

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

- QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended **June 30, 2023**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period from _____ to _____
Commission File Number **001-40440**

Senti Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

86-2437900
(I.R.S. Employer
Identification Number)

2 Corporate Drive, First Floor
South San Francisco, CA 94080
(Address of principal executive offices and zip code)

(650) 239-2030
(Registrant's telephone number, including area code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	SNTI	The Nasdaq Global Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or 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 7(a)(2)(B) of the Securities Act.

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

As of August 1, 2023 there were 44,545,186 shares of the registrant's common stock, par value \$0.0001 per share, issued and outstanding.

[Table of Contents](#)

SENTI BIOSCIENCES, INC.

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I - FINANCIAL STATEMENTS</u>	
Item 1.	
FINANCIAL STATEMENTS (UNAUDITED)	
Condensed Consolidated Balance Sheets	1
Condensed Consolidated Statements of Operations and Comprehensive Loss	2
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	3
Condensed Consolidated Statements of Cash Flows	5
Notes to Condensed Consolidated Financial Statements	6
Item 2.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS 24
Item 3.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 35
Item 4.	CONTROLS AND PROCEDURES 35
<u>PART II - OTHER INFORMATION</u>	
Item 1.	LEGAL PROCEEDINGS 37
Item 1A.	RISK FACTORS 37
Item 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS 108
Item 3.	DEFAULTS UPON SENIOR SECURITIES 108
Item 4.	MINE SAFETY DISCLOSURES 108
Item 5.	OTHER INFORMATION 108
Item 6.	EXHIBITS 108
	SIGNATURES 110

PART 1 - FINANCIAL INFORMATION**Item 1. FINANCIAL STATEMENTS (UNAUDITED)****SENTI BIOSCIENCES, INC.****Condensed Consolidated Balance Sheets**
(unaudited)
(in thousands, except share and per share data)

	<u>June 30,</u>	<u>December 31,</u>
	<u>2023</u>	<u>2022</u>
Assets		
Cash and cash equivalents	\$ 36,752	\$ 57,621
Accounts receivable	567	626
Short-term investments	22,883	40,942
Prepaid expenses and other current assets	3,290	3,390
Total current assets	63,492	102,579
Restricted cash	3,336	3,366
Property and equipment, net	58,940	56,136
Operating lease right-of-use assets	17,469	18,418
Other long-term assets	393	293
Total assets	<u>\$ 143,630</u>	<u>\$ 180,792</u>
Liabilities and Stockholders' Equity (Deficit)		
Accounts payable	\$ 2,585	\$ 2,267
Finance lease liabilities - related party, current portion	95	—
Early exercise liability, current portion	135	135
Deferred revenue	164	799
Accrued expenses and other current liabilities	4,991	12,864
Operating lease liabilities	2,456	1,988
Total current liabilities	10,426	18,053
Finance lease liabilities - related party, net of current portion	49	—
Operating lease liabilities, net of current portion	35,640	35,103
Contingent earnout liability	20	227
Early exercise liability, net of current portion	79	146
Total liabilities	46,214	53,529
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; zero shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.0001 par value; 500,000,000 shares authorized at June 30, 2023 and December 31, 2022; 44,465,006 and 44,062,534 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	308,117	300,544
Accumulated other comprehensive income	—	1
Accumulated deficit	(210,705)	(173,286)
Total stockholders' equity	97,416	127,263
Total liabilities, preferred stock and stockholders' equity	<u>\$ 143,630</u>	<u>\$ 180,792</u>

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

SENTI BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue				
Contract revenue	\$ 687	\$ 1,108	\$ 1,723	\$ 1,962
Grant income	250	250	500	500
Total revenue	937	1,358	2,223	2,462
Operating expenses				
Research and development	10,952	9,247	22,270	16,849
General and administrative	9,620	13,882	19,422	19,141
Total operating expenses	20,572	23,129	41,692	35,990
Loss from operations	(19,635)	(21,771)	(39,469)	(33,528)
Other income (expense)				
Interest income, net	794	27	1,855	31
Change in fair value of contingent earnout liability	148	8,878	207	8,878
Gain on extinguishment of convertible notes	—	1,289	—	1,289
Other income (expense)	(4)	25	(12)	(30)
Total other income (expense), net	938	10,219	2,050	10,168
Net loss	(18,697)	(11,552)	(37,419)	(23,360)
Other comprehensive loss				
Unrealized loss on investments	(3)	—	(1)	—
Comprehensive loss	\$ (18,700)	\$ (11,552)	\$ (37,420)	\$ (23,360)
Net loss per share, basic and diluted	\$ (0.42)	\$ (0.86)	\$ (0.85)	\$ (2.80)
Weighted-average shares outstanding, basic and diluted	44,278,427	13,446,622	44,175,274	8,336,451

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

SENTI BIOSCIENCES, INC.

Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	19,517,988	\$ 171,833	2,972,409	\$ —	\$ 3,619	\$ —	\$ (115,076)	\$ (111,457)
Exercise of common stock options	—	—	172,606	—	422	—	—	422
Vesting of early exercise of common stock options	—	—	143,524	—	375	—	—	375
Stock-based compensation expense	—	—	—	—	661	—	—	661
Net loss	—	—	—	—	—	—	(11,808)	(11,808)
Balance as of March 31, 2022	19,517,988	171,833	3,288,539	—	5,077	—	(126,884)	(121,807)
Conversion of redeemable convertible preferred stock into common stock in connection with the Reverse Recapitalization, net of transaction cost	(19,517,988)	(171,833)	19,517,988	2	171,833	—	—	171,835
Issuance of common stock upon Reverse Recapitalization, net of transaction costs	—	—	19,975,963	2	112,180	—	—	112,182
Contingent earnout liability recognized upon closing of the Reverse Recapitalization	—	—	—	—	(9,688)	—	—	(9,688)
Cancellation and exchange of convertible note in connection with PIPE financing	—	—	517,500	—	5,184	—	—	5,184
Gain recognized on fair value of embedded derivative on SPAC merger date	—	—	—	—	(1,289)	—	—	(1,289)
Exercise of common stock options	—	—	27,233	—	74	—	—	74
Vesting of early exercise of common stock options	—	—	41,047	—	102	—	—	102
Stock-based compensation expense	—	—	—	—	9,225	—	—	9,225
Net loss	—	—	—	—	—	—	(11,552)	(11,552)
Balance as of June 30, 2022	—	\$ —	\$ 43,368,270	\$ 4	\$ 292,698	\$ —	\$ (138,436)	\$ 154,266

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

SENTI BIOSCIENCES, INC.

Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2022	—	\$ —	44,062,534	\$ 4	\$ 300,544	\$ 1	\$ (173,286)	\$ 127,263
Vesting of early exercise of common stock options	—	—	12,660	—	34	—	—	34
Stock-based compensation expense	—	—	—	—	3,763	—	—	3,763
Unrealized gain (loss) on investments	—	—	—	—	—	2	—	2
Net loss	—	—	—	—	—	—	(18,722)	(18,722)
Balance as of March 31, 2023	—	—	44,075,194	4	304,341	3	(192,008)	112,340
Vesting of early exercise of common stock options	—	—	12,660	—	34	—	—	34
Issuance of common stock under Employee Stock Purchase Plan (ESPP)	—	—	377,152	—	308	—	—	308
Stock-based compensation expense	—	—	—	—	3,434	—	—	3,434
Unrealized gain (loss) on investments	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(18,697)	(18,697)
Balance as of June 30, 2023	—	\$ —	44,465,006	\$ 4	\$ 308,117	\$ —	\$ (210,705)	\$ 97,416

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

SENTI BIOSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (37,419)	\$ (23,360)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,221	512
Amortization of operating lease right-of-use assets	919	1,433
Accretion of discount on short-term investments	(952)	—
Gain on extinguishment of convertible notes	—	(1,289)
Change in fair value of contingent earnout liability	(207)	(8,878)
Stock-based compensation expense	7,197	9,886
Other non-cash charges	(5)	21
Changes in assets and liabilities:		
Accounts receivable	64	(90)
Prepaid expenses and other assets	—	(1,372)
Accounts payable	885	234
Accrued expenses and other current liabilities	(2,082)	203
Deferred revenue	(635)	(999)
Operating lease liabilities	1,035	7,945
Net cash from operating activities	(29,979)	(15,754)
Cash flows from investing activities		
Purchases of short-term investments	(17,990)	—
Maturities of short-term investments	37,000	—
Purchases of property and equipment	(10,176)	(18,640)
Net cash from investing activities	8,834	(18,640)
Cash flows from financing activities		
Proceeds from Merger and related PIPE financing, net of transaction costs	—	112,464
Proceeds from issuance of common stock upon exercise of stock options	—	521
Proceeds from issuance of common stock under Employee Stock Purchase Plan (ESPP)	308	—
Proceeds from issuance of convertible notes	—	5,175
Principal finance lease payments	(62)	—
Net cash from financing activities	246	118,160
Net decrease in cash and cash equivalents	(20,899)	83,766
Cash, cash equivalents, and restricted cash, beginning of period	60,987	59,291
Cash, cash equivalents, and restricted cash, end of period	\$ 40,088	\$ 143,057
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	\$ 36,752	\$ 139,800
Restricted cash	3,336	3,257
Total cash, cash equivalents and restricted cash	\$ 40,088	\$ 143,057
Supplemental disclosures of noncash financing and investing items		
Purchases of property and equipment in accounts payable and accrued expenses	\$ 1,796	\$ 9,371
Merger and related PIPE financing costs included in accounts payable and accrued expenses	\$ —	\$ 263

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

**Notes to Condensed Consolidated Financial Statements
(unaudited)****1. Organization and Description of Business**

Senti Biosciences, Inc. and its subsidiaries (the “Company” or “Senti”), is a biotechnology company that was founded to create a new generation of smarter medicines that outmaneuver complex diseases using novel and unprecedented approaches. Senti has built a synthetic biology platform that enables it to program next-generation cell and gene therapies with what the Company refers to as “gene circuits.” These gene circuits, which are created from novel and proprietary combinations of DNA sequences, reprogram cells with biological logic to sense inputs, compute decisions and respond to their cellular environments. The Company is headquartered in South San Francisco, California.

On June 8, 2022 (the “Closing Date”), Dynamics Special Purpose Acquisition Corp. (“Dynamics” or “DYNS”) consummated a merger pursuant to which Explore Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and wholly owned subsidiary of Dynamics, merged with and into Senti Sub I, Inc., formerly named Senti Biosciences, Inc. (“Legacy Senti”), with Legacy Senti surviving as a wholly-owned subsidiary of Dynamics (such transactions, the “Merger,” and, collectively with the other transactions described in the merger agreement (as defined below, the “Reverse Recapitalization”). As a result of the Merger, Dynamics was renamed Senti Biosciences, Inc.

Liquidity and Going Concern

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

The Company has devoted substantially all of its efforts to organizing and staffing, business planning, raising capital, and conducting preclinical studies and has not realized substantial revenues from its planned principal operations. To date, the Company raised aggregate gross proceeds of \$299.5 million from the Merger and PIPE Financing, the issuance of shares of our common stock, the issuance of shares of our redeemable convertible preferred stock, the issuance of convertible notes and, to a less extent, through collaboration agreements and government grants.

At June 30, 2023 and December 31, 2022, the Company had an accumulated deficit of \$210.7 million and \$173.3 million, respectively. The Company’s net losses were \$37.4 million and \$23.4 million for the six months ended June 30, 2023 and 2022, respectively. Substantially all of the Company’s net losses resulted from costs incurred in connection with the Company’s research and development programs and from general and administrative costs associated with the Company’s operations. The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future as the Company advances its preclinical activities and clinical trials for its product candidates in development.

As of June 30, 2023 and December 31, 2022, the Company had cash, cash equivalents and short-term investments of \$59.6 million and \$98.6 million, respectively. As of August 11, 2023, the issuance date of the condensed consolidated financial statements as of and for the three and six months ended June 30, 2023, there is uncertainty about whether the Company’s combined cash, cash equivalents, and short-term investments will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements, beyond twelve months from the issuance date of these financial statements and therefore the Company concluded that substantial doubt existed about the Company’s ability to continue as a going concern.

On August 10, 2023, the Company announced a transaction with GeneFab, LLC (“GeneFab”), a new independent contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. The transaction provided the Company with additional capital and reduced longer-term operating expenses. Refer to Note 13, Subsequent Events, for further details of the GeneFab transaction.

The Company’s continued existence is dependent upon management’s ability to raise capital and develop profitable operations. Management is devoting substantially all of its efforts to developing its business and raising capital, which included the framework agreement with GeneFab, and there can be no assurance that the Company’s

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

efforts will be successful. No assurance can be given that management's actions will result in profitable operations or the meeting of ongoing liquidity needs.

2. Summary of Significant Accounting Policies***Basis of Presentation***

The accompanying condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The condensed consolidated financial statements include the accounts of Senti Biosciences, Inc., and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. We have one business activity and operate in one reportable segment.

Unless otherwise noted, the Company has retroactively adjusted all common and preferred share and related price information to give effect to the exchange ratio established in the Merger Agreement.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the valuation of stock-based awards, the accrual for research and development expenses, the valuation of contingent earnout, the valuation of convertible notes, the valuation of common and redeemable convertible preferred stock, standalone selling price ("SSP") and the determination of the incremental borrowing rate. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying interim condensed consolidated financial statements and the related footnote disclosures are unaudited. These unaudited interim financial statements have been prepared on the same basis as the audited financial statements, and in management's opinion, include all adjustments, consisting of only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2023 and its results of operations for the three and six months ended June 30, 2023 and 2022, and cash flows for the six months ended June 30, 2023 and 2022. The results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the year ended December 31, 2023 or any other period. The December 31, 2022 year-end condensed consolidated balance sheet was derived from audited annual financial statements but does not include all disclosures from the annual financial statements.

Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2022 and the related notes included in the Company's Form 10-K, filed with the SEC on March 22, 2023, which provides a more complete discussion of the Company's accounting policies and certain other information. There have been no material changes to the Company's significant accounting policies as of and for the three and six months ended June 30, 2023, as compared to the significant accounting policies described in the Company's audited annual consolidated financial statements as of and for the year ended December 31, 2022.

Recent Accounting Standards

The Company believes that the impact of recently issued accounting standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

SENTI BIOSCIENCES, INC.

Notes to Condensed Consolidated Financial Statements
(unaudited)

3. Fair Value Measurements

The following tables summarize the estimated value of cash equivalents and restricted cash (in thousands):

	June 30, 2023						
	Adjusted Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cash and cash equivalents	Restricted cash	Short-term investments
Cash	\$ 4,559	\$ —	\$ —	\$ 4,559	\$ 4,559	\$ —	\$ —
Level 1:							
Money market funds	35,529	—	—	35,529	32,193	3,336	—
Subtotal	35,529	—	—	35,529	32,193	3,336	—
Level 2:							
U.S. Treasury securities	6,482	—	—	6,482	—	—	6,482
U.S. agency securities	13,907	1	(1)	13,907	—	—	13,907
Commercial Paper	2,494	—	—	2,494	—	—	2,494
Corporate debt securities	—	—	—	—	—	—	—
Subtotal	22,883	1	(1)	22,883	—	—	22,883
Total	\$ 62,971	\$ 1	\$ (1)	\$ 62,971	\$ 36,752	\$ 3,336	\$ 22,883

	December 31, 2022						
	Adjusted Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cash and cash equivalents	Restricted cash	Short-term investments
Level 1:							
Money market funds	\$ 45,412	\$ —	\$ —	\$ 45,412	\$ 42,046	\$ 3,366	\$ —
Subtotal	45,412	—	—	45,412	42,046	3,366	—
Level 2:							
U.S. Treasury securities	14,866	4	(3)	14,867	—	—	14,867
U.S. agency securities	5,938	—	—	5,938	3,983	—	1,955
Commercial Paper	28,122	—	—	28,122	5,994	—	22,128
Corporate debt securities	7,590	1	(1)	7,590	5,598	—	1,992
Subtotal	56,516	5	(4)	56,517	15,575	—	40,942
Total	\$ 101,928	\$ 5	\$ (4)	\$ 101,929	\$ 57,621	\$ 3,366	\$ 40,942

No securities have contractual maturities of longer than one year. There were no transfers between Levels 1, 2, or 3 for any of the periods presented.

SENTI BIOSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The following table presents a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	Contingent Earnout Liability
Fair value as of December 31, 2022	\$ (227)
Change in fair value included in other income (expense)	207
Fair value as of June 30, 2023	<u>\$ (20)</u>

The fair value of the Contingent Earnout Liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy.

In determining the fair value of the Contingent Earnout Liability, the Company used a Monte Carlo simulation value model using a distribution of potential outcomes. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including the current Company common stock price, expected volatility, risk-free rate, expected term and expected dividend yield. Refer to Note 6, *Stockholders' Equity (Deficit)*, for further details of the Contingent Earnout Liability.

4. Other Financial Statement information

Prepaid Expenses and Other Current Assets

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

	June 30, 2023	December 31, 2022
Prepaid expenses (including prepaid rent)	\$ 1,874	\$ 1,871
Deposits	1,277	1,418
Other	139	101
Total prepaid expenses and other current assets	<u>\$ 3,290</u>	<u>\$ 3,390</u>

Property and Equipment, Net

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

	June 30, 2023	December 31, 2022
Leasehold improvements	\$ 46,748	\$ 1,869
Lab equipment	13,336	8,265
Furniture and fixtures	583	326
Computer equipment and software	383	389
Construction in progress	2,029	48,273
Property and equipment at cost	63,079	59,122
Less: accumulated depreciation	(4,139)	(2,986)
Property and equipment, net	<u>\$ 58,940</u>	<u>\$ 56,136</u>

Buildout of the current good manufacturing practice (cGMP) facility in Alameda was completed in June 2023 and the assets were placed in service. On August 10, 2023, the Company announced a transaction with GeneFab, a new independent contract manufacturing and synthetic biology biofoundry. As part of the transaction the Company subleased its cGMP facility in Alameda, CA to GeneFab. Refer to Note 13, Subsequent Events, for further details of the GeneFab transaction.

Depreciation totaled \$0.8 million and \$0.3 million for the three months ended June 30, 2023 and 2022, respectively, and \$1.2 million and \$0.5 million for the six months ended June 30, 2023 and 2022, respectively.

SENTI BIOSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Accrued Expenses and Other Liabilities

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

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Accrued employee-related expenses	\$ 2,099	\$ 3,743
Accrued professional and service fees related to facility construction	1,615	7,342
Accrued professional and service fees other	1,245	1,750
Other accrued expenses	32	29
Total accrued expenses and other current liabilities	\$ 4,991	\$ 12,864

5. Operating Leases

The Company's operating leases are primarily for its corporate headquarters located in South San Francisco, California ("HQ lease") and for additional office and laboratory space located in Alameda, California ("Alameda lease"). The corporate headquarters lease has an initial term of eight years expiring in 2027, with an option to renew for an additional eight years unless canceled by either party thereafter. The Alameda lease has an initial term of eleven years expiring in 2032, with an option to renew the lease for up to two additional terms of five years. The exercise of these renewal options is not recognized as part of the ROU assets and lease liabilities, as the Company did not conclude, at the commencement date of the leases, that the exercise of renewal options or termination options was reasonably certain. The Alameda lease provides for a tenant improvement allowance of up to \$17.5 million for the costs relating to the design, permitting and construction of the improvements, to be disbursed by the landlord no later than December 31, 2023. The Company is deemed to be the accounting owner of the tenant improvements primarily because the Company is the principal in the construction and design of the assets, is responsible for costs overruns and retains substantially all economic benefits from the leasehold improvements over their economic lives. Accordingly, the tenant improvement allowance is considered an incentive and was deducted from the initial measurement of the ROU asset and lease liability. The Company estimated the timing of tenant improvement reimbursements at the lease commencement date and upon receipt of the cash incentives, the Company recognized the cash received as an increase in the lease liability. On August 10, 2023, the Company announced a transaction with GeneFab, a new independent contract manufacturing and synthetic biology biofoundry. As part of the transaction the Company subleased the cGMP facility in Alameda to GeneFab. Refer to Note 13, Subsequent Events, for further details of the GeneFab transaction.

A summary of total lease costs and other information for the period relating to the Company's operating leases is as follows:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Operating lease cost	\$ 1,320	\$ 1,325	\$ 2,629	\$ 2,650
Short-term lease cost	25	27	56	30
Variable lease cost	378	182	622	353
Total lease cost	\$ 1,723	\$ 1,534	\$ 3,307	\$ 3,033

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

	Six Months Ended June 30,	
	2023	2022
Other information:		
Operating cash flows net inflows and (outflows) from operating lease	\$ (675)	\$ 6,740
ROU assets obtained in exchange for operating lease obligations (including remeasurement of ROU and lease liabilities due to changes in the timing of receipt of lease incentives)	\$ (30)	\$ 199
Weighted-average remaining lease term	7.9 years	8.2 years
Weighted-average discount rate	9.1%	9.1%

For the three months ended June 30, 2023 and 2022, the Company received \$1.0 million and \$5.6 million, respectively, of \$17.5 million tenant improvement allowance. For the six months ended June 30, 2023 and 2022, the Company received \$2.0 million and \$8.1 million, respectively, of the \$17.5 million tenant improvement allowance. Through June 30, 2023, the Company received \$16.2 million of the tenant improvement allowance inception-to-date.

As of June 30, 2023 and 2022, amounts disclosed for ROU assets obtained in exchange for lease obligations include amounts added to the carrying amount of ROU assets resulting from lease modifications and reassessments.

