basic and diluted	\$ (3.62)	\$ (5.77)	\$ (12.98)	\$ (17.84)
Weighted-average number of shares used in computing net loss per share—basic and diluted	1,261,290	1,257,299	1,260,569	1,254,953

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	For the Nine Months Ended September 30,	
	2025	2024
Stock options to purchase common stock	293,050	234,654
Unvested restricted stock units	2,274	5,080
Warrants issued to employees and contractor to purchase common stock	229	229
Warrants issued related to convertible notes and other equity agreements	1,143	20,609

14. RESTRUCTURING AND RELATED CHARGES

In November 2024, the Company announced a restructuring initiative to streamline operations and focus resources on advancing the clinical development of solnerstotug (the "2024 Restructuring"). As part of the 2024 Restructuring, the Company closed its research site in Rockville, Maryland, and reduced its workforce by approximately 46%, with the majority of reductions occurring in the preclinical research and development group. These actions were intended to extend the Company's cash runway. The 2024 Restructuring costs primarily related to one-time termination benefits and ongoing benefit arrangements, both of which included severance payments and extended benefits coverage. Aggregate costs also included certain contract termination costs.

The following table summarizes the accrued liabilities activity recorded in connection with the 2024 Restructuring as of September 30, 2025 (in thousands):

	Personnel	Other	Total
Balance at January 1, 2024	\$ —	\$ —	\$ —
Restructuring and other costs	723	31	754
Cash payments	(278)	—	(278)
Balance at December 31, 2024	445	31	476
Restructuring and other costs, net	25	(2)	23
Cash payments	(346)	(16)	(362)
Balance at March 31, 2025	124	13	137
Restructuring and other costs, net	—	(3)	(3)
Cash payments	(124)	(6)	(130)
Balance at June 30, 2025	—	4	4
Restructuring and other costs, net	—	(4)	(4)
Cash payments	—	—	—
Balance at September 30, 2025	\$ -	\$ -	\$ -

15. SUBSEQUENT EVENTS

On October 30, 2025, the Company announced the discontinuation of development of its lead therapeutic candidate, solnerstotug, and initiated a comprehensive review of strategic alternatives to maximize stockholder value. These alternatives include, but are not limited to, a sale of assets, licensing arrangements, collaborations, a sale of the Company, a business combination, a merger, or an orderly wind-down of operations. In connection with the strategic review, the Company also announced its plan to discontinue development of solnerstotug and implement a workforce reduction to preserve cash. The Company expects to incur aggregate cash charges of approximately \$1.6 million in connection with the reduction in force of approximately 65% of its workforce, primarily consisting of severance payments and other employee termination-related expenses, with the remaining employees forming a small team to assist in exploring strategic alternatives and managing compliance with regulatory and financial reporting requirements. The estimated charges that the Company expects to incur are subject to a number of assumptions, and actual results may differ from these estimates. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the reduction in force. The Company has not set a definitive timeline for the completion of the strategic review, and there is no assurance that the process will result in any transaction being announced or completed.

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

Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words and phrases “designed to,” “may,” “might,” “can,” “will,” “to be,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “likely,” “continue,” “ongoing” or similar expressions, or the negative of such words, are intended to identify “forward-looking statements.” We have based these forward-looking statements on our current expectations and projections about future events. Because such statements include risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those below in this Quarterly Report under the caption “Risk Factors,” and in our other filings with the Securities and Exchange Commission, or SEC. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes for the year ended December 31, 2024, which are included in our Annual Report on Form 10-K filed with the SEC on March 28, 2025.

Unless otherwise indicated, all information in this Quarterly Report on Form 10-Q gives effect to a 1-for-20 reverse stock split of our common stock that became effective on June 16, 2025 (the “Reverse Stock Split”), and all references to historical share and per share amounts give effect to the Reverse Stock Split.

Overview

We are a clinical-stage biotechnology company that has been focused on the discovery and development of next-generation therapeutics for cancer patients.

On October 30, 2025, we announced the discontinuation of development of our lead product candidate, solnerstotug, and initiated a comprehensive review of strategic alternatives to maximize stockholder value. These alternatives include, but are not limited to, a sale of assets, licensing arrangements, collaborations, a sale of the Company, a business combination, a merger, or an orderly wind-down of operations.

On November 14, 2025, we announced the implementation of a workforce reduction to preserve cash, pursuant to which we reduced our workforce by approximately 65% (the “2025 Workforce Reduction”). We expect to incur aggregate cash charges of approximately \$1.6 million in connection with the 2025 Workforce Reduction, primarily consisting of severance payments and other employee termination-related expenses, with the remaining employees forming a small team to assist in exploring strategic alternatives and managing compliance with regulatory and financial reporting requirements.

We are devoting substantial time and resources to the strategic review. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a definitive timeline for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distribution to our stockholders. If a strategic transaction is not completed, including if our board of directors determines that no potential transactions or counterparties would be in the best interests of our stockholders, our board of directors may decide to pursue a dissolution and liquidation.

Our pipeline consists of one clinical-stage program and three preclinical programs.

- **Solnerstotug** (formerly referred to as SNS-101) is our conditionally active monoclonal antibody targeting the immune checkpoint VISTA (V-domain Ig suppressor of T-cell activation).
 - o On October 17, 2025, we disclosed results from the dose expansion portion of our Phase 1/2 trial of solnerstotug. The Phase 1 dose expansion is a multi-center, open-label study evaluating solnerstotug as monotherapy and in combination with Libtayo® (cemiplimab), Regeneron’s PD-1 inhibitor. The study enrolled patients with a basket of “hot” tumor types (that typically respond to immunotherapy) (n=44), of whom 41 had previously received and progressed on PD-(L)1 therapy, as well as patients with “cold” tumor types (that typically exhibit primary resistance to immunotherapy) (n=20).

- o As of the September 8, 2025 data cutoff, 35 efficacy-evaluable “hot” tumor patients had received cemiplimab with either 15 mg/kg (n=19) or 3 mg/kg dose (n=16) of solnerstotug. Six clinical responses, including five in patients with PD-(L)1 resistant tumors, occurred at the higher 15 mg/kg solnerstotug dose, and no objective responses were observed at the 3 mg/kg dose.
- o Among 41 “hot” tumor patients that received and progressed on a prior PD-(L)1 therapy, the overall 6-month PFS rate was 37%, which compares favorably with historical benchmarks in this setting. At 15 mg/kg, 6-month PFS reached 50% among PD-(L)1 resistant patients, surpassing rates historically seen in this treatment-refractory population. At 3 mg/kg, 6-month PFS was 24% among PD-(L)1 resistant patients.
- o On October 30, 2025, we announced our intention to discontinue development of solnerstotug and terminate the Phase 1/2 trial in an orderly manner.
- **SNS-102** is our conditionally active monoclonal antibody targeting VSIG4 (V-Set and Immunoglobulin Domain Containing 4), an immune checkpoint often expressed on macrophages.
- **SNS-103** is our conditionally active monoclonal antibody targeting ENTPDase1 (ecto-nucleoside triphosphate diphosphohydrolase-1), also known as CD39.
- **SNS-201** is a bispecific antibody that is being designed to conditionally activate Cluster of Differentiation 28 (CD28). It is a bispecific format with monovalent CD28 engagement and bivalent pH-selective VISTA binding for efficient engagement at low pH.

We do not have any product candidates approved for sale, have not generated any revenue from product sales, and do not expect to generate any revenue from product sales for at least the next several years. We have largely funded our operations with proceeds from the sale of convertible preferred stock, common stock and convertible debt. Through the date of this Report, we have raised an aggregate of \$123.4 million of gross proceeds from private placements of our equity and convertible debt securities and net proceeds of \$138.5 million from our initial public offering, or IPO, in February 2021.

We have incurred significant operating losses over the last several years. Our net loss was \$16.4 million and \$22.4 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of \$278.4 million.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses and negative cash flows for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will decrease.

Going Concern

Based on our available cash, cash equivalents and marketable securities and current operating plans excluding any financing, we will not have sufficient cash and cash equivalents to fund our operating expenses and capital requirements beyond one year from the issuance of the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, and therefore, we have concluded that there is substantial doubt about its ability to continue as a going concern.

Components of Our Results of Operations

Operating Expenses

Research and Development Expense

Our research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- the cost of manufacturing our product candidates including the cost of contract manufacturing organizations, or CMOs, that manufacture product for use in our preclinical studies and clinical trials and perform analytical testing, scale-up and other services in connection with our development activities;
- the cost of outsourced professional scientific development services;
- employee-related expenses, including salaries, benefits and stock-based compensation for employees engaged in the research and development function;

- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- fees for maintaining licenses and other amounts due under our third party licensing agreements;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

Our direct external research and development expenses consist primarily of third party costs, such as fees paid to CROs, CMOs, research/testing laboratories and outside consultants in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate these costs to specific product candidates because many of them are deployed across several of our development programs and, as such, are not separately classified. We use internal resources primarily to conduct research and manage our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple development programs and, therefore, we do not track their costs by program and, as such, are not separately classified. Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Research and development activities have been central to our business model, prior to our decision to wind down clinical operations in October 2025. We generally expect that our research and development expenses will decrease as we wind down these operations. We may also incur other charges or cash expenditures due to events that may occur as a result of, or associated with, our wind down of clinical operations and review of strategic alternatives. The exact amounts of the charges and costs that we expect to incur, and the timing thereof, are currently unknown and such costs and charges could be material to our results of operation and financial condition.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the scope, progress, outcome and costs of our preclinical studies, our current product candidates and any other product candidates we may acquire or develop;
- manufacturing of our product candidates or making arrangements with third-party manufacturers for both clinical and commercial supplies of these product candidates;
- successful patient enrollment in, and the initiation, duration and completion of clinical trials;
- the cost of gaining regulatory approvals for our product candidates, subject to the successful outcome of ongoing and future clinical trials; and
- the extent of any required post-marketing approval commitments to applicable regulatory authorities.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and significant additional development costs.