Maturities of the Company's lease liabilities as of June 30, 2023, were as follows (in thousands):

2023, for the remainder of the year	\$ 3,560
2024	7,254
2025	7,478
2026	7,712
2027	5,769
Thereafter	24,384
Total undiscounted lease payments	56,157
Less imputed interest	(16,750)
Tenant improvement allowance remaining	(1,311)
Total lease liabilities	\$ 38,096

6. Stockholders' Equity (Deficit)

Common Stock

Holders of common stock are entitled to one vote per share, and to receive dividends and, upon liquidation or dissolution, are entitled to receive all assets available for distribution to stockholders. The holders have no preemptive or other subscription rights, and there are no redemption or sinking fund provisions with respect to such shares. Common stock is subordinate to the preferred stock with respect to dividend rights and rights upon liquidation, winding up, and dissolution of the Company; although, no preferred stock is outstanding as of June 30, 2023 and December 31, 2022. Through June 30, 2023, no cash dividends have been declared or paid.

Notes to Condensed Consolidated Financial Statements
(unaudited)

At June 30, 2023 and December 31, 2022, the Company was authorized to issue 500,000,000 shares of common stock, all at a par value of \$0.0001 per share, and had reserved the following shares for future issuance:

	June 30, 2023	December 31, 2022
Common Stock Purchase Agreement	8,327,049	8,327,049
Common stock options issued and outstanding	12,056,731	9,875,675
Restricted Stock Units (RSUs) issued and outstanding	335,884	447,948
Common stock shares available for future issuance under equity plans	3,087,881	2,948,472
Common stock shares available for future issuance under the 2022 Employee Stock Purchase Plan (the "ESPP")	546,155	481,627
Contingent earnout common stock	2,000,000	2,000,000
Unvested early exercised common stock	80,180	105,500
Total	<u>26,433,880</u>	<u>24,186,271</u>

Preferred Stock

In connection with the close of the Merger, the Company's Amended and Restated Certificate of Incorporation provides the Company's board of directors with the authority to issue \$0.0001 par value preferred stock in one or more series and to establish from time to time the number of shares to be included in each such series, by adopting a resolution and filing a certification of designations. Voting powers, designations, powers, preferences and relative, participating, optional, special and other rights shall be stated and expressed in such resolutions. There were 10,000,000 shares designated as preferred stock and none were outstanding as of June 30, 2023 and December 31, 2022.

Common Stock Purchase Agreement

On August 31, 2022, the Company entered into a Common Stock Purchase Agreement and a Registration Rights Agreement (collectively referred to as the "Purchase Agreement") with Chardan Capital Markets LLC ("Chardan"). Pursuant to the Purchase Agreement, the Company has the right, in its sole discretion, to sell to Chardan up to the lesser of (i) \$50.0 million of newly issued shares of the Company's common stock, and (ii) the Exchange Cap (as defined below) (subject to certain conditions and limitations), from time to time during the 36-month term of the Purchase Agreement. Under the applicable NASDAQ rules, the Company may not issue to Chardan under the Purchase Agreement more than 8,727,049 shares of common stock, which number of shares is equal to 19.99% of the common shares outstanding immediately prior to the execution of the Purchase Agreement unless certain exceptions are met (the "Exchange Cap"). The purchase price of the shares of common stock will be determined by reference to the Volume Weighted Average Price ("VWAP") of the common stock during the applicable purchase date, less a fixed 3% discount to such VWAP. However, the total shares to be purchased on any day may not exceed 20% of the trading volume, and the total purchase price on any day may not exceed \$3.0 million. As consideration for Chardan's commitment to purchase shares of common stock at the Company's direction upon the terms and subject to the conditions set forth in the Purchase Agreement, upon execution of the Purchase Agreement, the Company issued 100,000 shares of its common stock to Chardan and paid a \$0.4 million document preparation fee. Upon execution of the Purchase Agreement, the Company recognized an expense of \$0.7 million within general and administrative expenses in the Company's Condensed Consolidated Statements of Operations and Comprehensive Loss for the Chardan related costs and legal fees incurred in connection with the agreement.

Other than the issuance of the commitment shares of the Company's common stock to Chardan, the Company issued 300,000 common stock shares up until December 31, 2022 aggregating to net proceeds of \$0.7 million, under the Purchase Agreement. There were no shares issued within six months ended June 30, 2023.

Contingent Earnout Equity

Following the closing of the Merger, former holders of Legacy Senti common stock and preferred stock may receive up to 2,000,000 additional shares of the Company's common stock in the aggregate, in two equal tranches of 1,000,000 shares of common stock per tranche. The first and second tranches are issuable if the closing volume

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

weighted average price (“VWAP”) per share of common stock quoted on the Nasdaq (or the exchange on which the shares of common stock are then listed) is greater or equal to \$15.00 and \$20.00, respectively over any twenty trading days within any thirty-day trading period. The first and second tranche term is two and three years, respectively, from the closing of the Merger. If there is a change of control within the three-year following the closing of the Merger that results in a per share price equal to or in excess of the \$15.00 and \$20.00 share price milestones not previously met, then Company shall issue the earnout shares to the holders of Legacy Senti common stock and preferred stock.

The estimated fair value of the total Contingent Earnout Shares at the Closing on June 8, 2022, was \$9.8 million based on a Monte Carlo simulation valuation model. Of this amount, \$9.7 million was accounted for as a Contingent Earnout Liability because the triggering events that determine the number of Contingent Earnout Shares required to be issued include events that are not solely indexed to the common stock of the Company. The remaining balance of \$0.1 million relates to holders of Legacy Senti common stock that are subject to repurchase were accounted for as stock-based compensation expense and recorded as an expense, as there was no remaining service period.

The Contingent Earnout Liability was remeasured to fair value as of June 30, 2023, resulting in the recording of a non-cash gain of \$0.1 million for the three months ended June 30, 2023, and a non-cash gain of \$0.2 million for the six months ended June 30, 2023, classified within change in fair value of contingent earnout liability in the condensed consolidated statements of operations and comprehensive loss.

Assumptions used in the valuation are described below:

	June 30, 2023	December 31, 2022
Current stock price	\$ 0.63	\$ 1.41
Expected share price volatility	93.0%	85.0%
Risk-free interest rate	4.9%	4.3%
Estimated dividend yield	0.0%	0.0%
Expected term (years)	1.9	2.4

7. Revenue

The Company’s revenue consists of amounts received related to research services provided to customers.

Contract Revenue

In April 2021, the Company entered into a research collaboration and license agreement with Spark Therapeutics, Inc. (“Spark”). Under the agreement, the Company will be responsible for a research program, which includes designing, building and testing five cell type specific-synthetic promoters for use in developing certain gene therapies using the Company’s proprietary technology. The Company received an upfront payment from Spark of \$3.0 million and Spark is obligated to reimburse the Company for costs and expenses incurred for the research program. The Company expected to complete the research program over a two-year period.

The Company assessed this agreement in accordance with ASC 606, *Revenue Recognition* (“ASC 606”) and concluded that the contract counterparty, Spark, is a customer. The Company identified only one combined performance obligation in the agreement, which is to perform research services, the related joint research plan and committees for the five specified promoters. The Company determined that the research activities for each of the five promoters are not distinct given there is one single research plan that is performed by the same research team and research results for one promoter may provide insights for other promoters.

Pursuant to the agreement, once the research program is completed and the Company delivers a data package to Spark, Spark has 24 months (the “Evaluation Period”) to determine whether Spark will exercise its options to obtain field-limited, royalty-bearing licenses to develop, manufacture and commercialize promoters corresponding to each of the five specified promoters being researched. For each licensed promoter option that is exercised, the Company is eligible to receive a license fee, potential research, development and commercial milestone payments and royalties

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

on product sales. Spark may generally terminate the agreement upon 90 days prior written notice or 180 days prior written notice if the licensed promoter is in clinical trials or is being commercialized at the time of termination.

The Company evaluated Spark's optional rights to license, develop, manufacture and commercialize each of the promoter profiles to determine whether they provide Spark with any material rights to purchase the promoter licenses at an incremental discount. The Company's proprietary technology used to develop the promoters is in the early stages of development, so technological feasibility and probability of developing a product is highly uncertain. As a result, determining the SSP for the optional rights is subject to significant judgment. Given the subjectivity associated with determining the SSP for the right to a future license related to unproven technology at contract inception, the Company also evaluated whether the contract consideration associated with the research services represents the SSP for those services. The Company determined the transaction price, inclusive of the upfront payment and reimbursement of costs and expenses incurred for the research program, is commensurate with SSP for the research being conducted given the specialized nature and reliance on proprietary technology. Based on the Company's assessment of the optional consideration and the qualitative factors of feasibility and probability of development combined with the quantitative assessment that research services are priced at their SSP, the Company concluded that the license option does not provide Spark with an incremental discount and therefore does not constitute a material right. The transaction price associated with the research services in this agreement consists of the fixed upfront amount of \$3.0 million and variable consideration.

For Spark collaboration agreement, the Company will recognize the transaction price as research and development services are provided, using a cost-based input method to measure the progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes that the cost-based input method is the best measure of progress because other measurements would not reflect how the Company transfers the control related to the performance obligation to our customers.

In December 2022, the Company amended the research collaboration and license agreement with Spark to allow for an increase in budget and a two-month extension of the research program. As there were no changes to performance obligations and the services to be provided are not distinct from those already transferred, the transactions was accounted for as a contract modification and a cumulative catch-up of \$(0.7) million was recognized in December 2022.

In May 2023, the Company amended the research collaboration and license agreement with Spark to allow for an increase in budget and additional two-month extension of the research program. As there were no changes to performance obligations and the services to be provided are not distinct from those already transferred, the transactions was accounted for as a contract modification with no cumulative catch-up necessary.

As of June 30, 2023 and December 31, 2022, there was a total of \$0.2 million and \$0.8 million, respectively, remaining of the upfront payment to be recognized over the remaining period of the research program.

For the three months ended June 30, 2023 and 2022, the Company recorded revenue, which was previously included in deferred revenue at the beginning of each period, of \$0.2 million and \$0.5 million, respectively. For the six months ended June 30, 2023 and 2022, the Company recorded revenue, which was previously included in the deferred revenue at the beginning of each period, of \$0.6 million, and \$1.0 million respectively. Contract asset balances related to unbilled revenue for our collaboration agreements were zero as of June 30, 2023 and 2022, and are presented within prepaid expenses and other current assets on the condensed consolidated balance sheets.

Grant Income

In 2021, the Small Business Innovation Research ("SBIR") awarded the Company a grant in the amount of \$2.0 million over two years subject to meeting certain terms and conditions. The purpose of the grant is to support the further development of SENTI-202 for acute myeloid leukemia towards clinical development.

Grant income was recognized when qualified research and development costs were incurred and the Company obtained reasonable assurance that the terms and conditions of the grant were met.

**Notes to Condensed Consolidated Financial Statements
(unaudited)****Entity-wide information**

During the three months ended June 30, 2023, Customers A and B accounted for 73% and 27%, respectively, of revenue. During the three months ended June 30, 2022, Customers A and B accounted for 82% and 18%, respectively, of revenue. During the six months ended June 30, 2023, Customers A and B accounted for 78% and 22%, respectively, of revenue. During the six months ended June 30, 2022, Customers A and B accounted for 80% and 20%, respectively, of revenue.

All revenues were generated in the United States for the three and six months ended June 30, 2023 and 2022.

8. Stock-Based Compensation**2016 Stock Incentive Plan (as Amended and Restated)**

The Company's 2016 Stock Incentive Plan (the "2016 Plan") provides for the grant of incentive stock options, non-qualified stock options and restricted stock awards to employees, directors, and consultants of the Company.

Stock options granted under the 2016 Plan generally vest over four years and expire no later than ten years after the grant date.

Following the Merger, the 2016 Plan was terminated. No additional stock awards will be granted under the 2016 Plan. All awards previously granted and outstanding as of the effective date of the Merger, were adjusted to reflect the impact of the Merger, but otherwise remain in effect pursuant to their original terms. The shares underlying any award granted under the 2016 Plan that are forfeited back to or repurchased or reacquired by the Company, will revert to and again become available for issuance under the 2022 Plan.

2022 Stock Incentive Plan

On June 8, 2022, upon the Merger, the Company adopted a 2022 Stock Incentive Plan (the "2022 Plan"). The 2022 Plan provides for the grant of incentive stock options to employees, and for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants.

The exercise price of an option granted under the 2022 Plan shall not be less than the fair market value of a common stock share on the date of grant. With respect to a 10% stockholder, the exercise price of an option granted shall not be less than 110% of the fair value of the common stock share on the date of grant.

Stock options granted under the 2022 Plan generally vest over four years and expire no later than ten years after the grant date.

The Company initially reserved 2,492,735 shares of common stock for issuance under the 2022 Plan. On the first day of each year commencing January 1, 2023, the 2022 Plan will automatically increase by 5% of the outstanding number of shares of common stock of the Company on the last day of the preceding calendar year or such lesser number of shares as approved by the Company's Board of Directors prior to the effective date of the annual increase. In addition, the shares underlying any award granted under the 2016 Plan that are forfeited back to or repurchased or reacquired by the Company, will revert to and again become available for issuance under the 2022 Plan.

As of June 30, 2023, the total number of shares of common stock available for issuance under the 2022 Plan is 1,942,991.

2022 Inducement Equity Plan

On August 5, 2022, the Company adopted a 2022 Inducement Equity Plan (the "2022 Inducement Plan"). The 2022 Plan provides for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards,

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

restricted stock unit awards, performance awards and other forms of awards to persons not previously an employee of the Company and its affiliates.

The exercise price of an option granted under the 2022 Inducement Plan shall not be less than the fair market value of a common stock share on the date of grant.

Stock options granted under the 2022 Inducement Plan generally vest over four years and expire no later than ten years after the grant date.

The Company initially reserved 2,000,000 shares of common stock for issuance under the 2022 Inducement Plan.

As of June 30, 2023, the total number of shares of common stock available for issuance under the 2022 Inducement Plan is 1,144,890.

2022 Employee Stock Purchase Plan

On June 8, 2022, upon the Merger, the Company adopted a 2022 Employee Stock Purchase Plan (the "ESPP"). The ESPP allows eligible employees to purchase shares of the Company's common stock at a price equal to 85% of the lower of the fair market values of the stock on the first day of an offering or on the date of purchase. The Company's ESPP operates with rolling offering periods, which are generally 24 months.

The Company initially reserved 592,584 shares of common stock for issuance under the ESPP. On the first day of each year commencing January 1, 2023, the 2022 Plan will automatically increase by 1% of the outstanding number of shares of common stock of the Company on the last day of the preceding calendar year or such lesser number of shares as approved by the Company's Board of Directors prior to the effective date of the annual increase.

As of June 30, 2023, the total number of shares of common stock available for issuance under the ESPP is 546,155.

Stock options

The following table summarizes the Company's stock option activity and related information under all equity plans, excluding performance and market awards:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	4,191,426	\$ 3.18	9.1	\$ 6
Granted	2,794,596	\$ 1.64		
Forfeited	<u>(411,588)</u>	\$ 3.55		
Outstanding at June 30, 2023	<u>6,574,434</u>	\$ 2.50	9.0	\$ 2
Vested and exercisable at June 30, 2023	<u>1,247,904</u>	\$ 3.63	7.9	\$ 2

The weighted-average grant date fair values of stock options granted during the six months ended June 30, 2023 and 2022 were \$1.18 and none, respectively. The aggregate intrinsic values of stock options exercised during the six months ended June 30, 2023 and 2022 were none and \$0.5 million, respectively.

As of June 30, 2023, the unrecognized stock-based compensation expense related to stock options was approximately \$8.6 million, expected to be recognized over a weighted-average period of 2.6 years.

Early Exercise of Stock Options into Restricted Stock

For the six months ended June 30, 2023 and 2022, the Company issued zero shares of common stock upon exercise of unvested stock options. As of June 30, 2023 and December 31, 2022, 80,180 and 105,500 shares were held by employees subject to repurchase at an aggregate price of \$0.2 million and \$0.3 million, respectively.

Notes to Condensed Consolidated Financial Statements
(unaudited)

Performance Awards

In connection with the Merger, on December 19, 2021, Legacy Senti approved 8,400,892 performance award options to existing employees that vest contingent upon the satisfaction of both a four-year service condition and a performance condition tied to the consummation of the Merger. The awards and the associated recognition of stock-based compensation were contingent on the Merger being consummated. As of the approval date of the performance awards, Legacy Senti did not have sufficient common stock available for issuance. Upon the Merger, the Company increased the number of shares authorized and 6,796,074 awards were granted on June 8, 2022. Refer to Note 6, *Stockholders' Equity (Deficit)*, for further details of the shares of common stock authorized.

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	5,368,501	\$ 9.92	9.0	\$ —
Forfeited	(201,952)	\$ 9.92		
Outstanding at June 30, 2023	<u>5,166,549</u>	<u>\$ 9.92</u>	8.4	\$ —
Vested and exercisable at June 30, 2023	<u>1,436,378</u>	<u>\$ 9.92</u>	8.1	\$ —

There were no performance based options granted or exercised during the six months ended June 30, 2023, and there were 6,796,074 performance based options granted and no performance based options exercised during the six months ended June 30, 2022.

As of June 30, 2023, the unrecognized stock-based compensation expense related to performance based options was approximately \$7.8 million, expected to be recognized over a weighted-average period of 1.8 years.

Market Awards

In connection with the Business Combination Agreement with DYNs, on December 19, 2021, Legacy Senti approved 605,451 market award options to its co-founder and Chief Executive Officer, Dr. Timothy Lu, that vest contingent upon the satisfaction of all three of the following conditions: a service condition, a performance condition tied to the consummation of the Merger, and market conditions. The market condition is achieved in four tranches, where 25% of the options will vest when the trading price of the Company's stock is above various thresholds of price per share. The award and the associated recognition of stock-based compensation were contingent on the Merger being consummated. The estimated fair value of the market awards at the grant date was based on a Monte Carlo simulation valuation model. As of the approval date, Legacy Senti did not have sufficient common stock available for issuance to allow for exercise of the stock options. Upon the Merger, the Company increased the number of shares authorized and 315,748 awards were granted on June 8, 2022. Through June 30, 2023, these market awards did not meet the vesting thresholds. Refer to Note 6, *Stockholders' Equity (Deficit)*, for further details of the shares of common stock authorized.

There were no market based options granted or exercised during the six months ended June 30, 2023, and there were 315,748 market based options granted and no market based options exercised during the six months ended June 30, 2022.

As of June 30, 2023, the unrecognized stock-based compensation expense related to market based options was approximately \$0.5 million, expected to be recognized over a weighted-average period of 0.9 years.

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

Restricted Stock Units

The following table summarizes the Company's restricted stock units activity and related information under all equity plans:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	447,948	\$ 2.50
Forfeited	(112,064)	\$ 2.50
Outstanding at June 30, 2023	335,884	\$ 2.50

As of June 30, 2023, the unrecognized stock-based compensation expense related to restricted stock units was approximately \$0.5 million, expected to be recognized over a weighted-average period of 1.2 years.

Stock-Based Compensation Expense

In determining the fair value of the stock-based awards, the Company uses the assumptions below for the Black-Scholes option pricing model, which are subjective and generally require significant judgment.

Fair Value of Common Stock — The fair value of the shares of common stock has historically been determined by the Company's board of directors as there was no public market for the common stock. The board of directors determined the fair value of the common stock by considering a number of objective and subjective factors, including: third-party valuations of the Company's common stock, the valuation of comparable companies, the Company's operating and financial performance, and general and industry-specific economic outlook, amongst other factors. As of the closing of the Merger and going forward, the fair value of common stock will be based on the publicly traded market value.

Expected Term — The expected term represents the period that the Company's stock options are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). The expected term for the ESPP purchase rights is the length of the purchase period.

Volatility — The expected volatility is based on the average historical volatility of comparable publicly-traded peer companies, over a period equal to the expected term of the stock option grants, as the Company was not publicly traded prior to the Merger and does not have a trading history for its common stock for a sufficient period of time subsequent to the Merger.

Risk-free Rate — The risk-free rate assumption is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividends — The Company has never paid dividends on its common stock and does not anticipate paying dividends on common stock. Therefore, the Company uses an expected dividend yield of zero.

The assumptions used to determine the grant date fair value of non-market based, stock options granted were as follows, presented on a weighted-average basis:

	Six Months Ended June 30,	
	2023	2022
Expected term (in years)	5.9	5.8
Expected volatility	83%	78%
Risk-free interest rate	3.5%	3.0%
Dividend yield	—	—

Notes to Condensed Consolidated Financial Statements
(unaudited)

Total stock-based compensation expense was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
General and administrative	\$ 3,081	\$ 7,863	\$ 6,320	\$ 8,322
Research and development	353	1,362	877	1,564
Total stock-based compensation expense	<u>\$ 3,434</u>	<u>\$ 9,225</u>	<u>\$ 7,197</u>	<u>\$ 9,886</u>

9. Income Tax

No provision for income taxes was recorded for the three and six months ended June 30, 2023 and 2022, respectively. Deferred tax assets generated from the Company's net operating losses have been fully reserved, as the Company believes it is not more likely than not that the benefit will be realized due to the Company's cumulative losses generated to date.

10. Net Loss Per Share

A reconciliation of net loss available to common stockholders and the number of shares in the calculation of basic and diluted loss per share is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	\$ (18,697)	\$ (11,552)	\$ (37,419)	\$ (23,360)
Weighted-average shares used in computing net loss per share, basic and diluted	44,278,427	13,446,622	44,175,274	8,336,451
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.42)</u>	<u>\$ (0.86)</u>	<u>\$ (0.85)</u>	<u>\$ (2.80)</u>

The following potential common stock securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive (on an as-converted basis):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Stock options to purchase common stock	12,056,731	8,779,368	12,056,731	8,779,368
Unvested early exercised options	80,180	288,807	80,180	288,807
Restricted stock units outstanding	335,884	—	335,884	—
Contingent earnout common stock	2,000,000	2,000,000	2,000,000	2,000,000
Total	<u>14,472,795</u>	<u>11,068,175</u>	<u>14,472,795</u>	<u>11,068,175</u>

The potential common stock securities above do not reflect 19,633,444 of potentially dilutive securities as a result of the option issued to GeneFab, as announced on August 10, 2023. Refer to Note 13, Subsequent Events, for further details of the GeneFab transaction.

11. Commitments and Contingencies

In the ordinary course of business, the Company enters into contractual agreements with third parties that include non-cancelable payment obligations, for which the Company is liable in future periods.

On June 3, 2021, the Company entered into a lease agreement for a new cGMP facility in Alameda, California to support planned initial clinical trials for our product candidates. The lease will expire in 2032 with future

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

undiscounted operating lease payments of \$46.0 million over an initial lease period of eleven years. Refer to Note 5, *Operating Leases*, for further details of the leases.

In 2021, the Company began construction of the cGMP facility. Buildout of the cGMP facility was completed in June 2023. As of June 30, 2023 the Company paid \$40.0 million in construction costs of the \$42.2 million purchase commitment. The agreements with the construction company provide for termination following a certain period after notice. Upon termination, the Company will be responsible for payment for work performed to date.

In 2021, the Company entered into a three-year collaboration and option agreement with BlueRock Therapeutics LP (“BlueRock”) under which the Company granted BlueRock an option to acquire an exclusive or non-exclusive license to develop, manufacture and commercialize cell therapy products. Refer to Note 12, *Related Parties*, for details into the BlueRock agreement. In consideration for the option, the Company is responsible for up to \$10.0 million in costs and expenses incurred over the three-year term.

As of June 30, 2023, purchase commitments related to sponsored research agreements amounted to approximately \$0.7 million.

The Company has entered into license agreements under which they are obligated to make annual maintenance payments of \$0.1 million and specified milestone and royalty payments. Future milestone and royalty payments under these agreements are not considered contractual obligations since the payments under these agreements are contingent upon future events, such as the Company’s achievement of specified development, regulatory, and sales milestones, or generating product sales. As of June 30, 2023, the Company is unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

Following the Closing, former holders of Legacy Senti common stock and preferred stock may receive up to 2,000,000 additional shares of the Company’s common stock in the aggregate, in two equal tranches of 1,000,000 shares of common stock per tranche. Refer to Note 6, *Stockholders’ Equity (Deficit)*, for further details of the contingent earnout liability.

Legal Proceedings

The Company is subject to claims and assessments from time to time in the ordinary course of business but does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company’s financial position, results of operations, or cash flows.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions and has never accrued any liabilities related to such obligations in its condensed consolidated financial statements. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors’ and officers’ insurance.

12. Related Parties***NEA***

NEA held 4,429,725 shares of the Company’s common stock as of June 30, 2023 and December 31, 2022. NEA held one of the six seats on the Company’s Board of Directors as of June 30, 2023 and December 31, 2022.

**Notes to Condensed Consolidated Financial Statements
(unaudited)*****Bayer Healthcare LLC***

On May 19, 2022, Legacy Senti issued to Bayer a \$5.2 million unsecured convertible promissory note (“the “May 2022 Note”). On June 8, 2022, the May 2022 Note was automatically cancelled and exchanged for 517,500 shares of Common Stock at a price of \$10.00 per share.

On May 21, 2021, the Company entered into a collaboration and option agreement (“BlueRock Agreement”) with BlueRock, a wholly-owned subsidiary of Bayer, pursuant to which the Company granted to BlueRock an option (“BlueRock Option”), on a collaboration program-by-collaboration program basis, to obtain an exclusive or non-exclusive license to develop, manufacture and commercialize cell therapy products that contain cells of specified types and which incorporate an option gene circuit from such collaboration program or a closely related derivative gene circuit. The Company is responsible for up to \$10 million in costs and expenses incurred in connection with the research plan and related activities to be conducted over a term of three years as specified in the collaboration and option agreement. If the Company and BlueRock agree to add new research activities to the research plan, then BlueRock will be obligated to reimburse the Company for the costs and expenses incurred that, together with costs and expenses incurred under the initial research plan, exceed \$10 million.

The Company concluded that the Agreement is not within the scope of ASC 808, *Collaborative Arrangements*, because the Company did not receive any consideration and therefore, is not exposed to both significant risks and rewards for the arrangement. The Company also determined that the agreement is also not currently within the scope of ASC 606 because the BlueRock Agreement does not currently meet the criteria of a contract with a customer, and will not be within the scope of ASC 606 until any consideration is paid. Potential future milestone payments and royalties are subject to BlueRock’s exercise of the BlueRock Option and execution of a commercial license agreement by both parties. Under the BlueRock Agreement, the specific financial terms for milestone payments and royalties will be negotiated and agreed to only after the option is exercised.

Bayer held 5,878,488 shares, of the Company’s common stock as of June 30, 2023 and December 31, 2022. Bayer held one of the six seats on the Company’s Board of Directors as of June 30, 2023 and December 31, 2022. Bayer’s parent company is Bayer AG, which served as the lead investor in our Series B financing prior to the Merger through its Leaps by Bayer unit. Accordingly, Bayer is considered a related party.

Seer, Inc.

In January 2023, the Company acquired lab automation equipment purchased from Seer, Inc. (“Seer”) (NASDAQ: SEER). Omid Farokhzad, a member of the Company’s board of directors is the Chief Executive Officer for Seer. The consideration of \$0.2 million, plus interest, will be paid over a two-year period, and title will transfer to the Company upon final payment. The transaction was classified as a finance lease in accordance with ASC 842.

GeneFab, LLC.

In August 2023, the Company entered into a framework agreement with GeneFab and Valere Bio, Inc., a Delaware corporation and the parent company of GeneFab (“Valere”), which is wholly owned by Celadon Partners, LLC, pursuant to which the Company, subject to the terms and conditions therein, (i) shall sell, assign and transfer its rights, title and interest in certain of the assets and contractual rights, including all of Company’s equipment and leasehold improvements at the Company’s facilities in Alameda (the “Alameda Facility”) and certain of the Company’s intellectual property related to the schematics for and design of the Alameda Facility, and (ii) sublease to GeneFab its premises under the lease for the Alameda Facility. In addition, the Company has agreed to grant a license to GeneFab under certain of its intellectual property rights to conduct manufacturing services and to research, develop, manufacture and commercialize products outside of oncology, pursuant to a license agreement under negotiation. As part of this transaction, the Company entered into a transition services agreement with GeneFab whereby certain services are to be provided by each party to the other party during a transition period beginning on the closing of the transaction.

On August 7, 2023, Philip Lee, Ph.D., the Company’s former Chief Technology Officer, notified the Company of his resignation as an employee and as Chief Technology Officer of the Company, effective on August 7, 2023, to join GeneFab as its Chief Executive Officer. Dr. Lee’s resignation was not the result of any disagreement with the Company on any matter relating to the Company’s operations, policies or practices.

**Notes to Condensed Consolidated Financial Statements
(unaudited)****13. Subsequent Events*****GeneFab, LLC.***

On August 10, 2023, the Company announced the transaction with GeneFab, a new independent contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. The Company sold, assigned and transferred its rights, title and interest in certain of the assets and contractual rights, including all of the Company's equipment and leasehold improvements at the Company's facilities in Alameda and certain of the Company's intellectual property related to the schematics for and design of the Alameda facility, and subleased to GeneFab its premises under the lease for the Alameda facility. The transaction provided the Company with additional capital and reduced longer term operating expenses.

- a. Under the terms of the agreement, the Company will receive \$37.8 million in cash before the end of 2025. Approximately \$18.9 million was due at closing, which amount was netted against prepayment owed by the Company for manufacturing and support services to GeneFab. The remaining \$18.9 million will be paid to the Company in installments in 2024 and 2025.
- b. The Company has agreed to prepay GeneFab \$18.9 million for manufacturing and research activities. In addition, the Company will receive \$8.0 million of manufacturing credit from GeneFab for their services.
- c. The Company subleased the cGMP facility in Alameda, CA to GeneFab, a portion of which will be subject to the satisfaction of certain conditions, which will support the clinical manufacturing of the Company's chimeric antigen receptor natural killer (CAR-NK) programs, including SENTI-202.
- d. The Company agreed to grant a license to GeneFab under certain of its intellectual property rights to conduct manufacturing services and to research, develop, manufacture and commercialize products outside of oncology, pursuant to a license agreement under negotiation.
- e. Philip Lee, Ph.D., former Co-Founder and Chief Technology Officer of the Company, assumed the role of Chief Executive Officer of GeneFab.
- f. GeneFab intends to extend offers of employment to approximately forty-six of the Company's employees currently employed in its research and development and manufacturing functions. Employees that accept the offers of employment will continue to be actively engaged in the CMC and manufacturing components for the clinical manufacturing of the Company's Gene Circuit products.
- g. GeneFab was provided an option to purchase up to \$20.0 million of the Company's common stock at an exercise price of \$1.01867. The Option is exercisable for a period of 36 months following the execution of the license agreement.
- h. The Company and GeneFab entered into a seller economic share agreement (the "**SESA**"), pursuant to which the Company will be entitled to receive ten percent of the realized gains of GeneFab's parent company arising and resulting from any cash or in-kind distributions from GeneFab in connection with the dividend or sale event, subject to the terms and conditions of the SESA.

As of June 30, 2023, the GeneFab transaction did not meet the assets held for sale classification as management had not committed to a plan to sell the long-term assets. As a result of the signing of the transaction non-binding term sheet in June 2023 with GeneFab and the change in the manner in which the Company expects to recover the assets subject to the GeneFab transaction, the asset group used in the long-lived impairment assessment was changed to two asset groups as of June 30, 2023, the oncology and non-oncology asset group, with the non-oncology including all the assets expected to be transferred in the GeneFab transaction. This asset group reassessment triggered a need to perform an impairment analysis for the non-oncology asset group that considered the final terms of the transaction and no impairment was deemed necessary.

NASDAQ Bid Price Compliance Notice

On August 7, 2023, the Company received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC notifying the Company that, for the last 30 consecutive trading days, the closing bid price of the Company's common stock had closed below the minimum bid price requirement of \$1.00 per share for

SENTI BIOSCIENCES, INC.

**Notes to Condensed Consolidated Financial Statements
(unaudited)**

continued listing on The Nasdaq Global Market. The Company has been provided an initial compliance period of 180 calendar days, or until February 5, 2024, to regain compliance with the minimum bid price requirement.

[Table of Contents](#)

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

Senti Biosciences, Inc. ("Senti") entered into a business combination agreement (the "Agreement") with Dynamics Special Purpose Corp. ("DYNS") on December 19, 2021. The transactions contemplated by the terms of the Agreement were completed on June 8, 2022 (the "Closing"), in conjunction with which DYNS changed its name to Senti Biosciences, Inc. (hereafter referred to, collectively with its subsidiaries, as "Senti," the "Company," "we," "us," or "our," unless the context otherwise requires). The transactions contemplated in the Agreement are collectively referred to as the "Merger."

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included under Part I, Item 1 of this Quarterly Report on Form 10-Q (this "Quarterly Report") as well as Senti's audited consolidated financial statements and notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2022 (the "Annual Report") and filed with the Securities and Exchange Commission (the "SEC") on March 22, 2023. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties.

Cautionary Statement Regarding Forward-Looking Statements

This Quarterly Report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that are not historical facts and involve risks and uncertainties that could cause actual results to differ materially from those expected and projected. All statements, other than statements of historical fact included in this Form 10-Q including, without limitation, statements in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" regarding the Company's financial position, business strategy and the plans and objectives of management for future operations, are forward-looking statements. Words such as "expect," "believe," "anticipate," "explore," "intend," "estimate," "seek," and variations and similar words and expressions are intended to identify such forward-looking statements. Such forward-looking statements relate to future events or future performance, but reflect management's current beliefs, based on information currently available. A number of factors could cause actual events, performance or results to differ materially from the events, performance and results discussed in the forward-looking statements. For information identifying important factors that could cause actual results to differ materially from those anticipated in the forward-looking statements, please refer to the Risk Factors section of the Annual Report and Part II, Item 1A of this Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (the "SEC"). The Company's securities filings can be accessed on the EDGAR section of the SEC's website at www.sec.gov. Except as expressly required by applicable securities law, the Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

Overview

Senti is a preclinical biotechnology company developing next-generation cell and gene therapies engineered with its gene circuit platform technologies to fight challenging diseases. Senti's mission is to create a new generation of smarter therapies that can outmaneuver complex diseases in ways previously not implemented by conventional medicines. To accomplish this mission, Senti has built a synthetic biology platform that it believes may enable it to program next-generation cell and gene therapies with what it refers to as "gene circuits." These gene circuits, which Senti created from novel and proprietary combinations of genetic parts, are designed to reprogram cells with biological logic to sense inputs, compute decisions and respond to their respective cellular environments. Senti's gene circuit platform technologies can be applied in a modality-agnostic manner, with applicability to natural killer (NK) cells, T cells, tumor-infiltrating lymphocytes ("TILs"), stem cells including Hematopoietic Stem Cells ("HSCs"), *in vivo* gene therapy and messenger ribonucleic acid (mRNA). All of Senti's current product candidates are in preclinical development. Senti's lead product candidates utilize allogeneic chimeric antigen receptor ("CAR") NK cells outfitted with its gene circuit technologies in several oncology indications with currently high unmet needs. Senti expects to file investigational new drug applications ("INDs") for multiple product candidates starting in 2023.

We have incurred net losses of \$18.7 million and \$11.6 million for the three months ended June 30, 2023 and 2022, respectively and \$37.4 million and \$23.4 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023 and December 31, 2022, we had cash, cash equivalents and short-term investments

[Table of Contents](#)

of \$59.6 million and \$98.6 million, respectively, and an accumulated deficit of \$210.7 million and \$173.3 million, respectively. Net cash flows used in operating activities were \$30.0 million and \$15.8 million during the six months ended June 30, 2023 and 2022, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant losses for the foreseeable future.

We anticipate that our expenses and operating losses will increase substantially over the foreseeable future. The expected increase in expenses will be driven in large part by our ongoing activities, if and as we:

- continue to advance our gene circuit platform technologies;
- continue preclinical development of our current and future product candidates and initiate additional preclinical studies;
- commence clinical studies of our current and future product candidates;
- acquire and license technologies aligned with our gene circuit platform technologies;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, and commercialization efforts;
- continue to develop, grow, maintain, enforce and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

Recent Developments

On August 10, 2023, we announced a transaction with GeneFab, LLC (“GeneFab”), a new independent contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. The transaction provided us with additional capital and reduced longer term operating expenses. In connection with the transaction, we will receive approximately \$37.8 million in cash before the end of 2025. Approximately \$18.9 million was due at closing, which amount was netted against prepayment owed by us for manufacturing and support services to GeneFab. The remaining \$18.9 million will be paid to us in installments in 2024 and 2025. In addition, we will receive \$8.0 million in manufacturing credit, subject to certain conditions, and will sublease our recently constructed 92,000 square foot current good manufacturing practice (cGMP) facility in Alameda, CA to GeneFab (a portion of which will be subject to the satisfaction of certain conditions).

Components of Results of Operations

Total Revenue

We currently have no therapeutic products approved for sale, and we have never generated any revenue from the sale of any therapeutic products. Total revenue consists of contract revenue related to research services provided to customers and grant income which is research funding received from grants.

Our ability to generate product revenues will depend on our partners’ ability to replicate our results and the successful development and eventual commercialization of our product candidates, which we do not expect for the foreseeable future, if ever. We may also look to generate revenue from collaboration and license agreements in the future.

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

[Table of Contents](#)

Research and Development Expenses

Research and development costs consist primarily of costs incurred for the discovery and preclinical development of our product candidates, which include:

- employee-related expenses, including salaries, related benefits, and stock-based compensation expenses for employees engaged in research and development functions;
- expenses incurred in connection with research, laboratory consumables and preclinical studies;
- the cost of consultants engaged in research and development related services and the cost to manufacture drug products for use in our preclinical studies and trials;
- facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs related to regulatory compliance; and
- the cost of annual license fees.

We have not historically tracked research and development expenses by program, with the exception of third-party research projects. We have various ongoing early-stage research and product candidate discovery projects and going forward, we expect to have various products undergoing clinical trials. Our internal resources, employees and infrastructure are not directly tied to any one research or product candidate discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding these costs incurred for these early-stage research and product candidate discovery programs on a project-specific basis.

Our direct external development program expenses reflect external costs attributable to our preclinical development candidates selected for further development as well as investigational new drug applications (“INDs”) and clinical development. Such expenses include third-party contract costs relating to manufacturing, clinical trial activities, translational medicine and toxicology activities. We do not allocate internal research and development costs which include personnel, facility costs, laboratory consumables and discovery and research related activities associated with our pipeline because these costs are deployed across multiple programs and our platform, and, as such, are not separately classified.

Research and development expenses consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Personnel-related expenses, including share-based compensation	\$ 4,571	\$ 3,866	\$ 9,379	\$ 6,664
External services and supplies	3,407	3,424	7,011	6,332
Office and facilities	2,636	1,782	5,229	3,528
Other	338	175	651	325
Total	\$ 10,952	\$ 9,247	\$ 22,270	\$ 16,849

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our preclinical development programs. Product candidates in clinical development generally have higher development costs than those in preclinical stages of development, primarily due to the increased size and duration of clinical trials. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical development of any of our product candidates. However, we expect that our research and development

[Table of Contents](#)

expenses and manufacturing costs will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future.

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

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon any or all of our programs;
- product-related side effects experienced by participants in our clinical trials or by individuals using therapeutics similar to our product candidates;
- delays in submitting IND applications or comparable foreign applications, or delays or failures to obtain the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the U.S. Food and Drug Administration (“FDA”) or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- Chemistry, manufacturing and control (“CMC”) challenges associated with manufacturing and scaling up biologic product candidates to ensure consistent quality, stability, purity and potency among different batches used in clinical trials;
- greater-than-anticipated clinical trial costs;
- poor potency or effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory authority inspection and review of a clinical trial or manufacturing site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines; and
- the FDA or other regulatory authorities interpret our data differently than we do.

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to corporate matters, professional fees for accounting and consulting services and an allocation of facility-related costs.

[Table of Contents](#)

General and administrative expenses consisted of the following (in thousands):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Personnel-related expenses, including share-based compensation	\$ 6,652	\$ 11,533	\$ 13,828	\$ 15,374
External services and supplies	1,546	1,505	2,837	2,446
Office and facilities	407	359	856	643
Insurance	414	161	918	202
Other	601	324	983	476
Total	<u>\$ 9,620</u>	<u>\$ 13,882</u>	<u>\$ 19,422</u>	<u>\$ 19,141</u>

We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development, manufacturing activities, and preclinical and clinical activities and to reflect increased costs associated with operating as a public company. These increased costs will likely include increased expenses for audit, legal, regulatory, tax and related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income (Expense)

Interest Income, net

Interest income, net consists of interest earned on our cash and cash equivalents, and short-term investments, if any, held during the year, net of interest expense.

Change in Fair Value of Contingent Earnout Liability

The change in fair value of the contingent earnout liability that was accounted for as a liability as of the date of the Merger, and is remeasured to fair value at each reporting period, resulting in a non-cash gain or loss.

Gain on Extinguishment of Convertible Notes

Our convertible note was extinguished as part of the Merger and the change in fair value was recorded in earnings.

[Table of Contents](#)**Results of Operations****Comparison of the Three Months Ended June 30, 2023 and 2022**

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Change
	2023	2022	
Revenue:			
Contract revenue	\$ 687	\$ 1,108	\$ (421)
Grant income	250	250	—
Total revenue	937	1,358	(421)
Operating expenses:			
Research and development	10,952	9,247	1,705
General and administrative	9,620	13,882	(4,262)
Total operating expenses	20,572	23,129	(2,557)
Loss from operations	(19,635)	(21,771)	2,136
Other income (expense):			
Interest income, net	794	27	767
Change in fair value of contingent earnout liability	148	8,878	(8,730)
Gain on extinguishment of convertible notes	—	1,289	(1,289)
Other expense	(4)	25	(29)
Total other income (expense), net	938	10,219	(9,281)
Net loss	<u>\$ (18,697)</u>	<u>\$ (11,552)</u>	<u>\$ (7,145)</u>

Contract revenue. For the three months ended June 30, 2023 and 2022, we generated revenue from contracts and license agreements of \$0.7 million and \$1.1 million, respectively. The decrease of \$0.4 million was primarily due to decline in services provided for the Spark collaboration project.

Grant income. For the three months ended June 30, 2023 and 2022, we generated revenue from grants of \$0.3 million and \$0.3 million, respectively, from the SBIR SENTI-202 grant funding.

Research and development expenses. Research and development expenses were \$11.0 million and \$9.2 million for the three months ended June 30, 2023 and 2022, respectively. The increase of \$1.7 million was primarily due to an increase of \$0.7 million in personnel-related expenses and an increase of \$0.9 million in facility costs.

General and administrative expenses. General and administrative expenses were \$9.6 million and \$13.9 million for the three months ended June 30, 2023 and 2022, respectively. The decrease of \$4.3 million was primarily due to a decrease of \$4.9 million in personnel-related expenses, which includes a \$4.8 million decrease in stock-based compensation expense, and an increase in insurance of \$0.3 million.

Interest income, net. Interest income was \$0.8 million and nominal for the three months ended June 30, 2023 and 2022, respectively, due to a higher average cash balances, as well as an increase in interest rates in the relevant periods.