General and Administrative Expense

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for legal, auditing and tax services, and insurance costs.

We generally expect that our general and administrative expenses will decrease as we discontinue development of solnerstotug

and wind down our clinical operations, including through the implementation of our 2025 Workforce Reduction. However, we may also incur other charges or cash expenditures due to events that may occur as a result of, or associated with, our wind down of clinical operations and review of strategic alternatives. The exact amounts of the charges and costs that we expect to incur, and the timing thereof, are currently unknown and such costs and charges could be material to our results of operation and financial condition.

Other Income (Expense)

Our other income (expense) consists of accretion on short-term investments, interest expense and gain or loss on fixed asset disposals.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

The following sets forth our results of operations for the three months ended September 30, 2025 and 2024:

<i>(in thousands)</i>	For the Three Months Ended September 30,		
	2025	2024	Change
Operating expenses:			
Research and development	\$ 2,536	\$ 4,637	\$ (2,101)
General and administrative	2,315	3,186	(871)
Total operating expenses	4,851	7,823	(2,972)
Loss from operations	(4,851)	(7,823)	2,972
Total other income	282	570	(288)
Net loss	\$ (4,569)	\$ (7,253)	\$ 2,684

Research and Development Expenses

Research and development expenses were \$2.5 million for the three months ended September 30, 2025, compared to \$4.6 million for the three months ended September 30, 2024. The decrease of \$2.1 million was primarily attributable to \$0.8 million of lower personnel costs, including stock-based compensation and incentives, \$0.4 million less expense associated with clinical trials, \$0.3 million of lower facilities and equipment cost, \$0.2 million less expense relating to lab supply purchases, \$0.2 million of lower preclinical research, \$0.1 million of lower manufacturing costs and \$0.1 million of lower outside research fees.

General and Administrative Expenses

General and administrative expenses were \$2.3 million for the three months ended September 30, 2025, compared to \$3.2 million for the three months ended September 30, 2024. The decrease of \$0.9 million was primarily attributable to \$0.7 million of lower personnel costs, including recruiting, stock-based compensation and incentives, \$0.1 million of lower consulting fees and \$0.1 million of lower facilities and equipment cost.

Other Income

Other income was \$0.3 million for the three months ended September 30, 2025, compared to other income of \$0.6 million for the three months ended September 30, 2024. The decrease of \$0.3 million was primarily related to a decrease in interest income.

Comparison of the Nine Months Ended September 30, 2025 and 2024

The following sets forth our results of operations for the nine months ended September 30, 2025 and 2024:

(in thousands)	For the Nine Months Ended September 30,		Change
	2025	2024	
Operating expenses:			
Research and development	\$ 8,794	\$ 14,138	\$ (5,344)
General and administrative	8,537	10,202	(1,665)
Total operating expenses	17,331	24,340	(7,009)
Loss from operations	(17,331)	(24,340)	7,009
Total other income	963	1,953	(990)
Net loss	<u>\$ (16,368)</u>	<u>\$ (22,387)</u>	<u>\$ 6,019</u>

Research and Development Expenses

Research and development expenses were \$8.8 million for the nine months ended September 30, 2025, compared to \$14.1 million for the nine months ended September 30, 2024. The decrease of \$5.3 million was primarily attributable to \$2.4 million of lower personnel costs, including stock-based compensation and incentives, \$1.1 million of lower facilities and equipment cost, \$0.8 million less expense relating to relating to lab supply purchases, \$0.5 million of lower manufacturing cost, \$0.4 million less outside research fees and \$0.3 million of lower preclinical research expense partially offset by \$0.2 million of higher expense associated with clinical trials.

General and Administrative Expenses

General and administrative expenses were \$8.5 million for the nine months ended September 30, 2025, compared to \$10.2 million for the nine months ended September 30, 2024. The decrease of \$1.7 million was primarily attributable to \$1.7 million of lower personnel costs, including recruiting, stock-based compensation and incentives, \$0.1 million lower cost for external administrative fees, \$0.1 million of less expense for directors and officers insurance and \$0.1 million of lower board fees, partially offset by \$0.3 million of higher consulting cost.

Other Income

Other income was \$1.0 million for the nine months ended September 30, 2025, compared to other income of \$2.0 million for the nine months ended September 30, 2024. The decrease of \$1.0 million was primarily related to a decrease in interest income.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any product revenue and have incurred net losses and negative cash flows from our operations. As of September 30, 2025, we had cash, cash equivalents and marketable securities of \$25.0 million. We have financed our operations through sales of our common stock, convertible preferred stock and convertible debt. Through the date of this Report, we have raised an aggregate of \$123.4 million of gross proceeds from private placements of our equity and convertible debt securities and net proceeds of \$138.5 million from our IPO in February 2021. Our net loss was \$16.4 million and \$22.4 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of \$278.4 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures.

We have discontinued development of solnerstotug and initiated a comprehensive review of strategic alternatives aimed at maximizing stockholder value. We are exploring a range of strategic alternatives that may include, among other options, a sale of assets, licensing arrangements, collaborations, a sale of the company, a business combination, a merger, or an orderly wind-down of operations.

As part of the cash preservation associated with the strategic review process, we have implemented a reduction in force of approximately 65% of our workforce. We estimate that we will incur cash expenditures of \$1.6 million, primarily consisting of severance payments and other employee termination-related expenses, which we expect to recognize the majority of such costs in the fourth quarter of 2025, with the remaining employees forming a small team to assist in exploring strategic alternatives and managing compliance with regulatory and financial reporting requirements. We expect to incur additional losses in the future to fund our operations during the exploration of strategic alternatives. Failure to manage discretionary spending or execute on a strategic alternative may adversely impact our ability to achieve our intended business objectives.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods below:

(in thousands)	For the Nine Months Ended September 30,	
	2025	2024
Net cash used in operating activities	\$ (16,589)	\$ (18,878)
Net cash provided by investing activities	17,691	25,591
Net cash used in financing activities	(534)	(593)
Net increase in cash and cash equivalents	\$ 568	\$ 6,120

Operating Activities

During the nine months ended September 30, 2025, net cash used in operating activities was \$16.6 million, primarily resulting from our \$16.4 million net loss and a \$1.9 million decrease in our operating assets and liabilities partially offset by increases in non-cash charges of \$1.7 million, primarily related to \$1.1 million of non-cash lease expense, \$1.0 million of stock compensation expense and \$0.1 million of depreciation and amortization, partially offset by \$0.6 million of accretion on marketable securities.

During the nine months ended September 30, 2024, net cash used in operating activities was \$18.9 million, primarily resulting from our \$22.4 million net loss and a \$0.7 million increase in our operating assets and liabilities, partially offset by increases in non-cash charges of \$4.3 million primarily related to \$2.7 million of stock compensation expense, \$1.2 million of non-cash lease expense, \$0.6 million for amortization of financing lease right-of-use assets, and \$0.4 million for depreciation and amortization, partially offset by \$0.6 million of accretion on marketable securities.

Investing Activities

During the nine months ended September 30, 2025, net cash provided by investing activities was \$17.7 million, primarily due to \$36.1 million in maturities of short-term investments and \$0.2 million of proceeds from the sale of property and equipment, partially offset by \$18.6 million in purchases of short-term investments.

During the nine months ended September 30, 2024, net cash provided by investing activities was \$25.6 million, primarily due to \$52.5 million in maturities of short-term investments, partially offset by \$26.8 million in purchases of short-term investments and \$0.1 million of purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2025, net cash used in financing activities was \$0.5 million, primarily consisting of \$0.6 million of principal payments under our financing leases, partially offset by \$0.1 million of proceeds from the sale of financing lease assets.

During the nine months ended September 30, 2024, net cash used in financing activities was \$0.6 million, primarily consisting of principal payments under our financing lease.

Material Cash Requirements

Our material cash requirements will have an impact on our future liquidity. Our material cash requirements represent material expected or contractually committed future payment obligations.

Operating Leases

We have operating lease arrangements for our corporate offices and lab facilities. As part of our adoption of ASC 842, we recorded operating ROU assets and operating lease liabilities for these leases as of January 1, 2022. As of September 30, 2025, we had operating lease payment obligations of \$1.9 million, with \$0.4 million payable for the remainder of 2025. See Note 6 in our condensed consolidated financial statements included elsewhere in this Form 10-Q for additional information.

Finance Leases

We lease research equipment and furniture under finance leases. As part of our adoption of ASC 842, we recorded financing ROU assets and financing lease liabilities for these leases as of January 1, 2022. As of September 30, 2025, we had finance lease

payment obligations of \$0.2 million, with \$0.1 million payable for the remainder of 2025. See Note 6 in our condensed consolidated financial statements included elsewhere in this Form 10-Q for additional information.

In the biopharmaceutical industry, it can take a significant amount of time and capital resources to successfully complete all stages of research and development and commercialize a product candidate. The ultimate length of time and spend required cannot be accurately estimated as it varies substantially according to the type, complexity, novelty and intended use of a product candidate. Please see the “Funding Requirements” section below for further details.

Funding Requirements

As of September 30, 2025, we had cash, cash equivalents and marketable securities of \$25.0 million. Depending on the outcome of our strategic review process, we may need to raise substantial additional capital to fund our future operations. However, we cannot guarantee that we will be able to obtain sufficient additional funding or that if we do obtain additional funding, that such funding will be obtainable on terms satisfactory to us.

Based on our available cash, cash equivalents, and marketable securities, and our current operating plans excluding any financing, we expect that our existing cash and cash equivalents will be unable to fund our operating expenses and capital requirements beyond one year from the issuance of our condensed consolidated financial statements. We have concluded that there is substantial doubt about our ability to continue as a going concern beyond one year from the issuance of the financial statements included in this Quarterly Report on Form 10-Q. We expect our expenses to decrease in connection with the wind down of our clinical operations. However, we may incur substantial additional expenses and other charges as we conduct our strategic alternatives review and evaluate and seek to consummate strategic transactions to maximize stockholder value.