Change in fair value of contingent earnout liability. For the three months ended June 30, 2023 and 2022, we recognized a non-cash gain of \$0.2 million and \$8.9 million, respectively. The decrease of \$8.7 million related to the remeasurement of the contingent earnout liability to fair value.

[Table of Contents](#)

Gain on extinguishment of convertible notes. For the three months ended June 30, 2022, we recognized a gain of \$1.3 million upon extinguishment of convertible notes as part of the Merger.

Comparison of the Six Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,		Change
	2023	2022	
Revenue:			
Contract revenue	\$ 1,723	\$ 1,962	\$ (239)
Grant income	500	500	—
Total revenue	2,223	2,462	(239)
Operating expenses:			
Research and development	22,270	16,849	5,421
General and administrative	19,422	19,141	281
Total operating expenses	41,692	35,990	5,702
Loss from operations	(39,469)	(33,528)	(5,941)
Other income (expense):			
Interest income, net	1,855	31	1,824
Change in fair value of contingent earnout liability	207	8,878	(8,671)
Gain on extinguishment of convertible notes	—	1,289	(1,289)
Other expense	(12)	(30)	18
Total other income (expense), net	2,050	10,168	(8,118)
Net loss	\$ (37,419)	\$ (23,360)	\$ (14,059)

Contract revenue. For the six months ended June 30, 2023 and 2022, we generated revenue from contracts and license agreements of \$1.7 million and \$2.0 million, respectively. The decrease of \$0.2 million was primarily due to decline in services provided for the Spark collaboration project.

Grant income. For the six months ended June 30, 2023 and 2022, we generated revenue from grants of \$0.5 million and \$0.5 million, respectively, from the SBIR SENTI-202 grant funding.

Research and development expenses. Research and development expenses were \$22.3 million and \$16.8 million for the six months ended June 30, 2023 and 2022, respectively. The increase of \$5.4 million was primarily due to an increase of \$2.7 million in personnel-related expenses, an increase of \$1.7 million in facility costs, and an increase of \$0.7 million in professional services costs.

General and administrative expenses. General and administrative expenses were \$19.4 million and \$19.1 million for the six months ended June 30, 2023 and 2022, respectively. The increase of \$0.3 million was primarily due to an increase of \$0.7 million in insurance, an increase of \$0.5 million in depreciation and amortization, an increase of \$0.4 million in professional services costs offset by a decrease of \$1.5 million in personnel-related expenses.

Interest Income, net. Interest income was \$1.9 million and nominal for the six months ended June 30, 2023 and 2022, respectively, due to a higher average cash balances, as well as an increase in interest rates in the relevant periods.

[Table of Contents](#)

Change in fair value of contingent earnout liability. For the six months ended June 30, 2023 and 2022, we recognized a non-cash gain of \$0.2 million and \$8.9 million, respectively. The decrease of \$8.7 million related to the remeasurement of the contingent earnout liability to fair value.

Gain on extinguishment of convertible notes. For the six months ended June 30, 2022, we recognized a gain of \$1.3 million upon extinguishment of convertible notes as part of the Merger.

Liquidity and Capital Resources

Sources of Liquidity

From inception to June 30, 2023, we raised aggregate gross proceeds of \$299.5 million from the Merger and PIPE Financing, the issuance of shares of our common stock, the issuance of shares of our redeemable convertible preferred stock, the issuance of convertible notes and, to a less extent, through collaboration agreements and governmental grants.

On August 31, 2022, we entered into the Purchase Agreement with Chardan. Pursuant to the Purchase Agreement, we have the right, in our sole discretion, to sell to Chardan up to the lesser of: (i) \$50.0 million of shares of our common stock; and (ii) 8,727,049 shares of common stock at 97% of the volume weighted average price (“VWAP”) of the common stock calculated in accordance with the Purchase Agreement, over a period of 36 months subject to certain limitations and conditions contained in the Purchase Agreement. Sales and timing of any sales of common stock are solely at our election, and we are under no obligation to sell any securities to Chardan under the Purchase Agreement. As consideration for Chardan’s commitment to purchase shares of our common stock at our direction upon the terms and subject to the conditions set forth in the Purchase Agreement, upon execution of the Purchase Agreement, we issued 100,000 shares of our common stock to Chardan and paid a \$0.4 million document preparation fee. We recognized an expense of \$0.7 million within general and administrative expenses in our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Chardan related costs and legal fees incurred in connection with the agreement.

Other than the issuance of the commitment shares of our common stock to Chardan we issued 300,000 shares of common stock up until June 30, 2023, aggregating to net proceeds of \$0.7 million under the Purchase Agreement. There were no shares issued within six months ended June 30, 2023.

We do not have any products approved for sale and have not generated any revenue from product sales or otherwise. We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of June 30, 2023, we had \$59.6 million in cash, cash equivalents and short-term investments, and an accumulated deficit of \$210.7 million, respectively.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, if at all. Should we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of our product candidates or delay our efforts to expand our product pipeline. We may also be required to sell or license to other parties rights to develop or commercialize our product candidates that we would prefer to retain.

On August 10, 2023, we announced the transaction with GeneFab, a newly formed independent contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. The transaction provided us with additional capital and reduced longer term operating expenses.

[Table of Contents](#)

Cash Flows

The following table sets forth a summary of our cash flows for each of the periods indicated (in thousands):

	Six Months Ended June 30,	
	2023	2022
Net cash from operating activities	\$ (29,979)	\$ (15,754)
Net cash from investing activities	8,834	(18,640)
Net cash from financing activities	246	118,160
Net change in cash and cash equivalents	\$ (20,899)	\$ 83,766

Operating Activities

For the six months ended June 30, 2023, net cash used in operating activities of \$30.0 million was primarily due to our loss of \$37.4 million with non-cash adjustments of \$7.2 million for stock-based compensation expense, \$2.1 million for depreciation and amortization of operating lease right-of-use-assets, \$1.0 million for accretion of discount on short-term investments, and \$0.2 million for the change in fair value of contingent earnout liability. Other material changes comprised of \$1.2 million decrease in accounts payable and accrued expenses and other current liabilities, \$0.6 million decrease in deferred revenue, offset by \$1.0 million increase in operating lease liabilities.

For the six months ended June 30, 2022, net cash used in operating activities of \$15.8 million was primarily due to our net loss of \$23.4 million with non-cash adjustments of \$9.9 million for stock-based compensation expense, \$8.9 million for the change in fair value of contingent earnout liability, \$1.9 million for depreciation and amortization of operating lease right-of-use assets and \$1.3 million for gain on extinguishment of convertible notes. Other material changes comprised of \$7.9 million increase in operating lease liabilities and \$0.4 million increase in accounts payable and accrued expenses and other current liabilities, offset by \$1.4 million increase in prepaid expenses and other assets and \$1.0 million decrease in deferred revenue.

Investing Activities

For the six months ended June 30, 2023, net cash provided by investing activities of \$8.8 million was due to \$37.0 million cash received upon maturity of short-term investments offset by \$18.0 million purchases of short-term investments and \$10.2 million purchases of property and equipment.

For the six months ended June 30, 2022, net cash used in investing activities of \$18.6 million, was entirely due to purchases of property and equipment.

Financing Activities

For the six months ended June 30, 2023, \$0.2 million cash was provided by financing activities primarily due to \$0.3 million proceeds from the issuance of common stock under Employee Stock Purchase Plan (ESPP).

For the six months ended June 30, 2022, net cash provided by financing activities of \$118.2 million was primarily due to \$112.5 million proceeds received from Merger and related PIPE financing activities, net of transaction cost, \$5.2 million from issuance of convertible notes and \$0.5 million proceeds from the issuance of common stock upon exercise of stock options.

Funding Requirements

Based upon our current operating plans, there is uncertainty about whether our existing cash, cash equivalents, and short-term investments will be sufficient to fund our operations, including clinical trial expenses and capital expenditure requirements, beyond twelve months from the date of this Quarterly Report. We anticipate that we will continue to seek additional funding, though the precise timing of such may prove uncertain. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Our assumptions may prove

[Table of Contents](#)

to be inaccurate, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing and manufacturing product candidates in preclinical studies and clinical trials is costly and the timing and expenses in these trials are uncertain.

On August 10, 2023, we announced the transaction with GeneFab, a newly formed independent contract manufacturing and synthetic biology biofoundry focused on next-generation cell and gene therapies. The transaction provided us with additional capital and reduced longer term operating expenses.

Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the number and development requirements of product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope and costs of any commercial manufacturing activities;
- the cost associated with commercializing any approved product candidates;
- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights, defending intellectual property-related claims and obtaining licenses to third-party intellectual property;
- the timing and amount of any milestone and royalty payments we are required to make under our present or future license agreements;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies and associated intellectual property.

In order to improve our liquidity, management is actively pursuing additional financing. We expect our expenses to increase substantially in connection with ongoing activities, particularly as we advance our preclinical activities and clinical trials for our product candidates in development. Accordingly, we will need to obtain substantial additional funding for continuing operations. If we are unable to raise capital when needed, or on attractive terms, we could be forced to delay, reduce or eliminate our research or drug development programs or any future commercialization efforts. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

Contractual Obligations and Commitments

On June 3, 2021, we entered into a lease agreement for a new cGMP facility in Alameda, California to support planned initial clinical trials for our product candidates. The lease will expire in 2032 with future undiscounted operating lease payments of \$46.0 million over an initial lease period of eleven years. See Note 5 - *Operating Leases* for details on our lease obligations.

In 2021, we began construction of the cGMP facility. Buildout of the cGMP facility was completed in June 2023. As of June 30, 2023, we have paid \$40.0 million in construction costs of the \$42.2 million purchase commitment. The agreements with the construction company provide for termination following a certain period after notice. Upon termination we will be responsible for payment for work performed to date.

During the year ended December 31, 2021, we entered into a three-year collaboration and option agreement with BlueRock Therapeutics LP (“BlueRock”) under which we granted BlueRock an option to execute an exclusive

[Table of Contents](#)

or non-exclusive license to develop, manufacture and commercialize cell therapy products (See Part I, Item 1, Notes to Condensed Consolidated Financial Statements (Unaudited), Note 12 - *Related Parties* for details into the BlueRock agreement). In consideration for the option, we are responsible for up to \$10.0 million in research and development costs and expenses associated with the collaboration plan incurred over the three-year term.

We have also entered into license agreements under which we are obligated to make annual maintenance payments of \$0.1 million and specified milestone and royalty payments. Milestone and royalty payment obligations under these agreements are contingent upon future events, such as our achievement of specified development, regulatory, and sales milestones, or generating product sales. As of June 30, 2023, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

We have entered into sponsored research agreements under which we are obligated to pay \$0.4 million and \$0.3 million in 2023 and 2024, respectively.

Following the closing of the Merger, former holders of Legacy Senti common stock and preferred stock may receive up to 2,000,000 additional shares of our common stock in the aggregate, in two equal tranches of 1,000,000 shares of common stock per tranche. Refer to Note 6, *Stockholders' Equity (Deficit)*, for further details of the contingent earnout.

Off-Balance Sheet Arrangements

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

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates and assumptions on historical experience, known trends and events, and various other factors that are believed to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies and estimates to be most critical to the preparation of our consolidated financial statements. We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are inherently 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 six months ended June 30, 2023, there have not been any other significant changes to our critical accounting policies and estimates, except as noted below, from those presented in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, that are of significance, or potential significance, to us.

Impairment of Long-Lived Assets

As a result of the change in the manner in which the Company expects to recover the assets subject to the GeneFab transaction, the asset group used in the long-lived impairment assessment was changed to two asset groups as of June 30, 2023, the oncology and non-oncology asset group, with the non-oncology including all the assets expected to be transferred in the GeneFab transaction. This asset group reassessment triggered a need to perform an impairment analysis for the non-oncology asset group that considered the final terms of the transaction as the fair value of the non-oncology asset group and no impairment was deemed necessary.

[Table of Contents](#)

Emerging Growth Company Status

The Jumpstart Our Business Startups Act (“JOBS”) Act permits an emerging growth company to take advantage of an extended transition to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company is an “emerging growth company” as defined in Section 2(a) of the Securities Act, and has elected to not take advantage of the benefits of this extended transition period.

We expect to remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of the Dynamics Initial Public Offering (“IPO”) (which occurred on May 25, 2021), (b) in which we have total annual revenue of at least \$1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds \$700 million as of the end of that fiscal year’s second fiscal quarter and our net sales for the year exceed \$100 million; and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the preceding, rolling three-year period.

Smaller Reporting Company Status

The Company is a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company if (1) the market value of our common stock held by non-affiliates is less than \$250 million as of the last business day of the second fiscal quarter, or (2) our annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter are less than \$100 million and the market value of our common stock held by non-affiliates is less than \$700 million as of the last business day of the second fiscal quarter.

Segment Information

We have one business activity and operate in one reportable segment.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a “smaller reporting company,” we are not required to provide this information.

Item 4. Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted 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 in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Evaluation of Disclosure Controls and Procedures

Prior to the Merger, we had been a private company with limited accounting personnel and other resources with which to address our internal control over financial reporting. In connection with our preparation and the audit of our consolidated financial statements as of and for the year ended December 31, 2021, we and our independent registered public accounting firm identified a material weakness, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in our internal control over financial reporting. The material weakness related to a lack of sufficient and adequate resources in the finance and accounting function that resulted in a lack of formalized risk assessment process, lack of segregation of duties, and ineffective process level control activities over the management review of journal entries, account reconciliations and non-routine transactions. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

[Table of Contents](#)

We have taken a number of remediation actions during the year ended December 31, 2022, and are continuing with our efforts. Remediation actions taken during the fiscal year ended December 31, 2022 and that continue include:

- hiring personnel with appropriate levels of experience in accounting, technology, and internal controls;
- engaging a professional accounting services firm to help us commence the documentation and assessment of our internal controls for complying with the Sarbanes-Oxley Act;
- implementing a risk assessment over financial reporting controls; and
- implementing new software tools.

While significant progress has been made to enhance our internal control over financial reporting, we are still in the process of building and enhancing our processes, procedures, and controls. Additional time is required to complete the remediation of these material weaknesses and the assessment to ensure the sustainability of these remediation actions. We believe the above actions, when complete, will be effective in the remediation of the material weakness described above.

Changes in Internal Control Over Financial Reporting

During the most recently completed fiscal quarter, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

The Company currently is not aware of any legal proceedings or claims that management believes will have, individually or in the aggregate, a material adverse effect on the Company's business, financial condition, results of operations, or cash flows.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before you decide to invest in common stock, you should consider carefully the risks described below, together with the information contained in the Quarterly Report on Form 10-Q for the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on May 9, 2023, including our financial statements and the related notes appearing in that Form 10-Q. We believe the risks described below are the risks that are material to us as of the date of the Annual Report. Factors that could cause our actual results to differ materially from those in the Annual Report are any of the risks described in the Item 1A below. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. If any of the following risks actually occur, our business, results of operations and financial condition would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose part or all of your investment.

Summary Risk Factors

The risk factors set forth below represent a summary of some of the principal risk factors which potential investors in our securities should be aware of. Although each of these risks is important, this list is not and is not intended to be a substitute for investors reviewing all of the information in this Quarterly Report, including all risk factors which follow this summary.

- We are a preclinical stage biotechnology company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We have identified a material weakness in our internal control over financial reporting. If our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- Members of our management team have limited experience in managing the day-to-day operations of a public company and, as a result, we may incur additional expenses associated with the management of our company.
- Our history of recurring losses and anticipated expenditures raises substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.
- We may not achieve the intended objectives of our strategic prioritization plan announced in January 2023.
- Our current product candidates are in preclinical development and have never been tested in humans. One or all of our current product candidates may fail in clinical development or suffer delays that materially and adversely affect their ability to receive regulatory approval or to attain commercial viability.
- If any of our current or potential future product candidates is ever tested in humans, it may not demonstrate the safety, purity and potency, or efficacy, necessary to become approvable or commercially viable.
- Our gene circuit platform technologies are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

[Table of Contents](#)

- We may not be successful in our efforts to use and expand our gene circuit platform to expand our pipeline of product candidates.
- The market, physicians, patients, regulators and potential investors may not be receptive to our current or potential future product candidates and may be skeptical of the viability and benefits of our gene circuit pipeline technology because it is based on a relatively novel and complex technology.
- The occurrence of serious complications or side effects in connection with use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates or, post-approval, revocation of marketing authorizations or refusal to approve applications for new indications, which could severely harm our business, prospects, operating results and financial condition.
- We and our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the time frames that we or they announce, which could have an adverse impact on our business and could cause our stock price to decline.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for our current or future product candidates that we may develop.
- We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.
- We rely on third parties to conduct our preclinical studies, and plan to rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily.
- Supply of our product candidates for preclinical and clinical development may become limited or interrupted or may not be of satisfactory quantity or quality, and we could experience delays relying on third-party manufacturers.
- We are exposed to a number of risks related to our supply chain for the materials required to manufacture our product candidates.
- We face competition from companies that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop platform technologies or product candidates more rapidly than we do, or if their platform technologies or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected.
- Our business entails a significant risk of product liability, and our inability to obtain sufficient insurance coverage could have a material adverse effect on our business, financial condition, results of operations and prospects.
- Our business, operations and clinical development plans and timelines could be adversely affected by the impact of global economic and political developments, including high inflation and capital market disruption, the war in Ukraine, economic sanctions and economic slowdowns or recession, including any lingering impact from the COVID-19 pandemic, or by the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we may conduct business, including our anticipated contract manufacturers, contract research organizations (“CROs”), shippers and others.

[Table of Contents](#)

Risks Related to Our Limited Operating History and Financial Condition

We are a preclinical stage biotechnology company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a preclinical stage biotechnology company with a history of losses. Since our inception, we have devoted substantially all of our resources to research and development, preclinical studies, building our management team and building our intellectual property portfolio, and we have incurred significant operating losses. Our net losses were \$37.4 million and \$23.4 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$210.7 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. To date, we have not generated any revenue from product sales, and we have not sought or obtained regulatory approval for any product candidate. Furthermore, we do not expect to generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies, clinical trials, manufacturing and the regulatory approval process for our current and potential future product candidates.

We expect our net losses to increase substantially as we:

- continue to advance our gene circuit platform technologies;
- continue preclinical development of our current and future product candidates and initiate additional preclinical studies;
- commence clinical trials of our current and future product candidates;
- acquire and license technologies aligned with our gene circuit platform technologies;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, and commercialization efforts;
- continue to develop, maintain, expand, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as public company.

However, the amount of our future losses is uncertain. Our ability to achieve or sustain profitability, if ever, will depend on, among other things, successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, ensuring our product candidates are manufactured on commercially reasonable terms, entering into potential future alliances, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient funds to finance business activities. If we, or our existing or potential future collaborators, are unable to commercialize one or more of our product candidates, or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve or sustain profitability, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We will need substantial additional funding. If we are unable to raise capital when needed on acceptable terms, or at all, we may be forced to restructure our business or delay, reduce, or terminate our research and product development programs, future commercialization efforts or other operations.

[Table of Contents](#)

We will need substantial additional funds to advance development of product candidates and our gene circuit platform, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize our current or potential future product candidates and technologies.

The development of biotechnology product candidates is capital-intensive. If any of our current or potential future product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, marketing and sales capabilities. We have used substantial funds to develop our gene circuit platform, SENTI-202, SENTI-301A, SENTI-401 and other potential product candidates, and we will require significant funds to continue to develop our platform and conduct further research and development, including preclinical studies and clinical trials. In addition, we expect to incur significant additional costs associated with operating as a public company.

As of June 30, 2023, we had \$59.6 million in cash, cash equivalents, and short-term investments. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of platform technologies and product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future capital requirements and the timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development of our current and potential future product candidates;
- the timing and progress of our development of our gene circuit platforms;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the terms of any third-party manufacturing contract or biomanufacturing partnership we may enter into;
- our ability to maintain our current licenses and collaborations, conduct our research and development programs and establish new strategic partnerships and collaborations;
- the progress of the development efforts of our existing strategic partners and third parties with whom we may in the future enter into collaboration and research and development agreements;
- the costs involved in obtaining, maintaining, enforcing and defending patents and other intellectual property rights;
- supply chain disruptions, global political and market conditions, and inflationary pressures on our business;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems and to hire and retain personnel, including personnel to support development of our product candidates and to satisfy our obligations as a public company.

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, grants and other marketing and distribution arrangements. 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.

[Table of Contents](#)

We cannot assure you that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms acceptable to us, if at all. If we are unable to obtain adequate financing when needed, our business, financial condition and results of operations will be harmed, and we may need to significantly modify our operational plans, or else we may not be able to continue as a going concern beyond twelve months from the issuance date of this Form 10-Q. For example, in January 2023 we announced a strategic plan to focus internal resources on SENTI-202 and SENTI-401, to develop gene circuits for other programs with potential partners, and to suspend research and development efforts for SENTI-301A. In the future, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs, or commercialization efforts. Further, if we are unable to continue as a going concern, we might have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. Because of the numerous risks and uncertainties associated with the development and commercialization of our current and potential future product candidates and the extent to which we may enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials, including related manufacturing costs.

To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our current and potential future product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Moreover, the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common stock to decline.

We do not expect to realize revenue from product sales or royalties from licensed products for the foreseeable future, if at all, and unless and until our current and potential future product candidates are clinically tested, approved for commercialization and successfully marketed.

We identified a material weakness in our internal control over financial reporting. If our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of shares of our common stock.

Prior to the closing of the Merger, we were a private company with limited accounting personnel and other resources with which to address our internal control over financial reporting. In connection with our preparation and the audit of our consolidated financial statements as of and for the years ended December 31, 2021, we and our independent registered public accounting firm identified a material weakness, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in our internal control over financial reporting. The material weakness related to a lack of sufficient and adequate resources in the finance and accounting function that resulted in a lack of formalized risk assessment process, lack of segregation of duties, and ineffective process level control activities over the management review of journal entries, account reconciliations and non-routine transactions.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

We implemented a risk assessment process and measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weakness, including hiring additional accounting personnel. However, the process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. Moreover, the rules governing the standards that must be met for our

[Table of Contents](#)

management to assess our internal control over financial reporting are complex and require significant documentation, testing, and remediation. To maintain and improve the effectiveness of our financial reporting, we will need to commit significant resources, implement and strengthen existing disclosure processes controls, reporting systems, and procedures, train personnel and provide additional management oversight, all of which may divert attention away from other matters that are important to our business.

We cannot be certain that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, an independent registered public accounting firm has not yet performed an evaluation of our internal control over financial reporting, though such an evaluation will be required when we lose our status as an “emerging growth company” and become an “accelerated filer” or a “large accelerated filer.” When an evaluation by an independent registered public accounting firm is performed, such firm may issue a report that is qualified if it is not satisfied with our controls or the level at which our controls are documented, designed, operated, or reviewed.

Our testing, or the 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. A material weakness in internal controls could result in our failure to detect a material misstatement of our annual or quarterly consolidated financial statements or disclosures. We may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. If we are unable to conclude that we have effective internal controls over financial reporting, investors could lose confidence in our reported financial information, which could have a material adverse effect on the trading price of the shares of our common stock.

We cannot be certain as to the timing of completion of our evaluation, testing and any remediation actions or the impact of the same on our operations. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be negatively impacted, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, our independent registered public accounting firm when required may issue an adverse opinion due to ineffective internal controls over financial reporting, and we may be subject to sanctions or investigation by regulatory authorities, such as the SEC. As a result, there could be a negative reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements. In addition, we may be required to incur costs in improving our internal control system and the hiring of additional personnel. Any such action could negatively affect our results of operations and cash flows.

Members of our management team have limited experience in managing the day-to-day operations of a public company and, as a result, we may incur additional expenses associated with the management of our company.

Members of our management team have limited experience in managing the day-to-day operations of a public company. As a result, we may need to obtain outside assistance from legal, accounting, investor relations, or other professionals that could be more costly than planned. These compliance costs will make some activities significantly more time-consuming and costly. If we lack cash resources to cover these costs in the future, our failure to comply with reporting requirements and other provisions of securities laws could negatively affect our stock price and adversely affect our potential results of operations, cash flow and financial condition.

Our ability to use net operating loss carryforwards (“NOLs”) and credits to offset future taxable income may be subject to certain limitations.

Our NOLs 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. NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for 20 taxable years under applicable U.S. federal income tax law. Under current U.S. federal income tax law, NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, NOLs generated 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, 2022, we had NOLs for U.S. federal

[Table of Contents](#)

and state income tax purposes of approximately \$100.3 million and \$55.0 million, respectively, a portion of which expire beginning in 2036 if not utilized. NOLs for U.S. federal tax reporting purposes of approximately \$96.8 million have an indefinite life.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), a corporation that undergoes an “ownership change” (defined under Section 382 of the Code and applicable Treasury Regulations as a greater than 50 percentage point change (by value) in a corporation’s equity ownership by certain stockholders over a rolling three-year period) 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 ownership changes in the past and may experience ownership changes in the future, including as a result of the Merger or subsequent shifts in our stock ownership (some of which are outside our control). Furthermore, our ability to utilize NOLs of companies that we 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 sheets, 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.

Changes in tax law may adversely affect us or our investors.

The U.S. rules dealing with federal, state, and local taxation are constantly under review by those involved in the legislative process, as well as by the U.S. Treasury Department. Changes to tax laws, which may have retroactive application, could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made and change are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial conditions, or results of operations. The existence, timing, and content of new tax laws are unpredictable, and could cause an increase in our or our shareholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

The sale or issuance of our common stock to GeneFab may cause significant dilution and the sale of the shares of common stock acquired by GeneFab, or the perception that such sales may occur, could cause the price of our common stock to fall.

Pursuant to an option under the transaction with GeneFab, GeneFab may choose to invest up to approximately \$20 million to purchase up to 19,633,444 shares of our common stock, subject to certain limitations, including stockholder approval in certain circumstances and compliance with applicable law, for a period of 36 months after the option agreement effective date and following execution of a license agreement. The exercise or conversion of these securities could result in a significant increase in the number of outstanding shares and substantially dilute the ownership interest of our existing stockholders. In addition, we have agreed to register for resale these shares purchased by GeneFab under their option, subject to certain restrictions. If GeneFab chooses to sell its shares in the Company, the price of our shares could fluctuate based on the market price of the common stock during the period in which such sales occur. Additionally, the sale of a substantial number of shares of our common stock, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

It is not possible to predict the number of shares of our common stock, if any, that we may sell to Chardan Capital Markets LLC, or Chardan, under our common stock Purchase Agreement, or the Purchase Agreement, with Chardan, or the actual gross proceeds resulting from those sales, or the dilution to our stockholders from those sales.

On August 31, 2022, we entered into the Purchase Agreement with Chardan, pursuant to which Chardan may purchase from us up to \$50.0 million in shares of our common stock (the “Total Commitment”), upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement. To date, we have sold \$0.7 million in shares of our common stock to Chardan. The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Chardan at our discretion from time to time until the earliest to occur of (i) October

[Table of Contents](#)

1, 2025, (ii) the date on which Chardan has purchased the Total Commitment pursuant to the Purchase Agreement, (iii) the date on which our common stock fails to be listed or quoted on Nasdaq or any successor market, and (iv) the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person or entity commences a proceeding against us, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors.

We generally have the right to control the timing and amount of any sales of our common stock to Chardan under the Purchase Agreement. Sales of our common stock to Chardan under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Chardan all or some of the common stock that may be available for us to sell to Chardan pursuant to the Purchase Agreement. Accordingly, we cannot guarantee that we will be able to sell all of the Total Commitment or how much in proceeds we may obtain under the Purchase Agreement. If we cannot sell securities under the Purchase Agreement, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could have a material adverse effect on our liquidity and cash position.

Because the purchase price per share of common stock to be paid by Chardan for the common stock that we may elect to sell to Chardan under the Purchase Agreement will fluctuate based on the market prices of our common stock at the time we elect to sell shares to Chardan pursuant to the Purchase Agreement it is not possible for us to predict, as of the date of this Quarterly Report on Form 10-Q and prior to any such sales, the number of shares of common stock that we will sell to Chardan under the Purchase Agreement, the purchase price per share that Chardan will pay for shares of common stock purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Chardan under the Purchase Agreement.

The actual number of shares of our common stock issuable will vary depending on the then current market price of shares of our common stock sold to Chardan and the number of shares of common stock we ultimately elect to sell to Chardan under the Purchase Agreement. If it becomes necessary for us to issue and sell to Chardan under the Purchase Agreement more than the 8,727,049 shares of common stock we registered pursuant to the Purchase Agreement, in order to receive aggregate gross proceeds equal to \$50.0 million under the Purchase Agreement, we will have to file with the SEC one or more additional registration statements to register under the Securities Act the resale by Chardan of any such additional shares of common stock we wish to sell from time to time under the Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our common stock under the Purchase Agreement. Under applicable Nasdaq rules, in no event may we issue to Chardan more than 19.99% of the total number of shares of common stock that were outstanding immediately prior to the execution of the Purchase Agreement, unless we obtain prior stockholder approval or if such approval is not required in accordance with the applicable Nasdaq rules. In addition, Chardan is not obligated to buy any common stock under the Purchase Agreement if such shares, when aggregated with all other shares of our common stock then beneficially owned by Chardan and its affiliates (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder), would result in Chardan beneficially owning common stock in excess of 4.99% of our outstanding shares of common stock. Our inability to access a portion or the full amount available under the Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business or results of operation.

Investors who buy common stock from Chardan at different times will likely pay different prices.

Pursuant to the Purchase Agreement, the timing, price and number of shares sold to Chardan will vary depending on when we choose to sell shares, if any, to Chardan. If and when we elect to sell any additional common stock to Chardan pursuant to the Purchase Agreement, after Chardan has acquired such common stock, Chardan may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices. As a result, investors who purchase shares from Chardan at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Chardan as a result of future sales made by us to Chardan at prices lower than the prices such investors paid for their shares from Chardan.

The sale or issuance of shares of our common stock to Chardan will result in additional outstanding shares and the resale of shares of our common stock by Chardan that it acquires pursuant to the Purchase Agreement, or the perception that such sales may occur, could cause the price of shares of our common stock to decrease.

[Table of Contents](#)

As of the date of this Form 10-Q, we have issued 400,000 shares of common stock to Chardan under the Purchase Agreement, including 100,000 shares issued to Chardan as consideration for its execution and delivery of the Purchase Agreement. The shares of common stock issuable under the Purchase Agreement may be sold by us to Chardan at our sole discretion, subject to the satisfaction of certain conditions in the Purchase Agreement, from time to time, until the earliest to occur of (i) October 1, 2025, (ii) the date on which Chardan has purchased the Total Commitment pursuant to the Purchase Agreement, (iii) the date on which our common stock fails to be listed or quoted on Nasdaq or any successor market, and (iv) the date on which, pursuant to or within the meaning of any bankruptcy law, we commence a voluntary case or any person or entity commences a proceeding against us, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors. The purchase price for shares of our common stock that we may sell to Chardan under the Purchase Agreement will fluctuate based on the trading price of shares of our common stock. Depending on market liquidity at the time, sales of shares of our common stock may cause the trading price of shares of our common stock to decrease. We generally have the right to control the timing and amount of any future sales of shares of our common stock to Chardan. Additional sales of shares of our common stock, if any, to Chardan will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Chardan all or some of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares of our common stock to Chardan, after Chardan has acquired shares of our common stock, Chardan may resell all, some or none of such shares of common stock at any time or from time to time in its discretion. Therefore, sales to Chardan by us could result in substantial dilution to the interests of other holders of shares of our common stock. In addition, if we sell a substantial number of shares of our common stock to Chardan under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares of our common stock or the mere existence of our arrangement with Chardan may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

We may use our cash resources, including proceeds from sales of our common stock made pursuant to the Purchase Agreement in ways with which you may not agree or in ways which may not yield a significant return.

We have broad discretion over the use of capital we have raised, including proceeds from sales of our common stock made pursuant to the Purchase Agreement, and you will not have the opportunity, as part of any decision to invest in our common stock, to assess whether the proceeds are being used appropriately. Accordingly, you will have to rely on the judgment of our management with respect to the use of these funds, with only limited information regarding management's specific intentions. We may spend all or a portion of the net proceeds of our prior financing activities, including sales of our common stock under the Purchase Agreement, in ways that are not what our stockholders may desire or that may not yield favorable results. Because of the number and variability of factors that will determine our use of the net proceeds, their ultimate use may vary substantially from their currently intended use. The failure by us to apply these funds effectively could harm our business, and the net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our common stock.

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

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. As of June 30, 2023, we had two letters of credit held with SVB in an aggregate amount of \$3.3 million related to our facility lease. Due to the receivership of SVB, we may be unable to access such funds. In addition, if any of our suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new

[Table of Contents](#)

commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

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

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

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

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to other working capital sources and/or delays, inability or reductions in our ability to enter into new credit facilities or access other working capital resources;
- Potential or actual breach of contractual obligations that require the Company to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in any credit agreements or credit arrangements; or
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws and otherwise have a material adverse impact on our business.

Risks Related to the Development and Clinical Testing of Our Product Candidates

Our current product candidates are in preclinical development and have never been tested in humans. One or all of our current product candidates may fail in clinical development or suffer delays that materially and adversely affect their commercial viability.

We have no products on the market or that have gained regulatory approval or that have entered clinical trials. None of our product candidates has ever been tested in humans. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing product candidates, either alone or with collaborators.

Before obtaining regulatory approval for the commercial distribution of our product candidates, we or a collaborator must conduct extensive preclinical studies, followed by clinical trials to demonstrate the safety, purity and potency, or efficacy of our product candidates in humans. There is no guarantee that the FDA will permit us to conduct clinical trials. Further, we cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs, our clinical protocols or if the outcome of our preclinical studies will ultimately support the further development of our preclinical programs or testing in humans. As a result, we cannot be sure that we will be able to submit IND or similar applications for our proposed clinical 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 for any of our product candidates to begin.

Our current product candidates are in preclinical development and we are subject to the risks of failure inherent in the development of product candidates based on novel approaches, targets and mechanisms of action. Although we anticipate initiating clinical trials for our lead product candidates, there is no guarantee that we will be able to proceed with clinical development of any of these product candidates or that any product candidate will demonstrate a clinical benefit once we advance these candidates to testing in patients. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by preclinical stage biotechnology companies such as ours.

We may not be able to access the financial resources to continue development of, or to enter into any collaborations for, any of our current or potential future product candidates. This may be exacerbated if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, a product candidate, such as:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon any or all of our programs
- adverse events experienced by participants in our clinical trials or by individuals using therapeutics similar to our product candidates;
- delays in submitting INDs or comparable foreign applications, or delays or failures to obtain the necessary approvals from regulatory authorities to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;

[Table of Contents](#)

- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- conditioning patients with fludarabine in advance of administering our product candidates, which may be difficult to source, costly, or increase the risk of infections and other adverse side effects;
- chemistry, manufacturing and control (“CMC”) challenges associated with manufacturing and scaling up biologic product candidates to ensure consistent quality, stability, purity and potency among different batches used in clinical trials;
- greater-than-anticipated clinical trial costs;
- poor potency or effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory authority inspection and review of a clinical trial or manufacturing site;
- delays as a result of a pandemic or events associated with a pandemic;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines; or
- the FDA or other regulatory authorities interpreting our data differently than we do.

Further, we and any existing or potential future collaborator may never receive approval to market and commercialize any product candidate. Even if we or any existing or potential future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or an existing or potential future collaborator may also be subject to post-marketing testing requirements to maintain regulatory approval.

If any of our current or potential future product candidates is ever tested in humans, it may not demonstrate the safety, purity and potency, or efficacy, necessary to become approvable or commercially viable.

None of our current product candidates have ever been tested in humans. We may ultimately discover that our current product candidates do not possess certain properties that we believe are helpful for therapeutic effectiveness and safety or would otherwise support the submission of an IND on the timelines we expect, or at all. We do not know if the observations we have made regarding our gene circuits generally and our product candidates in particular will translate into any clinical response when tested in humans. As an example, while the Tumor-Associated Antigen (“TAA”) CD33 has been clinically validated as a target for an approved antibody-drug conjugate therapy, it has not been clinically validated as a target for CAR-NK or CAR-T therapies, and may not prove to be a clinically sufficient target for the CAR-NK therapies we are developing. As a result of these uncertainties related to our gene circuit platform technologies and our product candidates, we may never succeed in developing a marketable product based on our current product candidates. If any of our current or potential future product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

[Table of Contents](#)

Our gene circuit platform technologies are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

We are seeking to identify and develop a broad pipeline of product candidates using our gene circuit platform technologies. The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. We are not aware of any FDA approved therapeutics utilizing similar technologies as ours. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our platform technologies is preliminary. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have not tested any of our current product candidates in humans, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. Further, relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates in humans, and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and efficacy of our product candidates. In addition, our gene circuit technologies have potential safety risks.

Given the novelty of our technologies, we intend to work closely with the FDA and comparable foreign regulatory authorities to evaluate our proposed approaches to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our platforms, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

The occurrence of serious complications or side effects in connection with the use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates, or, post-approval, revocation of marketing authorizations or refusal to approve applications for new indications, which could severely harm our business, prospects, operating results, and financial condition.

Undesirable side effects caused by any of our current or potential future product candidates could cause regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. While we have not yet initiated clinical trials for SENTI-202, SENTI-404, or any other product candidate, it is likely that there will be side effects associated with their use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. For example, if the NOT GATE gene circuit, as described below, engineered into one of our product candidates, such as SENTI-202, does not provide a clinically sufficient level of inhibition, it may kill healthy cells that it has been designed to preserve or may cause systemic immune cytotoxicity. It is possible that safety events or concerns such as these or others could negatively affect the development of our product candidates, including adversely impacting patient enrollment among the patient populations that we intend to treat. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. To date, we have not observed any such effects in our preclinical studies, but there can be no guarantee that our current or future product candidates will not cause such effects in clinical trials. Any of these occurrences may materially and adversely impact our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly large number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

[Table of Contents](#)

In the event that any of our current or potential future product candidates receives regulatory approval and we or others identify undesirable side effects caused by one of these products, any of the following events could occur, which could result in the loss of significant revenue to us and materially and adversely impact our results of operations and business:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions, or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events 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.

We may not be successful in our efforts to use and expand our gene circuit platform to expand our pipeline of product candidates.

A key element of our strategy is to use and advance our gene circuit platform to design, test and build our portfolio of product candidates focused on allogeneic gene circuit-equipped CAR-NK cell therapies for the treatment of cancer. Although our research and development efforts to date have resulted in our discovery and preclinical development of SENTI-202, SENTI-401 and other potential product candidates, none of these product candidates has advanced to clinical development. We cannot assure you that any of our existing product candidates will advance to clinical trials or, if they do, that such trials will demonstrate these product candidates to be safe or effective therapeutics, and we may not be able to successfully develop any product candidates. Even if we are successful in expanding our pipeline of product candidates, any additional product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future.

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Although a substantial amount of our efforts will focus on the planned clinical trials and potential approval of the current and potential future product candidates we are evaluating, a key element of our strategy is to discover, develop, and globally commercialize additional targeted therapies beyond our current product candidates to treat various conditions and in a variety of therapeutic areas. Even if we identify investigational therapies that initially show promise, we may fail to successfully develop and commercialize such products for many reasons, including the following:

[Table of Contents](#)

- the research methodology used may not be successful in identifying potential investigational therapies;
- competitors may develop alternatives that render our investigational therapies obsolete;
- investigational therapies we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- an investigational therapy may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio;
- an investigational therapy may not be capable of being produced in clinical or commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

Identifying new investigational therapies requires substantial technical, financial and human resources, whether or not any investigational therapies are ultimately identified. Because we have limited financial and human resources, we may initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, if we do not accurately evaluate the commercial potential or target market for a particular product candidate or technology, we may relinquish valuable rights to that product candidate or technology through collaborations, 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 or technology.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

The market, physicians, patients, regulators and potential investors may not be receptive to our current or potential future product candidates and may be skeptical of the viability and benefits of our gene circuit pipeline technology because it is based on a relatively novel and complex technology.

The market, physicians, patients, regulators and potential investors, may be skeptical of the viability and benefits of our gene circuit pipeline technology or our product candidates because they are based on a relatively novel and complex technology and there can be no assurance that our product candidates or platform technologies will be understood, approved, or accepted. If potential investors are skeptical of the success of our pipeline products, our ability to raise capital and the value of our stock may be adversely affected. If physicians, patients, or regulators do not understand or accept our gene circuit platform technologies or our product candidates, we may be delayed in or unable to develop our product candidates.

Even if regulatory approval is obtained for a product candidate, including SENTI-202 or SENTI-401, we may not generate or sustain revenue from sales of approved products. Market acceptance of our gene circuit platform

[Table of Contents](#)

technologies and our current and potential future product candidates, if approved, will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates and gene circuit technologies in general;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our product candidates;
- the success of our physician education programs;
- the availability of coverage and adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risk: benefits and costs of those treatments.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material adverse impact on our business, financial condition, results of operations, and prospects.

While we believe our pipeline will yield multiple INDs, we may not be able to file INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We expect our pipeline to yield multiple INDs beginning as early as 2023, including an IND for SENTI-202. We cannot be sure that submission of an IND will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. The manufacturing of our product candidates, including SENTI-202 and SENTI-401, remains an emerging and evolving field. Accordingly, we expect chemistry, manufacturing and control related topics, including product specifications, will be a focus of IND reviews, which may delay the clearance of INDs. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees (“IBCs”), as set forth in the National Institutes of Health (“NIH”), Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory

[Table of Contents](#)

unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

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

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimates, 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 interim, preliminary or topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim, preliminary or topline data from our clinical studies. Interim, topline or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline 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 and our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the time frames that we or they announce, which could have an adverse impact on our business and could cause our stock price to decline.

From time to time, we expect that we will make public statements regarding the expected timing of certain milestones and key events, such as the commencement and completion of preclinical and IND-enabling studies in our own internally-developed programs or in our product candidate discovery programs with collaborators, as well as the submission and clearance of INDs and the commencement and completion of planned clinical trials in those programs. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or any future collaborators' product candidate discovery and development programs, the amount of time, effort and resources committed by us and any future collaborators, and the numerous uncertainties inherent in the development of therapies. As a result, there can be no assurance that our or any future collaborators' programs will advance or be completed in the time frames we or they announce or expect. If we or any collaborators fail to achieve one or more of these milestones or other key events as planned, our business could be materially adversely affected, and the price of our common stock could decline.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our current and potential future product candidates are based on new technologies and discovery approaches, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, the FDA or other regulatory authorities may require us to perform additional testing before commencing clinical trials and be hesitant to allow us to enroll

[Table of Contents](#)

patients impacted with our targeted disease indications in our future clinical trials. If we are unable to enroll patients impacted by our targeted disease indications in our future clinical trials, we would be delayed in obtaining potential proof-of-concept data in humans, which could extend our development timelines. In addition, costs to treat patients and to treat potential side effects that may result from our product candidates may be significant. Accordingly, our clinical trial costs are likely to be high and could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We may not be able to initiate or continue any clinical trials for our current or potential future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. We cannot predict how difficult it will be to enroll patients for trials in the indications we are studying. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity and availability of clinical trial sites for prospective patients;
- willingness of physicians to refer their patients to our clinical trials;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential risks and benefits 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;
- our ability to obtain and maintain patient informed consents;
- patient eligibility and exclusion criteria for the trials;
- ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, such as potential pandemics that may limit the availability of patients, principal investigators or sites or clinical sites to participate in our clinical trials.