If we are successful in consummating a strategic transaction that enables us to continue to develop our current or new product candidates, we will require substantial additional funding to expand our operations, hire additional personnel, initiate and successfully complete preclinical studies and clinical trials, obtain marketing approval and generate revenue from sales of our product candidates, if approved, and protect our intellectual property. We would expect to finance our operations through the public or private sale of our equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Because of the uncertain outcome of our strategic review process and the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of our future expenses, and there is no assurance that we will ever be profitable or generate positive cash flow from operating activities.

If, for any reason, we utilize our capital resources more quickly than anticipated or are unable to obtain additional funding on a timely basis and/or complete a strategic transaction, we may be required to further revise our business plan and strategy or cease operations. This may limit the strategic options available to us. As a result, our business, financial condition, and results of operations could be materially affected.

Critical Accounting Policies and Significant Judgements and Estimates

This Management’s Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which are prepared in accordance with US GAAP. The preparation of our financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the nine months ended September 30, 2025, there were no significant changes to our critical accounting policies disclosed in our audited financial statements for the year ended December 31, 2024, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 28, 2025.

Recent Accounting Pronouncements

See Note 2 in our condensed consolidated financial statements included elsewhere in this Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements. Other than as disclosed in our financial statements, we do not expect that any recently issued accounting standards will have a material impact on our financial statements or will otherwise apply to our operations.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an Emerging Growth Company (“EGC”), as defined in the JOBS Act. As an EGC, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an EGC earlier if we have more than \$1.235 billion in annual revenue, we have more than \$700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than \$1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an EGC, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. We may choose to take advantage of some, but not all, of the available exemptions.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an EGC. Therefore, the reported results of operations contained in our condensed consolidated financial statements may not be directly comparable to those of other public companies.

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

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, 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 Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures.*Disclosure Controls and Procedures*

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and other procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is 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. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2025.

Changes in Internal Control over Financial Reporting:

There were no material changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended September 30, 2025 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

Item 1A. Risk Factors.

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Quarterly Report on Form 10-Q. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

SUMMARY OF RISK FACTORS

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- ***Risks Related to our Financial Position***
 - Our activities to evaluate and pursue potential strategic alternatives may not result in any transaction or enhance stockholder value.
 - Our recently implemented corporate restructuring intended to optimize our resource allocation and contain costs may not have the benefits we expect.
 - Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
 - We would need additional funding to re-initiate and complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to further delay, limit, reduce or terminate our product development or commercialization efforts.
 - We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
 - We do not currently have sufficient working capital to fund our planned operations for the next twelve months and substantial doubt exists as to our ability to continue as a going concern.
- ***Risks Related to the Development of our Product Candidates***
 - Our development efforts are in the early stages. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
 - Our business is highly dependent on the success of our product candidates that we advance into the clinic. All our product candidates will require significant additional preclinical, clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially. If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
 - Interim data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional data become available.
 - We will depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
 - Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

- ***Risks Related to our Dependence on Third Parties***

- We collaborate with third parties in connection with the development of our product candidates, and may depend upon future collaboration partners to commit to the research, development, manufacturing and marketing of our product candidates.
- We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

- ***Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters***

- Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

- ***Risks Related to the Commercialization of our Product Candidates***

- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.
- We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

- ***Risks Related to our Intellectual Property***

- If we are unable to obtain and maintain patent protection for our technologies and product candidates, including solnerstotug, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

- ***Risks Related to our Business Operations***

- We may need to grow the size of our organization, and we may experience difficulties in managing this growth.
- Our future success may depend on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

- ***Risks Related to our Securities and our Status as a Public Company***

- The trading price of our common stock may be volatile, and you could lose all or part of your investment.
- Our business and operations could be negatively affected by any securities litigation or stockholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.
- If we fail to maintain an effective system of internal control over financial reporting which results in material weaknesses, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud and investor confidence in our company and the market price of our common stock may be materially and adversely affected.

Risks Related to Our Financial Position

Our activities to evaluate and pursue potential strategic alternatives may not result in any transaction or enhance stockholder value.

We have begun evaluating and exploring a variety of strategic alternatives focused on maximizing stockholder value, including, but not limited to, an acquisition, merger, reverse merger, other business combination, sales of assets or other strategic transactions. Our ability to successfully execute on a strategic alternative is dependent on a number of factors and we may not be able to execute upon a transaction or other strategic alternative upon favorable terms within an advantageous timeframe and recognize significant value for our assets, if at all. Additionally, the negotiation and consummation of a transaction or other strategic alternative may be costly and time-consuming. Any executed strategic alternative may not maximize or even enhance stockholder value, could result in total costs and expenses that are greater than expected, could make it more difficult to attract and retain qualified personnel and may disrupt our operations, each of which could have a material adverse effect on our business.

The market price of our common stock may reflect a market assumption that a strategic alternative will occur, and a failure to complete a strategic alternative could result in negative investor perceptions and could cause a decline in the market price of our common stock, which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives. There can be no certainty that any strategic alternative will be completed, be on attractive terms, enhance stockholder value or deliver the anticipated benefits, and successful integration or execution of the strategic alternatives will be subject to additional risks. In addition, potential strategic alternatives that require stockholder successfully consummate a strategic alternative, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation, the amount of cash that will need to be reserved for commitments and contingent liabilities. Depending on these factors, the amount available for distribution to our common stockholders could be as low as zero and result in a total loss of investment to our stockholders.

We do not currently have sufficient working capital to fund our planned operations for the next twelve months and substantial doubt exists as to our ability to continue as a going concern.

Our historical financial statements have been prepared under the assumption that we will continue as a going concern. As of September 30, 2025, we had an accumulated deficit of \$278.4 million, and had cash, cash equivalents and marketable securities of \$25.0 million. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. Based on our current plans and forecasted expenses, we expect that our cash, cash equivalents and short-term investments as of the filing date, November 14, 2025, will not be sufficient to fund operation for twelve months after the financial statements are issued. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than expected. Until we can generate sufficient revenue, if ever, to fund our operations, we will need to finance future cash needs through public or private equity offerings, license agreements, debt financings or restructurings, collaborations, strategic alliances and marketing or distribution arrangements. While we have begun to implement cost reductions in 2025, we have finite cash resources available to fund our operations. As part of cost reductions, we have implemented a plan to reduce our workforce by approximately 65%. We also announced plans to explore a full range of strategic alternatives. Strategic alternatives under consideration may include, but are not limited to, among other options, a sale of assets, licensing arrangements, collaborations, a sale of the Company, a business combination, a merger, or an orderly wind-down of operations.

The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors and employees. Additional financing may not be available to us when needed or, if available, it may not be obtained on commercially reasonable terms. If we are not able to obtain the necessary additional financing or a strategic alternative on a timely or commercially reasonable basis, we may be required to wind down our operations and our stockholders will lose their investment.

We will need additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to further delay, limit, reduce or terminate our product development or commercialization efforts.

We will require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our product development programs or commercialization efforts.

To date, we have primarily financed our operations through the sale of equity securities. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We cannot assure you that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. While the long-term economic impact of international conflicts and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures are difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, increased inflation may result in increased operating costs (including labor costs) and may affect our operating budgets. In addition, the U.S. Federal Reserve has raised, and may in the future further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. If the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and our ability to pursue our business strategy.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

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

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales are likely to result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

To the extent that we raise additional capital through the sale of equity, warrants to purchase equity, and/or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our common stock to decline.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on attractive terms, we could be forced to further delay, reduce or altogether cease our research and development programs or future commercialization efforts.

We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We have incurred significant net losses since our inception. Our net loss was \$16.4 million and \$22.4 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of \$278.4 million. We have funded our operations to date primarily with proceeds from the sale of our equity securities and borrowings of convertible debt.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to research and development of solnerstotug and our TMAb platform. Investment in therapeutic 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 effect or an acceptable safety profile, gain regulatory approval and/or become commercially viable.

We expect that it will take at least several years until any of our product candidates receive marketing approval and are commercialized, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. Achievement will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development and commercialization of therapeutic product candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve and maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Because of the numerous risks and uncertainties associated with the development and commercialization of therapeutic product candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve and maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

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

Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

As an organization, we have not demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our operating history makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability, due to reasons including, among other things, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures.

A widespread public health crisis such as a pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the effects of public health crises could materially affect our business and the value of our common stock. It may have further negative impacts, such as (a) a global or U.S. recession or other economic crisis; (b) credit and capital markets volatility (and access to these markets, including by our suppliers and customers); (c) manufacturing supply disruption due to travel restrictions or other government actions; (d) disruptions in raw material supply, our manufacturing operations, or in our distribution and supply chain; and (e) our ability to conduct planned clinical trials and commercialization activities. The ultimate impact of a public health crisis is highly uncertain.

The Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Risks Related to the Development of our Product Candidates

Our development efforts are in the early stages. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

There is no assurance that any clinical trials of our product candidates will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA or other regulatory agencies for any of our product candidates. All of our product candidates, other than solnerstotug, are in preclinical development. In addition, we have paused further development of our preclinical product candidates. Although the FDA cleared our IND for solnerstotug in April 2023, there can be no assurance that the FDA will permit any future IND for our other product candidates to go into effect in a timely manner or at all. We would not be permitted to conduct further clinical trials in the United States without future INDs for our other product candidates.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- completing preclinical studies;
- submission of INDs for and receipt of allowance to proceed with our clinical trials or other future clinical trials;
- initiating, enrolling, and completing clinical trials;
- obtaining positive results from our preclinical studies and clinical trials that support a demonstration of efficacy, safety, and durability of effect for our product candidates;
- receiving approvals for commercialization of our product candidates from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- manufacturing our product candidates at an acceptable cost; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our product candidates and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which could materially harm our business.