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

[Table of Contents](#)

or adverse events independent from our product candidates, such patients may be unevaluable for purposes of the trial and, as a result, we may require additional enrollment. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of these clinical trials could be substantially delayed or prevented by many factors, including:

- further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, including the endpoint measures required for regulatory approval and our statistical plan;
- the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indications as our product candidates;
- any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient quantities or inability to produce quantities of consistent quality, purity and potency of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board (“IRB”) or ethics committee approval to conduct a clinical trial at a prospective site;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse events experienced by patients, including possible deaths;

[Table of Contents](#)

- lack of efficacy or failure to measure a statistically significant clinical benefit within the dose range with an acceptable safety margin during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- the impact of, and delays related to, health epidemics such as the COVID-19 pandemic;
- the need to suspend, repeat or terminate clinical trials as a result of non-compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and
- the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason with any future strategic collaborator that has responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we decide to seek orphan drug designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation for our current or future product candidates that we may develop.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. We may seek orphan drug designation for certain indications for our product candidates in the future. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Orphan drug designation can entitle a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

In addition, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which

[Table of Contents](#)

precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. The FDA may reduce the seven-year exclusivity if the same drug from a competitor demonstrates clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, and while we may seek orphan drug designation for our product candidates, we may never receive such designations. In addition, the FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

Risks Related to Third Parties

There can be no assurance that we will achieve all of the anticipated benefits of the transaction with GeneFab and we could face unanticipated challenges.

We may not realize some or all of the anticipated benefits from the transaction with GeneFab and we may encounter post-closing risks. We may experience increased difficulty and loss of institutional knowledge if the employees to we expect to transfer to GeneFab do not accept their offers of employment, which could harm our business. Moreover, the transition to a new company may require significant time and resources from the employees of GeneFab, which may disrupt GeneFab's business and distract management from other responsibilities, which may then result failure to achieve anticipated manufacturing production, which could adversely affect our timelines for our clinical trials and financial results.

We rely on third parties to conduct our preclinical studies, and plan to rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily.

We expect to rely on third-party clinical investigators, CROs, clinical data management organizations and consultants to design, conduct, supervise and monitor certain preclinical studies and any clinical trials. Because we intend to rely on these third parties and will not have the ability to conduct certain preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of such preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and contract manufacturing organizations and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical

[Table of Contents](#)

development timelines. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

Despite our reliance on third parties, we will ultimately be responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, including good laboratory practice, or GLP, good clinical practice, or GCP, cGMP, and cGTP. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs, clinical sites and investigators fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency, or EMA, or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates FDA regulatory requirements as well as federal or state healthcare laws and regulations or healthcare privacy and security laws.

If third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We depend on strategic partnerships and collaboration arrangements, such as our collaboration arrangements with Spark Therapeutics, Inc., or Spark, and BlueRock Therapeutics, Inc., or BlueRock, for the application of our gene circuit platform technology to the development and commercialization of potential product candidates in certain indications, and if these arrangements are unsuccessful, this could impair our ability to generate revenues and materially harm our results of operations.

Our business strategy for exploiting the potential of our gene circuit platform technology is dependent upon maintaining our current arrangements and establishing new arrangements with strategic partners, research collaborators and other third parties. We currently have collaboration agreements with Spark and BlueRock. These collaboration agreements provide for, among other things, research funding and significant future payments should certain development, regulatory and commercial milestones be achieved. Under these arrangements, our collaborators are typically responsible for:

- electing to advance product candidates through preclinical and into clinical development;
- conducting clinical development and obtaining required regulatory approvals for product candidates; and
- commercializing any resulting products.

As a result, we may not be able to conduct these collaborations in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations.

[Table of Contents](#)

Additionally, the development and commercialization of potential product candidates under our collaboration agreements could be substantially delayed, and our ability to receive future funding could be substantially impaired if one or more of our collaborators:

- shifts its priorities and resources away from our collaborations due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- ceases development in therapeutic areas which are the subject of our collaboration;
- fails to select a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product;
- changes the success criteria for a particular product candidate, thereby delaying or ceasing development of such product candidate;
- significantly delays the initiation or conduct of certain activities which could delay our receipt of milestone payments tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product candidate that competes, either directly or indirectly, with our product candidates;
- does not obtain the requisite regulatory approval of a product candidate;
- does not successfully commercialize a product candidate;
- encounters regulatory, resource or quality issues and is unable to meet demand requirements;
- exercises its rights under the agreement to terminate the collaboration, or otherwise withdraws support for, or otherwise impairs development under the collaboration;
- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments termination of research and development activities for such product candidate; and
- uses our proprietary information or intellectual property in such a way as to jeopardize our rights in such property.

In addition, the termination of our existing collaborations or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payment, sharing of profits, and other benefits under such agreement. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. Any of these events could have a material adverse effect on our ability to develop and commercialize any of our product candidates and may adversely impact our business, prospects, financial condition, and results of operations.

We may not be able to enter into additional strategic transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize current and potential future product candidates and technologies, impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we consider strategic transactions, such as collaborations, regional partnerships for the co-development and/or co-commercialization of our product candidates in selected territories, acquisitions of companies, asset purchases, joint ventures, out- or in-licensing of product candidates or technologies and partnerships involving our gene circuit platform technology. For example, we will evaluate and, if strategically

[Table of Contents](#)

attractive, seek to enter into collaborations, including with biotechnology or biopharmaceutical companies, contract development manufacturing organizations or hospitals. In addition, we announced in January, 2023 that we are actively pursuing strategic geographic partnerships for clinical development of SENTI-301A as part of a business realignment plan to extend our cash runway. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. If we are not able to enter into strategic transactions, we may not have access to required liquidity or expertise to further develop our potential future product candidates or our gene circuit platform. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business.

We also may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of acquiring such assets. Conversely, any new collaboration that we do enter into may be on terms that are not optimal for us, our product candidates or our technologies. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to negotiate and manage a collaboration or develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses;
- difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business;
- impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and
- the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and technologies and have a negative impact on the competitiveness of any product candidate or technology that reaches market.

In addition, to the extent that any future collaborators terminate a collaboration agreement, we may be forced to independently develop our current and future product candidates and technologies, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining, enforcing and defending intellectual property rights, or, in certain instances, abandon product candidates and technologies altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Manufacturing

Manufacturing our current or future product candidates is complex and the third parties upon whom we rely to provide manufacturing services may encounter difficulties in production. If we encounter such difficulties, our

[Table of Contents](#)

ability to provide supply of our current or future product candidates for preclinical studies and clinical trials or, if approved, for commercial sale, for commercial purposes could be delayed or halted entirely.

The process of manufacturing our current or future product candidates is complex and highly regulated, and it requires significant expertise, including the development of advanced manufacturing techniques and process controls. The process of manufacturing our product candidates is also extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminants are discovered in our product candidates or the manufacturing facilities in which they are made, the facilities may need to be closed for an extended period of time to investigate and remedy the contamination. As a result of the complexities, the cost to manufacture biologics in general, and our cell-based product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce.

We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third party manufacturing organizations, or CMOs, and in particular GeneFab, for the manufacture of our current or future product candidates. GeneFab and any other CMO may not be able to provide adequate resources or capacity to meet our needs. If GeneFab or any other CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. This could significantly delay our clinical trials supply as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates or products, if approved, 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.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts.

Supply of our product candidates for preclinical and clinical development may become limited or interrupted or may not be of satisfactory quantity or quality, and we may experience delays if GeneFab is unable to operate and we are required to relay on third-party back-up manufacturers.

Initial manufacturing efforts will focus on our lead programs, SENTI-202 and SENTI-401. We do not currently have arrangements in place for a redundant or second-source supply in the event the facility we sublease to GeneFab is not operational. Any delays in manufacturing our product candidates could impede, delay, limit or prevent our drug development efforts, which could harm our business, results of operations, financial condition and prospects.

We do not currently produce our product candidates in quantities sufficient for preclinical and clinical development. We cannot be sure that the manufacturing processes employed by GeneFab or the technologies incorporated for manufacturing will result in viable or scalable yields of our product candidates that will be safe, effective, and meet market demand. GeneFab and any other third-party manufacturers we may contract with must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP and cGTP. In the event that we or any third-party manufacturer fails to comply with such requirements or to perform obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to or enter into an agreement with another third party, which we may not be able to do on reasonable terms, or at all. In some cases, the technical skills or technology required to manufacture our current and future product candidates may be difficult or impossible to transfer to a third party and a feasible alternative may not exist. If we are required to change manufacturing facilities or manufacturers for any reason, we will be required to verify that the new facilities and procedures comply with quality standards and with all applicable regulations and

[Table of Contents](#)

guidelines. 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 the FDA or another regulatory authority. The delays associated with the verification of a new manufacturing could negatively affect our ability to develop product candidates in a timely manner or within budget.

In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, and to regulatory applications, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer, and therefore delay timelines. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

If we receive regulatory approval for any product candidate and we are unable to for any reason to have sufficient quantities of the product produced, or if we are unable to obtain or maintain third-party manufacturing on commercially reasonable terms, we may not be able to commercialize the product candidate successfully. Failure to execute on our manufacturing requirements and comply with cGMP and cGTP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of potential future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

GeneFab or any other third-party manufacturers that we use may be unable to successfully scale the manufacturing of our current or potential future product candidates in sufficient quality and quantity, which would delay or prevent us from developing our current and potential future product candidates and commercializing approved products candidates, if any. GeneFab has never operated a cGMP facility before.

In order to conduct clinical trials for our current and potential future product candidates or to commercialize any approved product candidates, we will need to manufacture large quantities of these product candidates. We expect to use GeneFab to produce required quantities of SENTI-202. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any current or potential future product candidate in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and may result in lower yields than initially expected. While we believe GeneFab will be able to sufficiently scale to produce commercial quantities, any significant revisions to the manufacturing process may create delays, which could negatively impact our overall development timelines. In addition, GeneFab has never operated a cGMP facility before. Difficulties may be encountered in operating the facility or meeting the requirements of the FDA or other regulatory authorities that we have not anticipated. If GeneFab cannot successfully scale the manufacture of any current or potential future product candidate in sufficient quality and quantity, the development, testing, clinical trials and commercialization of that product candidate may be delayed or infeasible and regulatory approval or commercial launch of any potential resulting product may be delayed or not obtained, which could significantly harm our business.

We are exposed to a number of risks related to our supply chain for the materials required to manufacture our product candidates.

Manufacturing our product candidates is highly complex and requires sourcing specialty materials. Many of the risks associated with the complexity of manufacturing our final products are applicable to the manufacture and

[Table of Contents](#)

supply of the raw materials. In particular, these starting materials are subject to inconsistency in yields, variability in characteristics, contamination, difficulties in scaling the production process and defects. Similar minor deviations in the manufacturing process for these starting materials could result in supply disruption and reduced production yields for our final product. In addition, we rely on third parties for the supply of these materials exposing us to similar risks of reliance on third parties as described above with respect to the manufacturing and supply of our drug products.

Our manufacturing processes requires many reagents, some of which are drug substance intermediates 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 and experience to support commercial production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As GeneFab continues to develop and scale the manufacturing process for our product candidates, we expect that there will be a need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. These rights may not be able to be obtained with respect to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for a product candidate that is already in clinical testing, the change may require us to perform both comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

Changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing, planned or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Risks Related to Our Business and Operations

If the market opportunities for our current and potential future product candidates, including SENTI 202 and SENTI-401, are smaller than we believe they are, our future product revenues may be adversely affected, and our business may suffer.

Our understanding of the number of people who suffer from diseases that our current product candidates may be able to treat are based on estimates. These estimates may prove to be incorrect, and new studies may reduce the

[Table of Contents](#)

estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our current or potential future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for our candidates may further be reduced if our estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from our product candidates.

Further, there are several factors that could contribute to making the actual number of patients who receive our current or potential future product candidates less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

We face competition from companies that have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop platform technologies or product candidates more rapidly than we do, or if their platform technologies or product candidates are more effective or have fewer side effects, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of cell and gene therapies is highly competitive. We compete with a variety of large pharmaceutical companies, multinational biopharmaceutical companies, other biopharmaceutical companies and specialized biotechnology companies, as well as technology and/or therapeutics being developed at universities and other research institutions. Our competitors are often larger and better funded than we are. Our competitors have developed, are developing or will develop product candidates and processes competitive with ours. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that are currently in development or that enter the market. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop product candidates. There is intense and rapidly evolving competition in the biotechnology and biopharmaceutical fields. We believe that while our gene circuit platform, its associated intellectual property portfolio, the characteristics of our current and potential future product candidates and our scientific and technical know-how together give us a competitive advantage in this space, competition from many sources remains.

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

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Our success largely depends on the continued service of key executive management, advisors and other specialized personnel, including Timothy Lu, our Chief Executive Officer, Kanya Rajangam, our Chief Medical and Development Officer, and Deborah Knobelman, our Chief Financial Officer. Our senior management may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our employees. The loss of one or more members of our executive team, management team or other key employees or advisors could delay our research and development programs and have a material adverse effect on our business, financial condition, results of operations and prospects.

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

[Table of Contents](#)

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.

We may experience difficulties in managing our growth and expanding our operations.

We have limited experience in therapeutic development. As our current and potential future product candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development and regulatory capabilities or contract with other organizations to provide these capabilities for us.

To manage our anticipated future growth, we will continue to implement and improve our managerial, operational, and financial systems, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating additional employees; managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems and procedures.

We may also experience difficulties in the discovery and development of potential future product candidates using our gene circuit platform if we are unable to meet demand as we grow our operations. In the future, we also expect to have to manage additional relationships with collaborators, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures and secure adequate facilities for our operational needs. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

Our strategic re-prioritization plan announced in January, 2023 may not result in the full anticipated benefits or may limit or disrupt our operations.

In January 2023, we announced a pipeline re-prioritization plan to streamline our internal research and development efforts, and focus our internal resources on SENTI-202 and SENTI-401, and, with potential partners, to develop gene circuits for other programs. We may not realize the potential benefits, savings, cash runway extensions or improvements in our cost structure from our re-prioritization efforts due to unexpected difficulties, delays, or costs. In particular, we may not be able to enter into partnerships for SENTI-301A or other programs that we do not intend to develop internally on acceptable terms or within the timeframes that we expect, and we may be forced to dedicate additional time and resources to the maintenance of these programs or to our efforts to secure partnerships. If we are unable to realize anticipated cost savings from the reorganization, our operating results and financial condition may be adversely affected. Furthermore, implementing changes to our corporate strategy may be disruptive to our operations. For example, we may engage in workforce reductions that could yield unexpected consequences, such as turnover beyond planned reductions or increased difficulty in our day-to-day operations. Any workforce reductions could harm our ability to attract and retain qualified personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully executing key technical and scientific initiatives.

[Table of Contents](#)

If any of our product candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.

We currently have no sales, marketing or distribution capabilities or experience. We will need to develop internal sales, marketing and distribution capabilities to commercialize each current and potential future product candidate that gains, if ever, FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into collaborations with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market any approved products or decide to co-promote products with third parties, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business and results of operations could be materially and adversely affected.

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

Our business is subject to risks associated with conducting business internationally. Some of our future clinical trials may be conducted outside of the United States and we may enter into key supply arrangements or do other business with persons outside of the United States. Furthermore, if we or any future collaborator succeeds in developing any products, we anticipate marketing them in the European Union and other jurisdictions in addition to the United States. If approved, we or any future collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as those relating to privacy, data protection and cybersecurity, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the commercialization of our product candidates in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;

[Table of Contents](#)

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises (including demand and payment for our products and exposure to foreign currency exchange rate fluctuations);
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease (including the COVID-19 pandemic), boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery law in other countries.

Any of these factors could harm our ongoing international operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

Our business entails a significant risk of product liability, and our inability to obtain sufficient insurance coverage could have a material adverse effect on our business, financial condition, results of operations and prospects.

As we conduct preclinical studies and future clinical trials of our current and potential future product candidates, we will be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of these product candidates. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we or any future collaborators may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our employees, principal investigators, consultants and commercial collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial collaborators. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and financial condition, including the imposition of significant criminal, civil

[Table of Contents](#)

and administrative fines or other sanctions, such as monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity obligations, reputational harm and the curtailment or restructuring of our operations.

We depend on sophisticated information technology systems and data processing to operate our business. If we experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, we may face costs, significant liabilities, harm to our brand and business disruption.

We rely on information technology systems and data processing that we or our service providers, collaborators, consultants, contractors or partners operate to collect, process, transmit and store electronic information in our day-to-day operations, including a variety of personal data, such as name, mailing address, email addresses, phone number and potentially clinical trial information. Additionally, we, and our service providers, collaborators, consultants, contractors or partners, do or will collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other information to host or otherwise process some of our anticipated future clinical data and that of users, develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes. Our internal computer systems and data processing and those of our third-party vendors, consultants, collaborators, contractors or partners, including future CROs may be vulnerable to a cyber-attack (including supply chain cyber-attacks), malicious intrusion, breakdown, destruction, loss of data privacy, actions or inactions by our employees or contractors that expose security vulnerabilities, theft or destruction of intellectual property or other confidential or proprietary information, business interruption or other significant security incidents. As the cyber-threat landscape evolves, these attacks are growing in frequency, level of persistence, sophistication and intensity, and are becoming increasingly difficult to detect. In addition to traditional computer “hackers,” threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing), phishing and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). These risks may be increased as a result of the COVID-19 pandemic, owing to an increase in personnel working remotely and higher reliance on internet technology. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

There can be no assurance that we, our service providers, collaborators, consultants, contractors or partners will be successful in efforts to detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data. Any failure by us or our service providers, collaborators, consultants, contractors or partners to detect, prevent, respond to or mitigate security breaches or improper access to, use of, or inappropriate disclosure of any of this information or other confidential or sensitive information, including patients’ personal data, or the perception that any such failure has occurred, could result in claims, litigation, regulatory investigations and other proceedings, significant liability under state, federal and international law, and other financial, legal or reputational harm to us. Further, such failures or perceived failures could result in liability and a material disruption of our development programs and our business operations, which could lead to significant delays or setbacks in our research, delays to commercialization of our product candidates, lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cashflow. For example, the loss or alteration of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Additionally, applicable laws and regulations relating to privacy, data protection or cybersecurity, external contractual commitments and internal privacy and security policies may require us to notify relevant stakeholders if there has been a security breach, including affected individuals, business partners and regulators. Such disclosures are costly, and the disclosures or any actual or alleged failure to comply with such requirements could lead to a materially adverse impact on the business, including negative publicity, a loss of confidence in our services or security measures by our business partners or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or other data protection obligations related to information security or security breaches.

[Table of Contents](#)

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

Our research, development and manufacturing involve the use of hazardous materials and various chemicals. We maintain quantities of various flammable and toxic chemicals that are required for our research, development and manufacturing activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing, handling and disposing of these materials comply with the relevant guidelines of the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. 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 these materials, this insurance may not provide adequate coverage against potential liabilities. Although we have some environmental liability insurance, we may not maintain adequate insurance for all environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our business, operations and clinical development plans and timelines could be adversely affected by global economic and political developments, including high inflation and capital market disruption, the war in Ukraine, economic sanctions and economic slowdowns or recessions, including any lingering impact from the COVID-19 pandemic, or the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we may conduct business, including our anticipated contract manufacturers, CROs, shippers and others.

Any global financial crisis or slowdown could cause volatility and disruptions in the capital and credit markets. Similarly, any global health epidemic, such as the COVID-19 pandemic, could cause disruptions in our operations and in the operations of third-party manufacturers, CROs, and other third-parties on whom we rely. More recently, the global economy has been impacted by increasing interest rates and high inflation, as well as by the war in Ukraine and the possibility of a wider European or global conflict. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, or at all. Additionally, a weak or declining economy or international trade disputes could strain our suppliers, some of whom are located outside the United States, potentially resulting in supply disruption. Also, the global COVID-19 pandemic and government measures taken in response have also had a significant impact on businesses and commerce worldwide. In connection with COVID-19, we implemented work-from-home policies for most employees. The effects of our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, 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 a health epidemic, 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 future clinical trials may be affected by the COVID-19 pandemic or other global 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 COVID-19 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

[Table of Contents](#)

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 to COVID-19 or experience additional restrictions by their institutions, city or state, our preclinical studies and future clinical trial operations could be adversely impacted.

The global COVID-19 pandemic has disrupted and may continue to disrupt healthcare delivery and healthcare regulatory systems. Such disruptions could divert healthcare resources, or delay the review and approval by the FDA or other regulatory bodies, thereby causing delay for our clinical trials. During a global health crisis, certain manufacturing facilities and materials may be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or manufacturing slots for the product candidates needed for our clinical trials, which could lead to delays in these trials. These and similar, and perhaps more severe, disruptions in our operations could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

The effects of a pandemic could have a material impact on our operations, and to the extent a pandemic adversely affects our business, results of operations, cash flows, financial condition and/or prospects, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Market volatility and economic downturns may harm our business and results of operations and negatively affect our stock price.

Our overall performance depends, in part, on worldwide economic conditions. In recent months, we have observed increased economic uncertainty in the United States and abroad. Impacts of such economic weakness include:

- declining overall demand for goods and services, leading to reduced profitability;
- reduced credit availability;
- higher borrowing costs;
- reduced liquidity;
- volatility in credit, equity and foreign exchange markets; and
- bankruptcies.