The therapeutic efficacy of our product candidates, including solnerstotug, is unproven in humans, and we may not be able to successfully develop and commercialize drug candidates pursuant to these programs.

Our TMAb product candidates are novel chemical and biologic entities and their potential benefit as therapeutic cancer drugs is unproven. For example, solnerstotug is a human monoclonal antibody targeting the novel immune checkpoint VISTA. There are currently no approved therapies that target VISTA. Our ability to generate revenues from our TMAb product candidates, which we do not expect will occur in the short-term, if ever, will depend heavily on their successful development and commercialization, which is subject to many potential risks. For example, our product candidates may not prove to be effective inhibitors of the molecular targets they are being designed to act against and may not demonstrate in patients any or all of the pharmacological benefits that may have been demonstrated in preclinical studies. These product candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If the FDA determines that any of our drug candidates are associated with significant side effects or have characteristics that are unexpected, we may need to delay or abandon their development or limit development to certain 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. Moreover, we may determine after conducting clinical trials or related studies that certain of our product candidates or platforms do not possess the anticipated therapeutic characteristics, and we may decide to abandon or discontinue any one of our studies, product candidates or platforms. For example, in June 2021 we announced the discontinuation of our SNS-301 program and terminated the Phase 1/2 clinic trial studying SNS-301 due to a lack of efficacy. In November 2022, we announced the suspension of our ImmunoPhage platform entirely and we are now focused exclusively on developing our TMAb platform.

Many drug candidates that initially showed promise in early stage testing for treating cancer have later been found to be ineffective and/or cause side effects that prevented further development of the compound or resulted in their removal from the market. For example, in a third-party clinical trial of an anti-VISTA monoclonal antibody, dose limiting toxicities caused by cytokine release syndrome resulted in early termination of the clinical trial. Although initial clinical data from our Phase 1/2 clinical trial of solnerstotug demonstrate favorable safety, pharmacokinetics and cytokine release profiles, as well as preliminary evidence of anti-tumor activity, there is no assurance that data from additional patients will produce similar results. As a result of these and other risks described herein that are inherent in the development and commercialization of novel therapeutic agents, we may not successfully develop and commercialize our drug candidates, in which case we may not achieve profitability and the value of our stock may decline.

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.

We do not have any products that have gained regulatory approval. Our business is substantially dependent on our ability to obtain regulatory approval for our preclinical programs. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls

are adequate with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA and other regulatory authorities regarding the design of our clinical trials and the type and amount of clinical data necessary to seek and gain approval for our product candidates.

The time required to obtain approval by the FDA and other regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial 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. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or other comparable regulatory authorities for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials, including with respect to our clinical trial of solnerstotug;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application, or BLA, or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or our facilities;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

Many of these risks are beyond our control, including the risks related to clinical development. If we are unable to develop, receive regulatory approval for, or successfully commercialize our product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

The FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Even if a product candidate were to successfully obtain approval from the FDA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product candidate or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our business is highly dependent on the success of our product candidates that we advance into the clinic. All of our product candidates may require significant additional preclinical, clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is utilizing our TMAb platform to develop conditionally active monoclonal antibodies, which we believe could generate safer and more effective cancer therapies. However, we currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are very early in our development efforts, and if any of our product candidates, including solnerstotug, encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. Our TMAb platform is

designed to generate next-generation antibodies that have potential to block immunosuppressive signals or activate immunostimulatory signals selectively within the tumor microenvironment. However, our TMAB platform may not produce product candidates that are safe and effective, or which compare favorably with other commercially available alternatives. Even if we are successful in continuing to build our pipeline and develop next-generation antibodies, the potential product candidates that we identify may not be suitable for clinical development, including as a result of lack of safety, lack of tolerability, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. We cannot provide you with any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our TMAB platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects, such as cytokine release syndrome, or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which could have a material adverse effect on our business and could potentially cause us to cease operations.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

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

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. 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. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. For example, in June 2021 we announced the discontinuation of our SNS-301 program and terminated the Phase 1/2 clinic trial studying SNS-301 due to a lack of efficacy. SNS-301 had been our lead product candidate and only clinical stage program. Furthermore, in November 2022 we announced the suspension of our ImmunoPhage platform entirely, including SNS-401-NG, which we were developing for the treatment of patients with Merkel cell carcinoma. Additionally, in October 2025, we announced that we were discontinuing development of solnerstotug and initiate a comprehensive review of strategic alternatives.

If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Other than solnerstotug, our product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials. In November 2024, we announced that we have paused further development of our preclinical product candidates. In October 2025, we announced that we have paused further

development of solnerstotug. Even if we resume preclinical development or solnerstotug development, we cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. It is impossible to predict accurately when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing.

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

- the FDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, particularly given their novel, first-in-human application, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA or regulatory authorities in other countries or jurisdiction to approve our BLA or other comparable application, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

It is impossible to predict when or if any of our current or future product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Human clinical trials are expensive, can take many years to complete, and are difficult to design and

implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for oncology product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Success in preclinical studies or clinical trials may not be predictive of results in future clinical trials.

Results from preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials are not necessarily predictive of final results. We do not know whether our candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in preclinical or clinical development despite positive results observed in early preclinical studies or having successfully advanced through initial clinical trials. For example, although we have generated preclinical data suggesting that the conditionally active properties of solnerstotug have the potential to lower the risk of side effects such as cytokine release syndrome, enhance the anti-tumor effects of PD-1 blockade, and produce anti-tumor activity as a monotherapy, those data were generated either from animal studies or ex vivo studies with human samples and there can be no assurances that similar results will be achieved in clinical trials of solnerstotug with human subjects. Any failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates.

Additionally, our clinical trial of solnerstotug utilizes an open-label study design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved therapy or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

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

We expect to publish from time to time interim topline or preliminary data from our 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. 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 topline 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. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials 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 reputation and business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, 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, topline, 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 depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment; and
- factors we may not be able to control, such as pandemics, that may limit patients, principal investigators or staff or clinical site available.

In addition, because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may 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.

The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and, therefore, may be small, and our projections regarding the size of the addressable market may be incorrect.

Our immuno-oncology approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancers are detected they are treated with first line of therapy with the intention of curing the cancer. This treatment generally consists of chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. If the patient's cancer relapses, then the patient is given a second line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations.

There is no guarantee that any of our product candidates, even if approved, would be approved for an early line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and 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 scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenues without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, could limit the commercial profile of an approved label, or could result in significant negative consequences following any potential marketing approval.

Our clinical trials will include cancer patients who are very sick and whose health is deteriorating. It is possible that some of these patients may experience similar side effects and that additional patients may die during our clinical trials for various reasons. The causes of death could include receiving our product candidates because the patient's disease is too advanced or because the patient experiences medical problems that may not be related to our product candidate. Even if the patient deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidates, including solnerstotug.

Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our therapeutic candidates, could result in the delay, suspension, clinical hold or termination of our clinical trials, the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may decide to remove such products from the marketplace;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any other product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations, or CROs, or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

Risks Related to Manufacturing and our Dependence on Third Parties

We currently rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies, as well as our clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates.

We currently rely on third-party contract research organizations, or CROs, academic institutions, study sites, clinical investigators and others to conduct, supervise, and monitor our preclinical studies and clinical trials, including our clinical trial of solnerstotug. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we currently have or plan to enter into agreements governing the activities of these third parties, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to develop solnerstotug and other current and future product candidates, or we may not obtain marketing approval for, or commercialize, solnerstotug or our other current and future product candidates in a timely manner or at all.

Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities could be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical studies are conducted in accordance with the FDA's GLP regulations, as appropriate. 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, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to the development of our product candidates. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if these parties are adversely impacted by a pandemic

limiting or materially affecting their ability to carry out their contractual duties, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for current and future product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize current and future 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 current and future product candidates may be harmed, our costs could increase and our ability to generate revenues 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, financial condition, results of operations, stock price and prospects may be materially harmed.

We collaborate with academic institutions for the development of our product candidates, including, for instance, our collaboration with the University of Washington. We may enter into additional collaborations for our other current or future product candidates or technologies. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we plan to conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of current and future product candidates, which could result in additional losses and deprive us of potential product revenue.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's 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.

Certain of our current and future product candidates, including solnerstotug, will be evaluated in combination with third-party drugs, and we will have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Certain of our current and future product candidates, including solnerstotug, will be evaluated in combination with checkpoint inhibitors, or CPIs. Our ability to develop and ultimately commercialize current and future product candidates used in combination with CPIs or other compounds will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with the commercialized product, if approved. In January 2023, we entered into a supply agreement with Regeneron to evaluate solnerstotug in combination with cemiplimab in our Phase 1/2 clinical trial. However, we cannot be certain that such agreement or any future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.

Any failure to enter into successful commercial relationships, or inability to source or purchase CPIs or other potential combination agents in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop solnerstotug and other current and future product candidates as potential combination therapies, which may materially harm our business, financial condition, results of operations, stock price and prospects. Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not encountered when developing single-agent product candidates. For example, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. Additionally, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party under terms unfavorable to us to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

In the event that Regeneron or any potential future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such CPIs. Additionally, should the supply from Regeneron or any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us or our collaborators, our clinical collaborations may be delayed. In the event we are unable to source an alternative supply, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We currently rely on CMOs for the production of solnerstotug and we expect to rely on CMOs for our other product candidates. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We currently have no plans to build our own clinical or commercial scale manufacturing capabilities for our TMAb product candidates. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We have entered into arrangements with a limited number of third-party contract manufacturing organizations, or CMOs, as part of our development of our TMAb product candidates. These CMOs will provide drug substance intermediate and drug product that will be subsequently labeled, packaged and distributed to our CROs. We may also enter into agreements with additional companies for the supply of substances for use in the development of our TMAb product candidates or any future product candidates or for the manufacture of such product candidates.

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

The facilities used by third-party manufacturers to manufacture solnerstotug or any other current or future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidates that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates or products. In addition, in the case of CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

As part of their manufacture of our product candidates, our CMO and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If our CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of

which could significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

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

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

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of any current or future product candidates for use in clinical trials or for commercial supply;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party CMO cannot perform as agreed, we may be required to replace such manufacturer and we may be unable to replace them on a timely basis or at all.

Because we rely on a limited number of suppliers for the raw materials used in our drug candidates, any delay, shortage or interruption in the supply of such raw materials or contamination in our manufacturing process could lead to delays in the manufacture and supply of our drug candidates.

We rely on third-parties to supply certain raw materials necessary to produce our drug candidates for preclinical studies and clinical trials. For example, we rely on third-parties to supply certain reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. We work with our CMOs to purchase these materials from our suppliers who may not always have long-term supply agreements in place, which could expose us to a variety of risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products. Any significant delay in the supply of raw materials for our drug candidates for a preclinical study or a clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our drug candidates, the commercial launch of our drug candidates could be delayed, or there could be a supply shortage, each of which could impair our ability to generate revenues from their sale.

In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our drug candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our drug candidates, could adversely impact or disrupt the commercial manufacture or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

We have entered, and may in the future enter into, partnership agreements with third parties for the development and commercialization of our product candidates. Our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential

commercialization. As such, we have entered into and may seek to enter into additional collaborations or partnerships with third parties for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Should we seek to collaborate with a third party with respect to a prospective development program, we may not be able to locate a suitable partner or to enter into an agreement on commercially reasonable terms or at all. Even if we succeed in securing partners for the development and commercialization of our product candidates, we have limited control over the time and resources that our partners may dedicate to the development and commercialization of our product candidates. In order to optimize the launch and market penetration of certain of our future product candidates, we may enter into distribution and marketing agreements with pharmaceutical industry leaders. For these product candidates, we would not market our products alone once they have obtained marketing authorization. These partnerships pose a number of risks, including the following:

- partners may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources or a change in strategic focus;
- partners may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- partners may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- partners may decide to pursue a competitive product developed outside of the collaboration arrangement;
- partners may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- partners may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, partnership agreements may not lead to development, regulatory approval or successful commercialization of product candidates in the most efficient manner or at all. Some partnership agreements are terminable without cause on short notice. Once a partnership agreement is signed, it may not lead to regulatory approval and commercialization of a product candidate. We also face competition in seeking out partners. If we are unable to secure new collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenues.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and

export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. Whether the results from our clinical trials will suffice to obtain approval will be a review issue and the FDA may not grant approval and may require that we conduct one or more controlled clinical trials to obtain approval. Additionally, even if FDA does grant approval for one or more of our product candidates, it may be for a more narrow indication than we seek. Regulatory authorities, including the FDA, also may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop.

We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted BLA, premarket approval application, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

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

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

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may submit marketing applications in countries other than the United States. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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 our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting for our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose

any marketing approval that we may have obtained, which could adversely affect our business, prospects and ability to achieve or sustain profitability.

If we are unable to successfully validate, develop and obtain regulatory approval for any required companion diagnostic tests for our product candidates or experience significant delays in doing so, we may fail to obtain approval or may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we may develop or engage third parties to develop or obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive benefit from our product candidates. Such companion diagnostics may be used during our clinical trials and may be required in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. Companion diagnostics are subject to regulation by the FDA, EMA and other regulatory authorities as medical devices and require separate regulatory approval prior to commercialization.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics. We and our future collaborators also may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval or such approval may be delayed, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue developing, selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic product candidates.

Our relationships with customers, healthcare professionals, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, administrative civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Our current and future business operations and activities may subject us to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our product candidates for which we obtain marketing approval. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The 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. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims, including the federal False Claims Act, or FCA, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money

to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the ACA, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as information regarding ownership and investment interests of such physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state and local laws require the registration of pharmaceutical sales representatives. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including compensation of physicians with stock or stock options, could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

The U.S. 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 current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA was passed, which substantially changed the way healthcare is financed by both

governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates 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 unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional Congressional action is taken.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the IRA, among other things, (1) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure single-source biologics that have been on the market for at least 11 years covered under Medicare, or the Medicare Drug Price Negotiation Program, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon 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 selected fifteen additional products covered under Part D for price negotiation in 2025. 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 if that will continue under the new framework.

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

Additional health reform measures may continue and affect our business in unknown ways, particularly given the recent change in administration. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently 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 may include, for example, directives to reduce agency workforce, 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 and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan, and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, or *Loper Bright*, the U.S. Supreme Court overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper Bright* decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new U.S. presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business in light of the higher proportion of SCD patients that utilize Medicare and Medicaid programs to pay for treatments.

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

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

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

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We are subject to the U.K. Bribery Act 2010, or the Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the Bribery Act, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act, or FCPA, violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. 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. 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 or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.

We currently plan to work to build our global commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, we currently have no sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to expand our sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenues and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or overseas.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations.

In addition to the current standard of care treatments for patients with cancers, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates in the field of immuno-oncology. Results from these studies and trials have fueled increasing levels of interest in the field of immuno-oncology.

Large pharmaceutical companies that have commercialized or are developing immunotherapies to treat cancer include AstraZeneca, Bristol Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer, Regeneron and Roche/Genentech. In addition, we may

compete with other immuno-oncology companies in our industry, such as Percheron Therapeutics, Kineta, PharmAbcine, Pierre Fabre and Curis, each of which are developing antibodies targeting VISTA, the target of our lead product candidate solnerstotug.

Our competitors with development-stage programs may obtain marketing approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates non-competitive and obsolete.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of our product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our

product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance could harm our business and could require us to seek additional financing.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective, may limit market acceptance our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our product candidates, if approved, achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates, if approved, that we commercialize will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective.

Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

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. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which could negatively impact prescriptions for our product candidates, if approved.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

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

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently do not have product liability in place as the cost of coverage exceeds the covered amount during clinical trials. Once we are ready for a product launch, we intend to bind a policy with product liability insurance coverage in the aggregate and a per incident limit at an amount adequate to cover estimated liabilities that we may incur. We may need to increase our insurance coverage if we re-initiate our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, 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. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technologies and product candidates, including solnerstotug, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States, Canada, China, the European Union and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications related to our technology and product candidates in the major pharmaceutical markets, including the United States,

Canada, China, major countries in Europe and Japan. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary positions, we typically file patent applications in the United States and other countries related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could threaten our ability to commercialize our product candidates. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the protections offered by laws of different countries vary. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Additionally, 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future our product candidates. 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 be certain that 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. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, *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 submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could significantly harm our business and results of operations.

Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents, should they issue, by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek

approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, 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 and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our TMAb technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including in the area of monoclonal antibodies and including patents held by our competitors. If any third-party patents cover our product candidates or technologies, we may not be free to manufacture or commercialize our product candidates as planned.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights and claims may also come from competitors against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization. There are and may in the future be additional third-party patents or patent applications with claims to, for example, materials, compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of any one or more of our product candidates. Moreover, we may fail to identify relevant third party patents or patent applications, or we may incorrectly conclude that the claims of an issued patent are invalid or are not infringed by our activities. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that any of our product candidates may infringe, or which such third parties claim are infringed by our technologies.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required or may choose to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, 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. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if successful, the defense of any claim of infringement or misappropriation is time-consuming, expensive and diverts the attention of our management from our ongoing business operations.

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

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

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established

companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not 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.

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

Competitors may infringe our patents, if issued, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we 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. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours 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 patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our 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. 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.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance 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. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, 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 proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

We may be subject to claims challenging the inventorship or ownership of our owned patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, disputes may arise from conflicting obligations of consultants or

others who are involved in developing our technology and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our product candidates or any other 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. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA 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 proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Furthermore, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

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

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection 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 pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly

and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and patent agencies outside the United States in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in-licensed from a third party, any failure on our part to maintain the in-licensed rights could jeopardize our rights under the relevant license and may expose us to liability.

Risks Related to our Business Operations

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, financial and other personnel, including personnel to support our product development and planned future commercialization efforts. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the preclinical, clinical and FDA review processes for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in immuno-oncology and the competition for these individuals is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. Our senior management may terminate their employment with us at any time, and we do not maintain “key person” insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research

institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- 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 programs and initiatives in pursuing such a strategic partnership, 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 and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake future acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to our Securities and our Status as a Public Company

An active trading market for our common stock may not continue to develop or be sustained.

Prior to our initial public offering, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for you to sell shares at an attractive price or at all.

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

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the common stock. In addition to the factors discussed elsewhere in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure and scope of health care payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;

- concerns regarding the safety of our product candidates or TMAb platform in general;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our common stock on Nasdaq;
- sales of our common stock by us, members of our senior management and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common stock at or above the price paid for the common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. From time to time, we have been, and may continue to be, subject to legal proceedings and claims in the ordinary course of business. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Our business and operations could be negatively affected by any securities litigation or stockholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our common stock or other securities or other reasons may in the future cause us to become the target of securities litigation or stockholder activism.

Securities litigation and stockholder activism, including proxy contests, could result in substantial costs and divert management's and the Board's attention and resources from our business. The potential of a proxy contest or other stockholder activism could interfere with our ability to execute on our strategic plan, give rise to perceived uncertainties as to our future direction, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Further, our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and stockholder activism.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

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

In addition, we have filed registration statements registering the issuance of all shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration

statements will be available for sale in the public market subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Furthermore, certain holders of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares 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.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

We are an “emerging growth company,” as defined in Section 2(a) of the Securities 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 the auditor attestation requirements in the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, compliance with any new requirements adopted by the PCAOB, disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and the requirements of holding advisory “say-on-pay” votes on executive compensation and stockholder advisory votes on golden parachute compensation not previously approved. Certain of these reduced reporting requirements and exemptions are also available to us due to the fact that we qualify as a “smaller reporting company” under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management’s assessment of internal control over financial reporting, are not required to provide a compensation discussion and analysis, are not required to provide a pay-for-performance graph or CEO pay ratio disclosure and may present only two years of audited financial statements and related MD&A disclosure.