These developments could lead to supply chain disruption, inflation, higher interest rates, and uncertainty about business continuity, which may adversely affect our business and our results of operations and negatively affect our stock price.

Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

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

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

[Table of Contents](#)

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

Rising inflation rates could negatively impact our revenues and profitability if increases in the prices of our products or a decrease in consumer spending results in lower sales. In addition, if our costs increase and we are not able to pass along these price increases to our customers, our net income would be adversely affected, and the adverse impact may be material.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. Increased inflation may result in decreased demand for our products and services, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may again 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 have the effect of further increasing economic uncertainty and heightening these risks.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our technology and current or future product candidates, or if our intellectual property rights are inadequate, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.

Our success depends in part on our ability to obtain and maintain protection for our owned and in-licensed intellectual property rights and proprietary technology. We rely on a combination of patents, trademarks, trade secret protection and confidentiality agreements, including in-licenses of intellectual property rights and biologic materials of others, to protect our current or future platform technologies, product candidates, methods used to manufacture our current or future product candidates and methods for treating patients using our current or future product candidates.

We own or in-license patents and patent applications relating to our platform technologies and product candidates. There is no guarantee that any patents covering our platform technologies or product candidates will issue from the patent applications we own, in-license or may file in the future, or, if they do, that the issued claims will provide adequate protection for our platform technologies or product candidates, or any meaningful competitive advantage. Further, there cannot be any assurance that such patents issued will not be infringed, designed around, invalidated by third parties or effectively prevent others from commercializing competitive technologies, products or product candidates.

The patent prosecution process is expensive, complex and time-consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. 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 or in-license may fail to result in issued patents, and, even if they do issue as patents, such patents may not cover our current or future technologies or product candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We do not have exclusive control over the preparation, filing and prosecution of patent applications under certain of our in-license agreements, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents, that we out-license to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Even if our owned or in-licensed patent applications issue as patents, they may not issue in

[Table of Contents](#)

a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner.

Further, although we make reasonable efforts to ensure patentability of our inventions, we cannot guarantee that all of the potentially relevant prior art relating to our owned or in-licensed patents and patent applications has been found. For example, publications of discoveries in 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, and in some cases not at all. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our product candidates, or the use of our technologies. We thus cannot know with certainty whether we or our licensors were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. There is no assurance that all potentially relevant prior art relating to our owned or in-licensed patent applications has been found. For this reason, and because there is no guarantee that any prior art search is absolutely correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent or to prevent our owned or in-licensed patent applications from issuing as patents. Invalidation of any of our patent rights, including in-licensed patent rights, could materially harm our business.

Moreover, the patent positions of biotechnology companies like ours are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. The relevant patent laws and their interpretation, both inside and outside of the United States, is also uncertain. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our platform technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe, misappropriate or otherwise violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our platform technology, product candidates, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may file or license in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Additionally, third parties, including our former employees and collaborators, may challenge the ownership or inventorship of our patent rights to claim that they are entitled to ownership and inventorship interest, and we may not be successful in defending against such claims. However, we are not currently facing any such challenges. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block—in some cases—potential competitors from practicing the claimed inventions of the issued patents.

The issuance, scope, validity, enforceability and commercial value of our pending patent rights are uncertain. The standards applied by the USPTO and foreign patent offices in granting patents are not always certain and moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. 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 owned or in-licensed patent applications or narrow the scope of any patent protection we may obtain from our owned or in-licensed patent applications. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidate and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors

[Table of Contents](#)

or other parties with similar technology. Additionally, our competitors may initiate legal proceedings, such as declaratory judgment actions in federal court or reexaminations or an *inter partes* review at the USPTO in an attempt to invalidate or narrow the scope of our patents. However, we are not currently facing any such proceedings. Furthermore, our competitors or other parties may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product candidate may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Even if patents do successfully issue from our owned or in-licensed patent application, and even if such patents cover our current or any future technologies or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any current or future technologies or product candidates that we may develop. Likewise, if patent applications we own or have in-licensed with respect to our development programs and current or future technologies or product candidates fail to issue, if their breadth or strength is threatened, or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us to develop current or future technologies or product candidates. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain or any loss of patent protection could have a material adverse impact on our business and ability to achieve profitability. We may be unable to prevent competitors from entering the market with a product that is similar or identical to any of our current or potential future product candidates or from utilizing technologies similar to those in our gene circuit platform technologies.

The filing of a patent application or the issuance of a patent is not conclusive as to its ownership, inventorship, scope, patentability, validity or enforceability. Issued patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, our patent applications or patent applications filed by our licensors, or any patents that grant therefrom, may be challenged through third-party submissions, opposition or derivation proceedings. By further example, any issued patents that may result from our owned or in-licensed patent applications may be challenged through reexamination, *inter partes* review or post-grant review proceedings before the USPTO, or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our owned or in-licensed patent rights, result in the loss of exclusivity, limit our ability to stop others from using or commercializing similar or identical platforms and product candidates, or allow third parties to compete directly with us without payment to us. In addition, if the breadth or strength of protection provided by any patents that might result from our owned or in-licensed patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future platforms or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, we currently co-own certain patent applications with third parties and may in the future co-own additional patents and patent applications with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent application, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions.

Our in-licensed patent rights may be subject to a reservation of rights by one or more third parties, such as the U.S. government. In addition, our rights in such inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

The patent protection and patent prosecution for some of our product candidates and technologies may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates and technologies, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates and technologies are controlled by our licensors or collaborators. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would.

If any of our licensors or collaborators fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates and technologies, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates and technologies may be adversely affected and we may not be able to prevent competitors from making, using and selling competing product candidates. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our current and future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our licensed European patents and patent applications could be challenged in the recently-created Unified Patent Court, or UPC, for the European Union, that is expected to be fully ratified in 2023. Under our current license agreements, we may not have the final or sole decision as to whether we are able to opt out certain of our in-licensed European patents and patent applications from the UPC. Our licensors may decide not to opt out of the UPC, which would subject our in-licensed European patents and patent applications to the jurisdiction of the UPC. Furthermore, even if our licensors decide to opt out of the UPC, we cannot guarantee that our licensors will comply with the legal formalities and requirements for properly opting out of the UPC. Thus, we cannot be certain that our in-licensed European patents and patent applications will not fall under the jurisdiction of the UPC. Under the UPC, a single European patent would be valid and enforceable in numerous European countries. A challenge to the validity of a European patent in a central revocation proceeding under the UPC, if successful, could result in a loss of patent protection in numerous European countries, which could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Further, we may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding(s) or defense activities may be less vigorous than had we conducted them ourselves.

We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either

[Table of Contents](#)

an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Further, our licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Additionally, some intellectual property that we have in-licensed or that we own may have been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government may have the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”).

More specifically, certain currently in-licensed patents that cover certain split, universal and programmable chimeric antigen receptor technology may be subject to march-in-rights. This technology is not embodied in any of our current product candidates. In addition, certain currently in-licensed patents that cover certain components and process for regulating the expression of a fusion protein with the use of a protease inhibitor are subject to march-in-rights, which technology can be embodied in certain regulator dial gene circuits. We also own a patent family claiming an invention made under research partially funded by the federal government. Such invention covers mesenchymal stem cells that express combinations of immune effectors for autoimmunity. While the foregoing invention is not embodied in any current product candidates, it is subject to march-in-rights. The U.S. government also has the right to take title to these inventions made through government funded programs if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We currently, and in the future may continue to, enter into agreements involving licenses or collaborations that provide for access or sharing of intellectual property. These intellectual property-related agreements may impose certain obligations and restrictions on our ability to develop and commercialize our product candidates and technologies that are the subject of such licenses.

We license rights from third parties to use certain intellectual property relevant to one or more of our current and future product candidates. In the future, we may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our current and future product candidates we may identify and pursue. These existing license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing,

[Table of Contents](#)

insurance, patent prosecution and enforcement or other obligations on us. For example, we are a party to three license agreements with the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, or NCI, for intellectual property relevant to our product candidates. For a more detailed description of the license agreements with NCI, see the section titled “*Business—Material License and Collaboration Agreements*” in the Annual Report on Form 10-K for the year ended December 31, 2022.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor’s express consent in order for an assignment or transfer to take place.

Further, we or our licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. 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, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors 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. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial conditions, results of operations and prospects.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our licensed rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that is the subject of such licensed rights could be materially adversely affected. Even where we have the right to control prosecution of patents and patent applications under license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed currently or in the future from various third parties is or may be subject to retained rights. Our predecessors or licensors do and may retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our product candidates, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies and licensed technology into commercial product candidates. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

If we fail to comply with our obligations under any existing or future license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or product candidates or we could lose certain rights to grant sublicenses.

We have certain obligations to third-party licensors from whom we license certain patent rights that are relevant to one or more current and future product candidates. In the future, we may need to obtain additional licenses from other third parties to advance our research and development activities or allow the commercialization of our current

[Table of Contents](#)

and future product candidates. Our existing license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. For a more detailed description of our existing license agreements, see the section titled “*Business—Material License and Collaboration Agreements*” in the Annual Report on Form 10-K for the year ended December 31, 2022. If we breach any of these obligations, including diligence obligations with respect to development and commercialization of product candidates covered by the intellectual property licensed to us, or use the intellectual property licensed to us in an unauthorized manner or we are subject to bankruptcy-related proceedings, we may be required to pay damages and the licensor may have the right to terminate the respective agreement or materially modify the terms of the license, such as by rendering currently exclusive licenses non-exclusive. License termination or modification could result in our inability to develop, manufacture and sell products that are covered by the licensed intellectual property or could enable a competitor to gain access to the licensed intellectual property.

In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our licensed rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that are the subject of such licensed rights could be materially adversely affected.

Our current or future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor’s intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Disputes may arise between us and our present and future licensors regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues, including but not limited to our right to transfer or assign the license;
- whether and the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties, including the terms and conditions thereof;
- our diligence obligations with respect to the development and commercialization of our product candidates that are covered by the license agreement, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the

[Table of Contents](#)

affected product candidates, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the agreements under which we currently license intellectual property or technology from the National Cancer Institute (“NCI”) and other third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while we currently do not have any liens, security interests, or other encumbrances on the intellectual property that we own, we may, in the future, need to obtain a loan or a line of credit that will require that we put up our intellectual property as collateral to our lenders or creditors. If we do so, and we violate the terms of any such loan or credit agreement, our lenders or creditors may take possession of such intellectual property, including the rights to receive proceeds derived from such intellectual property.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies or product candidates.

Patents have a limited lifespan. The term of individual patents and applications in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. Extensions of patent term may be available, but there is no guarantee that we would have patents eligible for extension, or that we would succeed in obtaining any particular extension, and no guarantee any such extension would confer a patent term for a sufficient period of time to exclude others from commercializing product candidates similar or identical to ours. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the USPTO during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug—and only those claims covering the approved drug, a method for using it or a method for manufacturing it—may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval or applicable approval in other jurisdictions, we expect to apply for patent term extensions on issued patents covering those products in the United States and other jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. We also may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and clinical trials along with our clinical and preclinical data. This could have a material adverse effect on our business and ability to achieve profitability.

The life of a patent and the protection it affords are limited. As a result, our owned and in-licensed patent portfolio provides us with limited rights that may not last for a sufficient period of time to exclude others from commercializing product candidates similar or identical to ours. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including

[Table of Contents](#)

generics or biosimilars. For example, given the large amount of time required for the research, development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current or any future technologies or product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States or elsewhere could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) was signed into law, which could increase the uncertainties and costs surrounding the prosecution of our owned or in licensed patent applications and the enforcement or defense of any future owned or in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after March 16, 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications. The Leahy-Smith Act also allows third-party submission of prior art to the USPTO during patent prosecution and sets forth additional procedures to challenge the validity of a patent by USPTO-administered post-grant proceedings, including derivation, reexamination, *inter partes* review, post-grant review and interference proceedings. The USPTO developed additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our issued owned or in-licensed patents, all of which could have a material adverse impact on our business prospects and financial condition.

As referenced above, for example, courts in the U.S. continue to refine the heavily fact-and-circumstance-dependent jurisprudence defining the scope of patent protection available for therapeutics, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This creates uncertainty about our ability to obtain patents in the future and the value of such patents. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. We cannot provide assurance that future developments in U.S. Congress, the federal courts and the USPTO will not adversely impact our owned or in-licensed patents or patent applications. The laws and regulations governing patents could change in unpredictable ways that could weaken our and our licensors’ ability to obtain new patents or to enforce our existing owned or in-licensed patents and patents that we might obtain or in-license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may have a material adverse effect on our and our licensors’ ability to obtain new patents or to protect and enforce our owned or in-licensed patents or patents that we may obtain or in-license in the future.

[Table of Contents](#)

We may be subject to lawsuits or litigation to protect or enforce our patents or other intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Third parties may attempt to invalidate our or our licensors' intellectual property rights via procedures including but not limited to patent infringement lawsuits, declaratory judgment actions, interferences, oppositions and *inter partes* reexamination proceedings before the USPTO, U.S. courts and foreign patent offices or foreign courts. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action. Even if such rights are not directly challenged, disputes could lead to the weakening of our or our licensors' intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management, and could have a material and adverse impact on our profitability, financial condition and prospects or ability to successfully compete.

We or our licensors may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our owned or in-licensed patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to our owned or in-licensed patent or other intellectual property rights, even if resolved in our favor, could be substantial, particularly in a foreign jurisdiction, and any litigation or other proceeding would divert our management's attention. Such litigation or proceedings could materially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Some of our competitors may be able to more effectively sustain the costs of complex patent litigation because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations.

If we or our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, claiming patent-ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non-enablement, anticipation or obviousness. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our product candidates or certain aspects of our platform technologies. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our product candidates and technologies if competitors or third parties design around such product candidates and technologies without legally infringing, misappropriating or violating our owned or in-licensed patents or other intellectual property rights.

Our European patents and patent applications could be challenged in the UPC. Though we may decide to opt out our European patents and patent applications from the UPC, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. Potentially, a single proceeding under the UPC could result in loss of patent protection in numerous European countries rather than each validated country separately. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents on current or future technologies or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors or other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing product candidates to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These product candidates may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of any owned and in-licensed patents we may obtain in other countries, or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our owned or in-licensed intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. Such proceedings could also put any owned or in-licensed patents at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits or other adversarial proceedings that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our and our licensors' efforts to enforce such intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of its patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business prospects may be materially adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of our potential future collaborators to develop, manufacture, market and sell our current or any future product candidates and to use our proprietary technologies without infringing, misappropriating or violating the proprietary and intellectual property rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the USPTO, U.S. courts, foreign patent offices or foreign courts. As the field of gene and cell therapies advances, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, there is uncertainty as to when, to whom, and with what claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;

[Table of Contents](#)

- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. Because patent applications can take many years to issue, there may also be currently pending patent applications that may later result in issued patents that our technology or product candidates may infringe. Further, we cannot guarantee that we are aware of all patents and patent applications potentially relevant to our technology or products. We may not be aware of potentially relevant third-party patents or applications for several reasons. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until a patent issues. Patent applications filed in the United States (after November 29, 2000) and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or platform technologies could have been filed by others without our knowledge. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. Additionally, claims pending in patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform, our product candidates or the use of our technologies.

Although no third party has asserted a claim of patent infringement against us as of the date of this Quarterly Report, others may hold proprietary rights that could prevent our product candidates from being marketed. We or our licensors, or any future strategic collaborator, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current or any potential future product candidates and technologies, including derivation, reexamination, *inter partes* review or post-grant review before the USPTO and similar proceedings in jurisdictions outside of the United States such as opposition proceedings. In some instances, we may be required to indemnify our licensors for the costs associated with any such adversarial proceedings or litigation. Third parties may assert infringement claims against us, our licensors or our strategic collaborators based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic collaborators to enforce or otherwise assert their patent rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are not invalid, enforceable and infringed, which could have a material adverse impact on our ability to utilize our platform technologies or to commercialize our current or any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity by presenting clear and

[Table of Contents](#)

convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence we believe to be clear and convincing, would invalidate the claims of any such U.S. patent.

Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we, or our licensors, or any future strategic collaborators are found to infringe, misappropriate or violate a third-party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney's fees, if we are found to have willfully infringed. In addition, we, or our licensors, or any future strategic collaborators may choose to seek, or be required to seek, a license from a third party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. We could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing our platform technologies or product candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Thus, it is possible that one or more third parties will hold patent rights to which we will need a license, which may not be available on reasonable terms or at all. If such third parties refuse to grant us a license to such patent rights on reasonable terms or at all, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing our product candidates, or to develop or license replacement technology, all of which may not be commercially or technically feasible. In such case, we may not be able to market such technology or product candidates and may not be able to perform research and development or other activities covered by these patents. This could have a material adverse effect on our ability to commercialize our product candidates and our business and financial condition.

Lastly, if our technology or products are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our shares of our common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or product candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or product candidates, which may not be available on commercially reasonable terms or at all.

Because the gene and cell therapy landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing, misappropriating or violating third-party rights. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict

[Table of Contents](#)

whether a third-party's pending application will issue with claims of relevant scope. Also, our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect.

There are numerous companies that have pending patent applications and issued patents broadly covering gene and cell therapy generally or covering related inventions that may be relevant for product candidates that we wish to develop. We are aware of third-party patents and patent applications that claim aspects of our current or potential future product candidates and modifications that we may need to apply to our current or potential future product candidates. There are also many issued patents that claim inventions that may be relevant to products we wish to develop. The holders of such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our current or future technologies, product candidates or elements thereof or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies or product candidates unless we successfully pursue litigation to narrow or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or product candidates. If such an infringement claim should successfully be brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or product candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders may also actively bring infringement, misappropriation, or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or product candidates that are held to be infringing, misappropriating or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or product candidates so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

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 protection for certain aspects of our current or future technologies and product candidates, we rely on trade secrets, including confidential and unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Our trade secrets include, for example, certain program specific synthesis, formulations, patient selection strategies and certain aspects of our research.

Trade secrets and know-how can be difficult to protect. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they

[Table of Contents](#)

are obligated to maintain confidentiality and to assign their inventions to us. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access (such as through a cybersecurity breach) to our trade secrets or independently develop substantially equivalent information and techniques. Moreover, individuals with whom we have such agreements may not comply with their terms. Any of these parties may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breaches. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

We may also become involved in inventorship disputes relating to inventions and patents developed by our employees or consultants under such agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret, or securing title to an employee-or consultant-developed invention if a dispute arises, is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions disfavor or are unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using the technology or information to compete with us. If, in the future, any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be materially and adversely harmed.

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

We are party to various contracts under which we are obligated to maintain the confidentiality of trade secrets or other confidential and proprietary information of third parties, including our licensors and strategic partners. In addition, many of our employees or consultants and our licensors' employees or consultants were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that one or more of these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of third parties, including former employers of our employees and consultants. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or may be enjoined from using such intellectual property. Any such proceedings and possible aftermath would likely divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against any such claims, litigation or arbitration could result in substantial costs and could be a distraction to management.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents as an inventor or co-inventor, or in our trade secrets or other intellectual property as a contributor to its development. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we or our licensors fail in

[Table of Contents](#)

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, intellectual property that is important to our product candidates. 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.

Also, our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and in-licensed patents or applications and any patent rights we may own or in-license in the future. The USPTO and various non-U.S. patent offices require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these requirements, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. In many cases, an inadvertent lapse, including due to the effect of the COVID-19 on us, our patent counsel or other applicable patent maintenance vendors, can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance 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, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical product candidates or platforms, which could have a material adverse effect on our business prospects and financial condition.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we use for name recognition by potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be materially adversely affected.

We may also license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these

[Table of Contents](#)

agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Intellectual property rights do not necessarily address all potential threats to our business.

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

- others may be able to create gene circuit technologies that are similar to our technologies or our product candidates, but that are not covered by the claims of any patents that we own, license or control;
- we or any strategic collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, license or control;
- we or our licensors might not have been the first to file patent applications covering certain of our owned and in-licensed inventions;
- others may independently develop the same, similar, or alternative technologies without infringing, misappropriating or violating our owned or in-licensed intellectual property rights;
- it is possible that our owned or in-licensed pending patent applications will not lead to issued patents;
- issued patents that we own, in-license, or control may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, including as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such trade secrets or know-how; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse impact on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

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

All of our current product candidates are in preclinical development and their risk of failure is high. It is impossible to predict when or if our candidates or any potential future product candidates will prove effective 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 for our current product candidates and then conduct extensive clinical trials to demonstrate the safety, purity and potency, or efficacy of that product candidate in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently

[Table of Contents](#)

uncertain. Failure can occur at any time during the development process. The results of preclinical studies and clinical trials of any of our current or potential future product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

We are currently conducting IND-enabling studies for our current product candidates. We may experience delays in completing our preclinical studies and initiating or completing our clinical studies. We do not know whether planned preclinical studies and clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Our development programs may be delayed for a variety of reasons, including delays related to:

- the FDA or other regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to initiate a clinical trial;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB or ethics committee approval at each clinical trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the FDA placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse events;
- any changes to our manufacturing process that may be necessary or desired;
- adding new clinical trial sites; and
- manufacturing sufficient quantities of our product candidates for use in clinical trials.

[Table of Contents](#)

Furthermore, we expect to rely on our CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our current or potential future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

If we experience delays in the completion of, or termination of, any clinical trial of any of our current or potential future product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our current or potential future product candidates.

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, be unable to commercialize our current or potential future product candidates.

Our current and any potential future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our potential future collaborators to begin selling them.