Under the JOBS Act, we will remain an emerging growth company until the earliest of (1) the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; (3) the issuance, in any three-year period, by our company of more than \$1.0 billion in non-convertible debt securities; and (4) December 31, 2026, which is the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. Under current SEC rules, however, we will continue to qualify as a “smaller reporting company” for so long as (i) we have a public float (i.e., the market value of common equity held by non-affiliates) of less than \$250 million or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than \$700 million.

We cannot predict if investors will find our shares of common stock to be less attractive because we may rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active trading market for our shares of common stock, and our share price may be more volatile.

Under the JOBS Act, emerging growth companies also can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our condensed consolidated financial statements may not be directly comparable to those of other public companies.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not intend to pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our common stock to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on,

among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. U.S. federal NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2024, we had NOL carryforwards for federal and state income tax purposes of approximately \$150.6 million and \$84.4 million, respectively, a portion of which expired beginning in 2025. Net operating loss carryforwards generated after December 31, 2017 for federal tax reporting purposes of \$114.4 million have an indefinite life. The remaining federal net operating losses are subject to a 20-year carryforward period.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have not determined whether our NOLs are limited under Section 382 of the Code. We may have experienced an ownership change in the past, and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Furthermore, our ability to utilize NOLs of companies that we have acquired or may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

We have incurred and expect to continue incurring significantly increased costs as a result of operating as a company whose common stock is publicly traded, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred significant legal, accounting and other expenses that we did not incur previously as a private company. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an emerging growth company or a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be 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 the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws;
- any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers or other employees that is governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Securities Exchange Act of 1934, or the Exchange Act, or any claim for which the U.S. federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation will provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If any other court of competent jurisdiction were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Insiders have substantial influence over us and could cause us to take actions that may not be, or refrain from taking actions that may be, in our best interest or in the best interest of our stockholders.

As of November 10, 2025, we believe that our directors, executive officers and principal stockholders, together with their affiliates, own, in the aggregate, more than 30% of our outstanding common stock. As a result, if these or certain of these stockholders were to choose to act together, they may be able to affect the outcome of matters submitted to our stockholders for approval, as well as our management and affairs, such as:

- the composition of our board of directors;
- the adoption of amendments to our certificate of incorporation and bylaws;
- the approval of mergers or sales of substantially all of our assets;
- our capital structure and financing; and
- the approval of contracts between us and these stockholders or their affiliates, which could involve conflicts of interest.

This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company and making some transactions more difficult or impossible without the support of these stockholders, even if such transactions are beneficial to other stockholders;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- requiring us to engage in transactions that may not be agreeable to or in the best interest of us or other stockholders.

General Risk Factors

Our business, operations and clinical development plans and timelines, as well as the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers, equipment suppliers and others, could be adversely affected by the effects of health epidemics.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. The effects of government orders may negatively impact productivity, disrupt our business and delay our

clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and clinical trials may be affected by health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward the pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

Our computer systems or data, or those of our collaborators or other contractors or consultants, may be compromised, which could result in adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; significant disruption of our product development programs and our ability to operate our business effectively; reputational harm; and other adverse consequences.

Our computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to a variety of disruptive and evolving threats, including computer viruses, malicious or unintentional actions or inactions that cause vulnerabilities, malware, software or hardware failure, supply chain attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential stuffing, ransomware, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of our research activities. Our ability to monitor these third parties 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 damages, or we may be unable to recover such awards. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. Similarly, 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 products/services) or the third-party information technology systems that support us and our services.

Certain functional areas of our workforce work remotely on a full- or part-time basis or otherwise utilize network connections, computers and devices outside of our premises or network, which poses additional risks to our business.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

We may choose or be required to expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, particularly where required by applicable data privacy and security laws or regulations or industry standards. Certain data privacy and security obligations require us to implement and maintain certain security measures.

While we have not experienced any significant system failure, accident or security breach to date, if such a significant event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials 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 breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, be exposed to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, our competitive position could be harmed, our reputation could be damaged, and the further development and commercialization of our product candidates could be delayed.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim.

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 reveal competitively sensitive details about the company and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We and the third parties with whom we work are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and otherwise harm our business.

We maintain sensitive information, including confidential business and personal information in connection with our preclinical studies and our employees, and are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these constantly evolving laws can be subject to varying interpretations. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

The General Data Protection Regulation, the GDPR, applies in the European Economic Area, the EEA, into which we may expand our business. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European data subjects. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data over prior EU law and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Privacy and data security laws in the United States at the federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, at the state level, the privacy and data protection landscape is changing rapidly. Many states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services if we become subject to these laws. For example, the California Consumer Privacy Act, or the CCPA, applies to personal information data of consumers, business representatives, and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain rights concerning their personal data. The CCPA provides for civil penalties for violations, as

well as a private right of action for certain data breaches. The CCPA provides fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA and other state privacy laws contain an exemption for certain personal information processed in connection with clinical trials, these developments could further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work should we become subject to these laws. Similar laws have been passed or are being considered in several other states, as well as at the federal and local levels. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties.

Our employees and personnel use generative artificial intelligence (“AI”) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are bound by contractual obligations and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security (and consumers’ data privacy obligations) are quickly changing in an increasingly stringent fashion and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations have in the past and may in the future necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change aspects of our business model or our clinical trials. Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations.

If we (or third parties with whom we work) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

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

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our common stock could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we continue to have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or research about us. If

one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

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

(a) Recent Sales of Unregistered Equity Securities

None.

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

Not applicable.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

During the fiscal quarter ended September 30, 2025, none of our officers or directors, as defined in Rule 16a-1(f), adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K.

Costs Associated with Exit or Disposal Activities

As part of the cash preservation associated with the strategic review process, our Board of Directors (the “Board”) has approved a reduction in force of approximately 65% of our workforce. The reduction in force is expected to be completed during the fourth quarter of 2025. We estimate that we will incur cash expenditures of \$1.6 million, primarily consisting of severance payments and other employee termination-related expenses, which we expect to recognize the majority of such costs in the fourth quarter of 2025. The estimated charges that we expect to incur are subject to a number of assumptions, and actual results may differ materially from these estimates. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, our workforce reduction.

Departure of Directors or Certain Officers; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

Departure of Named Executive Officers

On November 13, 2025, in connection with the reduction in force described above, our Board determined to terminate John Celebi, our Chief Executive Officer, Edward van der Horst, our Chief Scientific Officer, and Stephanie Krebs, our Chief Business Officer, effective as of 5:30 p.m. ET on November 14, 2025 (the “Effective Time”). Each of Mr. Celebi, Dr. van der Horst and Ms. Krebs will receive severance compensation as provided in each of their respective employment agreements as described in our proxy statement on Schedule 14A filed with the U.S. Securities and Exchange Commission on April 11, 2025.

In addition, each of Mr. Celebi, Dr. van der Horst and Ms. Krebs have entered into Consulting Agreements with the Company (collectively, the “Consulting Agreements”), effective as of November 14, 2025, pursuant to which they will perform consulting services for the Company. The Consultant Agreements will be for a term of six months and can be terminated by either party upon 15 days prior notice or immediately in the event of a breach which cannot be cured or if either party is accused of a crime or unethical conduct. Under the Consultant Agreements, each of Mr. Celebi, Dr. van der Horst and Ms. Krebs will perform consulting services at a rate of \$425 per hour for up to 20 hours per week. The foregoing description of the Consulting Agreements do not purport to be complete and are qualified by reference to the form of consulting agreement filed as an exhibit to this Quarterly Report on Form 10-Q.

Appointment of Christopher W. Gerry as President and Principal Executive Officer

On November 13, 2025, our Board approved the appointment of Christopher W. Gerry as our President and Principal Executive Officer, effective as of the Effective Time.

Mr. Gerry, age 46, has served as our General Counsel since July 2022. Previously, Mr. Gerry was the Deputy General Counsel at AVROBIO, Inc. from January 2021 to July 2022 and was the Associate General Counsel at AVROBIO from November 2019 to January 2021. Prior to that, Mr. Gerry was an associate at Cooley LLP from 2013 to 2019. Mr. Gerry holds a B.A. from Dickinson College and a J.D. from Boston University School of Law.

There are no arrangements or understandings between Mr. Gerry and any other person pursuant to which he was selected as an officer of the Company, and there is no family relationship between Mr. Gerry and any of the Company's other directors or executive officers. Mr. Gerry is not a party to any transactions of the type listed in Item 404(a) of Regulation S-K.

Resignation of Directors

On November 12, 2025, William Ringo notified the Company of his intent to resign from his duties as a member of the Board, effective November 14, 2025. Mr. Ringo's resignation was not due to any disagreement with the Company or any matter relating to the Company's operations, policies, or practices.

On November 12, 2025, James Peyer, Ph.D. notified the Company of his intent to resign from his duties as a member of the Board, effective November 14, 2025. Mr. Peyer's resignation was not due to any disagreement with the Company or any matter relating to the Company's operations, policies, or practices.

On November 12, 2025, John Celebi notified the Company of his intent to resign from his duties as a member of the Board, effective November 14, 2025. Mr. Celebi's resignation was not due to any disagreement with the Company or any matter relating to the Company's operations, policies, or practices.

Each of Mr. Ringo and Dr. Peyer will receive the full amount of compensation that would otherwise have been due to them for the fourth quarter under the Company's non-employee director compensation policy. In connection with Mr. Celebi's, Mr. Ringo's and Dr. Peyer's resignations, the Board approved a reduction in the size of the Board from six to three.