We have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and other regulatory authorities. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in regulatory policy during the period of product development, clinical trials and FDA regulatory review in the United States and other jurisdictions. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

[Table of Contents](#)

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenue from the particular product candidate for which we are seeking approval. Further, we and our potential future collaborators may never receive approval to market and commercialize any product candidate. Even if we or a potential future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

Once a product obtains regulatory approval, numerous post approval requirements apply, including periodic monitoring and reporting obligations, review of promotional material, reports on ongoing clinical trials and adverse events and inspections of manufacturing facilities. In addition, material changes to approved products, including any changes to the manufacturing process or labeling, require further review by the appropriate authorities before marketing. Approvals may also be withdrawn or revoked due to safety, effectiveness or potency concerns, including as a result of adverse events reported in patients or ongoing clinical trials, or failure to comply with cGMP. In addition to revocation or withdrawal of approvals, we and our partners may be subject to warnings, fines, recalls, criminal prosecution or other sanctions if we fail to comply with regulatory requirements. If we or our partners are unable to obtain or maintain regulatory approvals for our products and product candidates, our business, financial position, results of operations and future growth prospects will be negatively impacted and we or our partners may be subject to sanctions. If any of our product candidates prove to be ineffective, unsafe or commercially unviable, we may have to re-engineer our current or potential future product candidates, and our entire pipeline could have little, if any, value, which could require us to change our focus and approach to product candidate discovery and therapeutic development, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We will also be subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

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

If we succeed in developing any products, we intend to market them in the United States as well as the European Union and other foreign jurisdictions. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements.

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, but 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 or EMA 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 those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. 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 intend to charge for our products is also subject to approval.

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 or any partner we work with fail to comply with the regulatory requirements in international markets or fail to 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.

[Table of Contents](#)

We may in the future conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We may in the future choose to conduct one or more of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless (i) those data are applicable to the U.S. population and U.S. medical practice; (ii) the studies were performed by clinical investigators of recognized competence; and (iii) the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. For studies that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Even if we receive regulatory approval for any of our current or potential future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or potential future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or potential future collaborators obtain for any of our current or potential future product candidates will be subject to limitations on the approved indicated uses for which a product may be marketed or may be subject to the conditions of approval, or contain requirements for potentially costly post-marketing testing, and surveillance to monitor the safety and efficacy of such product candidate. In addition, if the FDA or any other regulatory authority approves any of our current or potential future product candidates, the

[Table of Contents](#)

manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for such product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practices for any clinical trials that we conduct post-approval. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including registering their establishments with the FDA and certain state agencies, ensuring that quality control and manufacturing procedures conform to cGMP and cGTP regulations and applicable product tracking and tracing requirements. Manufacturing facilities are subject to periodic announced and unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other regulatory requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions.

Later discovery of previously unknown problems with a product candidate, 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 candidate, withdrawal of the product candidate from the market or voluntary or mandatory product recalls;
- fines, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic collaborators;
- suspension or revocation of product approvals;
- suspension of any ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties or monetary fines.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy ("REMS") as part of a biologics license application, or BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

Furthermore, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians may prescribe, in their independent professional medical judgment, products for off-label uses as the FDA does not regulate the behavior of physicians in their choice of drug treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion.

[Table of Contents](#)

The FDA and other regulatory authorities have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex. The BPCIA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

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

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our product candidates profitably, if approved. Among policy-makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems, with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. See section titled "*Business - Government Regulation - Healthcare Reform*" in the Annual Report on Form 10-K for the year ended December 31, 2022.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from \$7,050 to \$2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease

[Table of Contents](#)

or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payers of healthcare services to contain or reduce the costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- our ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and to restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates, if approved.. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted 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.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other sensitive information to develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes.

[Table of Contents](#)

We and any potential future collaborators, partners or service providers may be subject to federal, state and foreign data protection laws, regulations and regulatory guidance, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws or contractual obligations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, such as the Health Insurance Portability and Accountability Act (“HIPAA”), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of any future potential collaborators or service providers.

In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, or if we otherwise violate applicable privacy and data security laws.

International data protection laws, including the EU’s General Data Protection Regulation, and the UK’s implementation of the same, or GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR imposes stringent data protection requirements for processing personal data of individuals within the European Economic Area, or EEA, and the UK, as well as potential fines for noncompliant companies of up to the greater of €20 million (£17.5 million) or 4% of annual global revenue. The GDPR imposes numerous requirements for the collection, use and disclosure of personal data, including stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information.

In addition, the GDPR places restrictions on cross-border data transfers. On June 4, 2021, the European Commission issued new forms of standard contractual clauses (one of the primary mechanisms for U.S. companies to import personal information from Europe) for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EEA (and not subject to the GDPR). The new standard contractual clauses do not apply in the UK, but the UK Information Commissioner’s Office issued a UK-specific transfer mechanism, the International Data Transfer Agreement. We are required to transition to the new forms of transfer mechanisms and doing so will require significant effort and cost. The new transfer mechanisms may also impact our business as companies based in Europe may be reluctant to utilize the new clauses to legitimize transfers of personal information to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new standard contractual clauses impose upon exporters. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

The GDPR has increased our responsibilities and potential liability in relation to personal data processed subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. In addition, any failure by us (or our business partners who handle personal data) to comply with GDPR and applicable laws and regulations relating to privacy and data protection of EEA member states and the UK may result in regulators prohibiting our processing of the personal data of EEA and UK data subjects, which could impact our operations and ability to develop our products and provide our services, including interrupting or ending EEA and UK clinical trials.

[Table of Contents](#)

In the U.S., state laws also govern the privacy and security of personal information and states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the “CCPA”) gives California residents expanded rights to access, correct, and delete their personal information, opt out of certain personal information sharing and certain uses of sensitive data, and receive detailed information about how their personal information is used by requiring covered companies to provide disclosures to California consumers (as that term is broadly defined and includes any of our current or future employees who may be California residents) and provide such residents ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches and statutory damages, which is expected to increase data breach class action litigation and result in significant exposure to costly legal judgments and settlements. It will also create a new California data protection agency authorized to issue substantive regulations which could result in increased privacy and information security enforcement. Although the law includes limited exceptions for health-related information, including clinical trial data, such exceptions may not apply to all of our operations and processing activities. As we expand our operations and trials (both preclinical and clinical), the CCPA may increase our compliance costs and potential liability. The CCPA has prompted the enactment of similar, comprehensive privacy and data protection legislation in other states, such as Virginia, Colorado, Utah, and Connecticut, which will all become effective in 2023. Furthermore, a number of other U.S. states have proposed similar privacy and data protection legislation, and it is possible that certain of these proposals will pass. In the event that we are subject to or affected by HIPAA, the GDPR, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Laws and regulations worldwide relating to privacy, data protection and cybersecurity are, and are likely to remain, uncertain for the foreseeable future. While we strive to comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity to the extent possible, we may at times fail to do so, or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel, collaborators, partners or vendors do not comply with applicable laws and regulations relating to privacy, data protection and cybersecurity, external and internal privacy and security policies and contractual obligations relating to privacy, data protection and cybersecurity. Actual or perceived failure to comply with any laws and regulations relating to privacy, data protection or cybersecurity in the U.S. or foreign jurisdictions could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators or service providers obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals’ privacy rights, failed to comply with applicable laws or regulations, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, result in regulatory actions and proceedings, in addition to private claims and litigation, and could result in adverse publicity that could harm our business.

We also are, or may be asserted to be, subject to the terms of our external and internal privacy and security policies, representations, certifications, publications and frameworks and contractual obligations to third parties related to privacy, data protection, information security and processing. Failure to comply or the perceived failure to comply with any of these, or if any of these policies or any of our representations, certifications, publications or frameworks are, in whole or part, found or perceived to be inaccurate, incomplete, deceptive, unfair or misrepresentative of our actual practices, could result in reputational harm, result in litigation, cause a material adverse impact to business operations or financial results and otherwise result in other material harm to our business.

If we or our existing or potential future collaborators, manufacturers or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates and may harm our reputation.

Healthcare providers, physicians and third-party payors, among others, will play a primary role in the prescription and recommendation of any product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers and customers, among others, may expose us to broadly

[Table of Contents](#)

applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. See section titled “*Business - Government Regulation - Other U.S. Healthcare Laws*” in the *Annual Report on Form 10-K for the year ended December 31, 2022*.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil, and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.

Even if we receive marketing and commercialization approval of a product candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after a product is made commercially available, both in the United States and any foreign jurisdiction in which we seek regulatory approval. The FDA and other regulatory authorities have significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product candidate from the market. The FDA and other regulatory authorities also have the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMP and cGTP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product candidate, manufacturer or facility, including withdrawal of the product candidate from the market. We intend to rely on third-party manufacturers and we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the U.S. or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

[Table of Contents](#)

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Further, due to the COVID-19 pandemic, millions of individuals have lost employer-based insurance coverage, which may adversely affect our ability to commercialize our products. It is unclear what effect, if any, the American Rescue Plan will have on the number of covered individuals. See section titled “*Business - Government Regulation - Coverage and Reimbursement*” in the *Annual Report on Form 10-K for the year ended December 31, 2022*.

Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

Cost-containment is a priority in the U.S. healthcare industry and elsewhere. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its product. Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the U.S. can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly

[Table of Contents](#)

or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We adopted a Code of Business Conduct and Ethics and we expect to prepare and implement policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Risks Related to Senti and the shares of our common stock

Our stock price is volatile, and you could lose part of all of your investment.

Similar to the trading prices of the common stock of other biotechnology companies, the trading price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our shares of our Common Stock may be influenced by many factors, including the other risks described in the section of the Quarterly Report entitled "Risk Factors" and the following:

- our ability to advance our current or potential future product candidates into the clinic;
- results of preclinical studies for our current or potential future product candidates, or those of our competitors or potential future collaborators;
- the impact of macroeconomic conditions;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our future products;
- our ability to successfully construct and operate our planned cGMP and cGTP facility;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization collaborators, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory authorities with respect to our future products, clinical trials, manufacturing process or sales and marketing terms;

[Table of Contents](#)

- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including, but not limited to, those with any sources of manufacturing supply and future commercialization collaborators;
- market conditions in the pharmaceutical and biotechnology sectors;
- market conditions and sentiment involving companies that have recently completed a business combination with a special purpose acquisition company, or SPAC;
- announcements by us or our competitors of significant acquisitions, strategic alliances, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which it is raised;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or the industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of shares of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of shares of our common stock;
- changes in accounting principles;

[Table of Contents](#)

- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, public health crises and other calamities; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for SPAC post-Merger businesses, pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility, including since the public announcement of the Business Combination Agreement in December 2021. This volatility can often be unrelated to the operating performance of the underlying business. These broad market and industry factors may seriously harm the market price of shares of our common stock, regardless of our operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

We may incur significant costs from class action litigation due to the expected stock volatility.

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of development efforts for our platform and product candidates, the development efforts of future collaborators or competitors, the addition or departure of key personnel, variations in quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years, including since the public announcement of the Business Combination Agreement in December 2021. In addition, recently there has been significant stock price volatility involving the shares of companies that have recently completed a Merger with a SPAC. When the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. Additionally, there has recently been a general increase in litigation against companies that have recently completed a Merger with a SPAC alleging fraud and other claims based on inaccurate or misleading disclosures. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of management.

We are an "emerging growth company" and it cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the shares of our common stock less attractive to investors and may make it more difficult to compare performance with other public companies.

We are an emerging growth company as defined in the JOBS Act, and we intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors may find shares of our common stock less attractive because we will continue to rely on these exemptions. If some investors find our shares of our common stock less attractive as a result, there may be a less active trading market for their common stock, and the stock price may be more volatile.

An emerging growth company may elect to delay the adoption of new or revised accounting standards. With DYNS making this election, Section 102(b)(2) of the JOBS Act allows us to delay adoption of new or revised accounting standards until those standards apply to non-public business entities.

We are also a "smaller reporting company" as defined in the Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

[Table of Contents](#)

As a result, the condensed financial statements contained in this Quarterly Report and those that we will file in the future may not be comparable to companies that comply with public business entities revised accounting standards effective dates.

If certain holders of our common stock sell a significant portion of their securities, it may negatively impact the market price of the shares of our common stock and such holders still may receive significant proceeds.

As of the date of this Quarterly Report on Form 10-Q, the market price of our common stock is below \$10.00 per share, which was the price per share of common stock sold in the initial public offering of our predecessor, DYNS, the per share price of the 5,060,000 shares of our Common Stock sold to certain investors in connection with our PIPE financing and also the per share value of the consideration issued to former stockholders of Senti Sub I, Inc. (formerly Senti Biosciences, Inc.) upon consummation of our Merger. However, certain of our stockholders who hold shares of our common stock that were (i) originally purchased by our predecessor's sponsor, Dynamics Sponsor LLC, in a private placement prior to our predecessor's initial public offering (the "Founder Shares") or (ii) issued to the Anchor Investors in consideration for their agreement not to redeem their shares of Class A common stock of DYNS in connection with the Merger. In particular, 4,878,972 of the Founder Shares registered for resale in our prospectus dated August 8, 2022 filed pursuant to Rule 424(b)(3) (Registration No. 333-265873), as supplemented from time to time (the "Prior Resale Prospectus"), were purchased at an effective price of \$0.004 per share, and 871,028 of the shares of our common stock held by the Anchor Investors and registered for resale in the Prior Resale Prospectus were issued solely in consideration for the Anchor Investors' agreement not to redeem their shares of Class A common stock as described above. Accordingly, holders of these 5,750,000 shares of our common stock could sell their securities at a per share price that is less than \$10.00 and still realize a significant return from the sale of those securities that could not be realized by our other stockholders. On August 1, 2023, the closing price of our common stock as reported on the Nasdaq Global Market was \$0.93 per share. Based on this closing price, the aggregate sales price of the Founder Shares would be approximately \$4.5 million and the aggregate sales price of the shares of our common stock held by the Anchor Investors would be approximately \$0.8 million.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

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

Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also filed registration statements on Form S-8 registering shares of common stock issued or reserved for future issuance under our equity compensation plans. Shares registered under a registration statement on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold in the public market, the market price of our common stock could decline.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Significant additional capital will be needed in the future to continue our planned operations, including further development of our gene circuit platform, preparing IND or equivalent filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner as determined from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of shares of our common stock.

[Table of Contents](#)

Pursuant to the Senti Biosciences, Inc. Equity Incentive Plan, our board of directors or compensation committee is authorized to grant stock options to our employees, directors and consultants. Initially, the maximum aggregate number of shares of our common stock that may be issued pursuant to stock awards under the Incentive Plan was 2,492,735 shares of our common stock. Additionally, the number of shares of our common stock reserved for issuance under the Incentive Plan automatically increases on January 1 of each year, beginning on January 1, 2023 and continuing through and including January 1, 2032, by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. In addition, on August 5, 2022, our board of directors adopted the 2022 Inducement Plan, pursuant to which an aggregate of 2,000,000 shares of our common stock have been reserved for issuance. Our issuance of additional shares of common stock or other equity securities of equal or senior rank would, all else being equal, have the following effects:

- the amount of cash available per share, including for payment of dividends in the future, may decrease;
- the relative voting strength of each previously outstanding share of common stock would be diminished; and
- the market price of shares of our common stock may decline.

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

We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of shares of our common stock.

We currently expect that securities research analysts will establish and publish their own periodic financial projections for our business. These projections may vary widely and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect research analyst coverage, if no analysts commence coverage of us, the trading price and volume for shares of our common stock could be adversely affected.

The obligations associated with being a public company will involve significant expenses and will require significant resources and management attention, which may divert from our business operations.

As a public company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. As a result, we will incur significant legal, accounting and other expenses that we did not previously incur. Our entire management team and

[Table of Contents](#)

many of our other employees will need to devote substantial time to compliance, and may not effectively or efficiently manage our transition into a public company.

These rules and regulations will result in us incurring substantial legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations will likely make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

Provisions in our second amended and restated certificate of incorporation (“Charter”), our amended and restated bylaws, or Bylaws, and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management, which could depress the trading price of shares of our common stock.

Our Charter, Bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our Charter and Bylaws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms, such that not all members of the board will be elected at one time;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our Bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our Charter and Bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of shares of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

[Table of Contents](#)

Any provision of our Charter, Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for shares of our common stock.

Our Bylaws designate the Court of Chancery of the State of Delaware as the exclusive forum for certain state law litigation that may be initiated by our stockholders and the U.S. federal district courts as the exclusive forum for certain securities law actions, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum and increase the costs for our stockholders to pursue certain claims against us.

Pursuant to our Bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our Charter or our Bylaws (including their interpretation, validity or enforceability); or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Stockholders cannot waive compliance with the Securities Act, the Exchange Act or any other federal securities laws or the rules and regulations thereunder. Unless we consent in writing to the selection of an alternate forum, the United States federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these exclusive forum provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder. The forum selection provisions in our Bylaws may impose additional litigation costs on stockholders in pursuing any such claims and may limit our stockholders' ability to litigate disputes with us in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce the federal forum provision. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities.

If we fail to satisfy the continued listing requirements of Nasdaq such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

[Table of Contents](#)

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General Risk Factors

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures similar to the response to the COVID-19 pandemic and may experience delays in their regulatory activities.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in the San Francisco Bay Area. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemics, including any potential effects from the current global spread of COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our headquarters, or the manufacturing facilities of our third-party contract manufacturers, may have a material adverse effect on our ability to operate our business, particularly on a daily basis and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics, such as the COVID-19 outbreak could further disrupt our operations and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the

[Table of Contents](#)

manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our headquarters or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material adverse effect on our business, financial condition, results of operations and prospects.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of preclinical studies and clinical trials or funding support by us or potential future collaborators;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any of our existing or potential future collaboration, licensing or similar arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject

[Table of Contents](#)

to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers, or that we 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 claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

[Table of Contents](#)

Item 6. Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

Exhibit Number	Description
10.1†*	Amendment No. 2 to the Research and License Agreement between Spark Therapeutics, Inc. and Senti Biosciences, Inc., dated May 12, 2023.
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	The cover page for the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101.

* Filed herewith.

** Furnished herewith. This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

† Portions of this exhibit (indicated by asterisks) have been omitted because the registrant has determined that the information is both not material and is of the type that the registrant treats as private or confidential.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized on this 11th day of August, 2023.

Date: August 11, 2023

SENTI BIOSCIENCES, INC.

By: /s/ Timothy Lu, M.D., Ph.D.
Name: Timothy Lu, M.D., Ph.D.
Title: Chief Executive Officer & President

By: /s/ Deborah Knobelman, Ph.D.
Name: Deborah Knobelman, Ph.D.
Title: Chief Financial Officer and Head of Corporate Development

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Timothy Lu, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, of Senti Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, 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 my 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: August 11, 2023

By: /s/ Timothy Lu, M.D., Ph.D.
Timothy Lu, M.D., Ph.D.
Chief Executive Officer and President
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Deborah Knobelman, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, of Senti Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, 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 my 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: August 11, 2023

By: /s/ Deborah Knobelman, Ph.D.
Deborah Knobelman, Ph.D.
Chief Financial Officer, Treasurer and Head of Corporate
Development
(Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report of Senti Biosciences, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Timothy Lu, M.D., Ph.D., Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: August 11, 2023

By: /s/ Timothy Lu, M.D., Ph.D.
Timothy Lu, M.D., Ph.D.
Chief Executive Officer and President
(Principal Executive Officer)

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

In connection with the Quarterly Report of Senti Biosciences, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Deborah Knobelman, Ph.D., Chief Financial Officer, Treasurer and Head of Corporate Development of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: August 11, 2023

By: /s/ Deborah Knobelman, Ph.D.
Deborah Knobelman, Ph.D.
Chief Financial Officer, Treasurer and Head of Corporate
Development
(Principal Financial and Accounting Officer)

*Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark “[***]”.*

**AMENDMENT NO. 2
TO THE RESEARCH COLLABORATION AND LICENSE AGREEMENT BETWEEN
SPARK THERAPEUTICS, INC. AND
SENTI BIOSCIENCES, INC.**

This Amendment No. 2 (“Amendment”) to the Research Collaboration and License Agreement is made effective as of May 12, 2023 (“Amendment Effective Date”), by and between **Spark Therapeutics, Inc.** (“Spark”) and **Senti Biosciences, Inc.** (“Senti”), together, the “Parties.”

WHEREAS, Spark and Senti are parties to the Research Collaboration and License Agreement dated April 9, 2021, and an Amendment No. 1 dated December 8, 2022 (together, the “Agreement”).

WHEREAS, the Parties desire to further amend the Agreement as more particularly set forth below.

NOW THEREFORE, in consideration of the foregoing premises and mutual covenants contained herein, intending to be legally bound hereby, the Parties agree to amend the Agreement as follows:

1. The Research Plan, including the Research Term, on a Promoter Profile-by-Promoter Profile basis, is updated as set forth in Exhibit C, Attachment 1, attached hereto. The Research Term will end on July 31, 2023.
2. The following is added to Section 7.2.1: “Spark will reimburse Senti for additional research support costs, not to exceed [***] of the ‘Research Budget.’”
3. Effect of Amendment. Except as amended herein, all other provisions of the Agreement shall remain in full force and effect.
4. Counterparts. This Amendment can be executed in counterparts, each of which shall be deemed to be an original, and all such counterparts together shall constitute one and the same Amendment.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date.

SENTI BIOSCIENCES, INC.

By: /s/ Tim Lu
Name: Tim Lu
Title: CEO
Date: 6/26/2023

SPARK THERAPEUTICS, INC.

By: /s/ Kevin McBride
Name: Kevin McBride
Title: Sr. Financial Reporting Lead
Date: 6/29/2023

EXHIBIT C, ATTACHMENT 1

[***]