In connection with the resignations, effective November 14, 2025, the Board appointed Bob Holmen as Board Chair; appointed Mr. Holmen, Thomas Ricks and Kristian Humer to the Nominating and Corporate Governance Committee; and appointed Mr. Humer as Chair of the Nominating and Corporate Governance Committee and to the Compensation Committee.

Item 6. Exhibits, Financial Statement Schedules.

(3) Exhibits

Exhibit Number	Description
3.1	<u>Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 11, 2021).</u>
3.2	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on June 13, 2025).</u>
3.3	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on December 9, 2022).</u>
3.4	<u>Certificate of Designations of the Series A Junior Participating Cumulative Preferred Stock of the Registrant, dated March 7, 2023 (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form 8-A, filed with the Securities and Exchange Commission on March 7, 2023, File No. 005-92222)</u>
3.5	<u>Certificate of Elimination of the Series A Junior Participating Cumulative Preferred Stock of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Annual Report on Form 10-K (File No. 001-39980), filed with the SEC on March 28, 2025).</u>
10.1*	<u>Form of Consulting Agreement, dated November 14, 2025, entered into with John Celebi, Edward van der Horst and Stephanie Krebs.</u>
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>

32.1** [Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)

101.INS XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).

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.

** This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Sensei Biotherapeutics, Inc.

Date: November 14, 2025

By: _____
/s/ John Celebi
John Celebi
President and Chief Executive Officer
Principal Executive Officer

Date: November 14, 2025

By: _____
/s/ Josiah Craver
Josiah Craver
Senior Vice President of Finance
Principal Financial and Accounting Officer

Exhibit 10.1

INDEPENDENT CONTRACTOR AGREEMENT

THIS INDEPENDENT CONTRACTOR AGREEMENT (together with Exhibit A, the “Agreement”) made as of November 14, 2025 (the “Effective Date”), is between [***], having an address at [***] (“Consultant”) and Sensei Biotherapeutics, Inc., having an address at 1405 Research Blvd, Suite 125, Rockville, MD 20850 (“Client”). Client desires to have the benefit of Consultant’s knowledge and experience, and Consultant desires to provide Consulting Services (defined below) to Client, all as provided in this Agreement.

1. Consulting Services. Client retains Consultant and Consultant agrees to provide consulting services to Client as it may from time to time reasonably request and as further specified in Exhibit A (“Business Terms Exhibit”) attached hereto (the “Consulting Services”). Any changes to the Consulting Services and/or any compensation adjustments in respect of the Consulting Services must be agreed upon in writing between Consultant and Client.

1.1 Performance. Consultant will render the Consulting Services (a) at such reasonably convenient times and places as Client and Consultant may agree, (b) under the general supervision of Client and (c) on a best-efforts basis. In performing the Consulting Services, Consultant will comply with all business conduct, regulatory and health and safety guidelines or regulations established by Client or any governmental authority with respect to the business of Client.

- 1.2 Obligations to Third Parties.** Consultant will not use or disclose any confidential information of any other third party in connection with any of the Consulting Services. Further, Consultant represents and warrants that the performance of the Consulting Services does not and will not breach any agreement which obligates Consultant to keep in confidence any confidential information of any third party or to refrain from competing with the business of any third party.
- 1.3 No Conflicts.** Consultant is under no contractual or other obligation or restriction which is inconsistent with Consultant's execution of this Agreement or the performance of the Consulting Services. During the Term of this Agreement, Consultant will not enter into any agreement, either written or oral, in conflict with Consultant's obligations under this Agreement. Consultant will arrange to provide the Consulting Services in such manner and at such times that the Consulting Services will not conflict with Consultant's responsibilities under any other agreement, arrangement or understanding or pursuant to any employment relationship Consultant has at any time with any third party. Consultant represents and warrants to Client that the Developments (as defined in Section 3.1) do not violate the intellectual property rights of any third party.
- 1.4 Absence of Debarment.** Consultant represents that Consultant has not been suspended, debarred or subject to temporary denial of approval, and to the best of Consultant's knowledge, is not under consideration to be suspended, debarred or subject to temporary denial of approval, by the Food and Drug Administration from working in or providing services, directly or indirectly, to any applicant for approval of a drug product or any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992.

2. Compensation.

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Exhibit 10.1

- 2.1. Consulting Services.** In consideration of the Consulting Services rendered by Consultant to Client, Client agrees to pay Consultant for time actually spent providing the Consulting Services as set forth in the Business Terms Exhibit. The amounts paid to Consultant will be consistent with industry norms and will reasonably compensate Consultant for time and effort expended on the Client's behalf. For the avoidance of doubt, the payment provided hereunder to Consultant does not take into account the volume or value of any referrals or business that otherwise may be generated between the parties. Similarly, it imposes no obligation, express or implied, to purchase, order, or lease any Client product, or to arrange for or recommend the purchase, order, or lease of any Client product. Consultant shall maintain records of hours spent providing the Consulting Services and submit to Client, via e-mail to apayable@senseibio.com, on a monthly basis, an invoice of the time so recorded for the preceding month. Such invoices shall specify the times Consulting Services were provided and the work performed during that period and will be payable in U.S. Dollars. All undisputed payments will be made by Client within forty-five (45) days from Client's receipt of Consultant's invoice.
- 2.2. Travel Expenses.** For travel on behalf of Client, Client will reimburse Consultant for reasonable and necessary travel expenses, including lodging and meal expenses, in accordance with Client's travel policy. Client assumes no obligation to reimburse for travel expenses that are unreasonable or unrelated to Client business. All air and train travel is expected to be "economy" class unless prior approval is authorized in advance. Client expects Consultant to use at least the same level of care and discretion in spending while on authorized travel as Consultant would use with respect to Consultant's own expenses, and every effort should be made to minimize expenses chargeable to Client. All business-related expenses should be documented from actual receipts or copies thereof to support the

expense incurred. Consultant shall record such expenses on the invoice described in Section 2.1, and, absent a good faith dispute, Client shall provide payment to Consultant for such expenses within forty-five (45) days following receipt of such invoices.

- 2.3. Equity Awards.** The parties understand and agree that Consultant's performance of Consulting Services hereunder during the Term will (i) constitute uninterrupted Continuous Service (as defined in Client's 2021 Equity Incentive Plan) by Consultant to Client and (ii) deem Consultant an Eligible Person (as defined in Client's 2018 Equity Incentive Plan), in each case for purposes of any Client equity awards (including but not limited to stock options and restricted stock units) held by Consultant as of the Effective Date. All matters of vesting and exercisability of Consultant's equity awards shall be governed by the terms of Client's applicable equity incentive plan and Consultant's applicable equity award documents.

3. Proprietary Rights.

- 3.1. Developments.** "Developments" means ideas, concepts, discoveries, inventions, developments, improvements, know-how, trade secrets, designs, processes, methodologies, materials, products, formulations, data, documentation, reports, algorithms, notation systems, computer programs, works of authorship, databases, devices, equipment and any other creations (whether or not patentable or subject to copyright or trade secret protection) that are developed or conceived or reduced to practice by Consultant, either alone or jointly with others, and that result from or relate to the performance of the Consulting Services.
- 3.2. Ownership.** All Developments will be the exclusive property of Client. Consultant hereby assigns and, to the extent any such assignment cannot be made at present, hereby assigns to Client, without further compensation, all right, title and interest in and to all Developments

Exhibit 10.1

and any and all related patents, patent applications, copyrights, copyright applications, trademarks, trade names, trade secrets and other proprietary rights in the United States and throughout the world. During and after the Term, Consultant will cooperate fully in obtaining patent and other proprietary protection for the Developments, all in the name of Client and at Client's cost and expense, and, without limitation, will execute and deliver all requested applications, assignments and other documents, and take such other measures as Client may reasonably request, in order to perfect and enforce Client's rights in the Developments. Consultant appoints Client its attorney to execute and deliver any such documents on Consultant's behalf in the event Consultant fails to do so. Consultant acknowledges that all copyrightable materials developed or produced by Consultant during the performance of the Consulting Services constitute "works made for hire" pursuant to the United States Copyright Act (17 U.S.C. Section 101).

- 3.3. Records and Reporting.** Consultant shall make and maintain adequate and current written records of all Developments. Such records shall be furnished to Client as and when requested by Client and will be the exclusive property of Client. Consultant will promptly disclose all Developments to Client.
- 3.4. Work at Third Party Facilities.** Consultant will not make any use of any funds, personnel, equipment, facilities or other resources of any third party in performing the Consulting Services nor to take any other action that would result in a third party owning or having a right in any Developments.

4. Confidential Information and Materials.

- 4.1 Definitions.** “Confidential Information” means any and all non-public information of Client, including that of third parties that Client has an obligation to maintain as confidential and that developed by Consultant in the performance of the Consulting Services, pertaining to Client’s technologies, products, intellectual property, finances, operations and/or business, and whether or not labeled as being confidential information of Client. “Materials” means any biological, chemical or similar materials of Client which are furnished by Client to Consultant in order to perform the Consulting Services. If the provision of Materials is contemplated under this Agreement, the Materials to be provided are so identified in the Business Terms Exhibit.
- 4.2 Obligations of Confidentiality.** During the Term of this Agreement and thereafter, Consultant will not directly or indirectly (a) publish, disseminate or otherwise disclose, (b) use for Consultant’s own benefit or for the benefit of a third party or (c) deliver or make available to any third party, any Confidential Information or Materials, other than in furtherance of the purposes of this Agreement and only then with the prior written consent of Client. Consultant will exercise all reasonable precautions to physically protect the integrity and confidentiality of the Confidential Information and Materials and will not remove any Confidential Information or Materials from Client’s premises, other than in furtherance of the purposes of this Agreement and then only with Client’s prior written consent. For avoidance of doubt, Consultant’s duty of confidentiality under this Agreement does not amend or abrogate in any manner Consultant’s continuing duties or obligations under any prior agreement between Consultant and Client.
- 4.3 Exceptions.** Consultant will have no obligations of confidentiality and non-use with respect to any portion of the Confidential Information which:

Exhibit 10.1

- (a) is or later becomes generally available to the public by use, publication or the like, through no breach of this Agreement by, or act or omission of, Consultant;
- (b) is obtained from a third party who had no obligation of confidentiality and the legal right to disclose the same to Consultant; or
- (c) Consultant already possesses, as evidenced by its written records that predate the receipt thereof from Client.

In the event that Consultant is required (by oral questions, interrogatories, request for information or documents, subpoena, civil investigative demand or similar process) to disclose any Confidential Information, Consultant will give Client prompt notice thereof so that Client may seek an appropriate protective order. Consultant will reasonably cooperate with Client in its efforts to seek such a protective order.

Consultant acknowledges receipt of the following notice under 18 U.S.C § 1833(b)(1): “An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.”

4.4 Material Non-Public Information. Consultant acknowledges that certain of the foregoing types of Confidential

Information disclosed to Consultant, or of which Consultant otherwise becomes aware of, during the term of this Agreement may be or be deemed to be “material non-public information” (“MNPI”) within the meaning of the federal or state securities laws. MNPI will only be disclosed to Consultant on a need to know basis and for the specific purpose of providing the Consulting Services, and Consultant shall use such MNPI only for such specific purpose. Consultant agrees to abide by all securities and related laws, rules and regulations in connection with providing the Consulting Services including, without limitation, those laws, rules and regulations relating to the receipt, handling and use of MNPI. Consultant agrees that it will not buy or sell common stock or other securities (including, but not limited to, derivatives and options) of Client on the basis of MNPI regarding Client or otherwise.

- 4.5 Remedies.** It is understood and agreed that Client will be irreparably injured by a breach of this Section 4; that money damages will not be an adequate remedy for any such breach; and that Client will be entitled to seek equitable relief, including injunctive relief and specific performance, without having to post a bond, as a remedy for any such breach, and such remedy will not be Client’s exclusive remedy for any breach of this Section 4.

5. Term and Termination.

- 5.1. Term.** This Agreement will commence on the Effective Date and continue for the term specified on the Business Terms Exhibit (the “Term”), unless sooner terminated pursuant to the express terms of this Section 5 or extended by mutual written agreement of the parties.
- 5.2. Automatic Termination.** If Consultant fails to timely return the executed Separation Agreement to Client, then this Agreement will automatically terminate effective as of the day

Exhibit 10.1

after the deadline for Consultant's execution of the Separation Agreement, and no benefits or compensation will be due to Consultant under this Agreement. If Consultant has the right to revoke the Separation Agreement under its terms and exercises such right as described therein, then this Agreement will automatically terminate on the day of such revocation and no benefits or compensation will be due to Consultant under this Agreement.

- 5.3. Termination by Either Party.** Either party may terminate this Agreement at any time without cause upon not less than fifteen (15) days prior written notice.
- 5.4. Termination for Breach.** Either party may immediately terminate this Agreement at any time upon written notice in the event of a breach of this Agreement which cannot be cured (e.g., a breach of Section 4) or in the event either party is accused of a crime or unethical conduct.
- 5.5. Effect of Expiration/Termination.** Upon any expiration or termination of this Agreement, for any reason, neither Consultant nor Client will have any further obligations under this Agreement, except that (a) Consultant will terminate all Consulting Services in progress in an orderly manner and as otherwise requested by Client, (b) Client will pay Consultant any monies due and owing Consultant for Consulting Services actually performed up to the time of expiration or termination of this Agreement, including any orderly completion of the Consulting Services requested by Client, (c) Consultant will immediately return to Client all Confidential Information provided to Consultant under this Agreement except for one (1) copy which Consultant may retain solely for legal archival purposes, (d) Consultant will immediately return to Client all unused Materials provided to Consultant under this

Agreement, (e) Consultant will immediately deliver to Client all Developments and records of Developments, and (f) the terms and conditions of Sections 1.3, 1.4, 3, 4, 5.5, 6 and 7 will survive expiration or termination of this Agreement.

6. Indemnification. Consultant will indemnify and hold Client harmless from and against any claim, loss, damage, cost or expense including, without limitation, reasonable attorneys' fees, arising from or relating to any breach of this Agreement including, without limitation, Section 1.3, Section 7.1 and Section 7.2.

7. Miscellaneous.

7.1. Independent Contractor. All Consulting Services will be rendered by Consultant as an independent contractor and this Agreement does not create an employer-employee, principal-agent, joint venture or partnership relationship between Consultant and Client. Consultant will have no right to receive any employee benefits, such as health and accident insurance, sick leave or vacation which are accorded to employees of Client. Consultant will not in any way represent Consultant to be an employee, partner, joint venturer or agent of Client. Notwithstanding the above, this Agreement does not amend or abrogate in any manner any benefits owed to Consultant under any qualified retirement plan or health and welfare benefit plan in which Consultant was a participant during Consultant's previous employment relationship with Client.

7.2. Taxes. Consultant will pay all required taxes on Consultant's income from Client under this Agreement. Consultant shall provide Client with all required tax information, including without limitation, an IRS Form W-9 "Request for Taxpayer Identification Number and Certification." Failure to provide such information may result in withholding of payments to Consultant.

Exhibit 10.1

- 7.3. Use of Name.** Consultant consents to the use by Client of Consultant's name in written materials and oral presentations to current or prospective business partners, investors or other third parties, provided that such materials or presentations accurately describe the nature of Consultant's relationship with or contribution to Client.
- 7.4. Assignability and Binding Effect.** The Consulting Services to be rendered by Consultant are personal in nature. Consultant may not assign or transfer this Agreement or any of Consultant's rights or obligations under this Agreement. Client shall have the right to assign this Agreement to an affiliated company or in connection with the merger, consolidation, sale or transfer of all or substantially all of the business to which this Agreement relates. This Agreement will be binding upon and inure to the benefit of the parties and their respective legal representatives, heirs, successors and permitted assigns.
- 7.5. Notices.** Any notices from one party to the other will be in writing and will be given by addressing the same to the other at the address set forth in this Agreement, and in the case of notices to Client shall also be emailed to LegalNotices@senseibio.com. Notices to Client will be marked "Attn: General Counsel". Notice will be deemed to have been duly given when (a) deposited in the United States mail with proper postage for first class registered or certified mail, return receipt requested, (b) sent by any reputable commercial courier, or (c) delivered personally.
- 7.6. Headings.** 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.

- 7.7. **No Modification.** This Agreement may be changed only by a writing signed by authorized representatives of both parties.
- 7.8. **Severability.** In the event that any one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect. If any provision of this Agreement is held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law.
- 7.9. **Entire Agreement.** This Agreement constitutes the entire agreement of the parties with regard to the Consulting Services, and supersedes all previous written or oral representations, agreements and understandings between the parties relating to the Consulting Services. For the avoidance of doubt, this Agreement does not supersede or modify any surviving representations, agreements and understandings previously entered into by Consultant in Consultant's capacity as an employee of Client (collectively, the "Existing Agreements"). In the event of a conflict between this Agreement and the terms of the Existing Agreements with respect to Consultant's post-employment obligations, the Existing Agreements will control.
- 7.10. **Governing Law.** This Agreement will be governed by, and construed and enforced in accordance with, the laws of the Commonwealth of Massachusetts applicable to contracts made and to be performed therein, without giving effect to the principles thereof relating to the conflict of laws.
- 7.11. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same

instrument.

Exhibit 10.1

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Exhibit 10.1

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Effective Date.

Sensei Biotherapeutics, Inc.

[***]

By:

Name: Christopher W. Gerry

Title: General Counsel

Date:

By:

Name: [***]

Date:

Exhibit 10.1

EXHIBIT A BUSINESS TERMS

EXHIBIT

Independent Contractor Agreement with Sensei Biotherapeutics

1. Consulting Services:

Consultant will personally provide the following Consulting Services:

- **Business Wind-Down Support:** Assisting Client from time to time with winding down Client's business and operations, including termination of Client's clinical trial of solnerstotug, vendor and service provider matters, regulatory filings and compliance, and other operational wind-down activities.
- **Strategic Alternatives:** Assisting Client from time to time with exploring, negotiating and executing strategic alternatives, including licensing agreements, asset sales, mergers, acquisitions or similar transactions, and responding to due diligence requests and providing subject matter expertise in connection with such transactions.
- **General Advisory Services:** Such other consulting services as reasonably requested by Client from time to time and consistent with Consultant's prior role and expertise.

2. Compensation:

During the Term, Consultant shall be paid an hourly rate of \$425 per hour. Consultant shall not provide more than twenty (20) hours of Consulting Services per week without the written consent of Client.

3. Term:

The Term of this Agreement will be for six (6) months, unless terminated earlier pursuant to the terms of this Agreement or extended by mutual written consent.

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John Celebi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 of Sensei Biotherapeutics, Inc. (the “registrant”);
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 14, 2025

By: /s/ John Celebi
John Celebi
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Josiah Craver, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 of Sensei Biotherapeutics, Inc. (the “registrant”);
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 14, 2025

By: /s/ Josiah Craver
Josiah Craver
Senior Vice President of Finance
(Principal Financial Officer and Accounting Officer)

**CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics, Inc. (the “Company”), and Josiah Craver, Senior Vice President of Finance of the Company, each hereby certifies that, to the best of his knowledge:

- (1) The Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, to which this Certification is attached as Exhibit 32.1 (the “Quarterly Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned has set his hand hereto as of the 14th day of November 2025.

/s/ John Celebi
John Celebi
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Josiah Craver
Josiah Craver
Senior Vice President of Finance
(Principal Financial Officer and Accounting Officer)

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing
