UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

OR

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT OF 1934**

From the transition period from to .

Commission File Number 001-36076

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**65-1311552**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
12278 Scripps Summit Drive, San Diego, CA	**92131**
(Address of principal executive offices)	**(Zip Code)**

(858) 875-1800

(Registrant's telephone number, including area code)

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	FATE	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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

As of November 6, 2025, 115,352,289 shares of the registrant's common stock, par value $0.001 per share, were issued and outstanding.

FATE THERAPEUTICS, INC.

FORM 10-Q

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RISK FACTOR SUMMARY

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

- Our product candidates and programs represent novel therapeutic approaches to treating disease, and our product candidates may cause undesirable side effects or have other properties that could delay or halt their preclinical or clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. If we fail to complete the preclinical or clinical development of, or to obtain regulatory approval for, our product candidates on a timely basis or at all, our business would be significantly harmed.
- Development of our product candidates will require substantial additional funding, which, if available, may cause dilution to our stockholders, and without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates. Additionally, we may not be able to secure adequate funding on acceptable terms or on a timely basis.
- Our proprietary induced pluripotent stem cell (iPSC) product platform enables the production of next-generation product candidates, and we have multiple iPSC-derived cell product candidates currently undergoing clinical development. We may elect to deprioritize or discontinue the clinical development of one or more of our product candidates for any number of reasons, including due to our prioritization of product candidates, data or results from our ongoing clinical trials, and the competitive therapeutic landscape for which our product candidates are being developed. In addition, one or more of our product candidates undergoing clinical development may have therapeutic potential in more than one disease area, and we may elect to prioritize clinical development in one disease area over another disease area.
- We use iPSC technology and gene-editing technology in the creation of our product candidates. If we are unable to use these technologies in the creation of our product candidates, our business would be significantly harmed.
- We may face delays in initiating, conducting or completing our clinical trials, including difficulties recruiting appropriate clinical trial investigators, enrolling patients in our clinical trials, or manufacturing adequate clinical supplies, and we may not be able to initiate, conduct or complete our clinical trials at all.
- We face significant competition in an environment of rapid technological change from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively, including with respect to the recruitment of patients and investigative sites to participate in our clinical trials.
- Initial, interim and preliminary data from our preclinical studies or clinical trials may change as more data becomes available and are subject to audit and verification procedures that could result in material changes in the final data. Furthermore, results from our ongoing or future clinical trials involving our product candidates may differ materially from initial, interim and preliminary data as well as previous study results.
- The manufacture and distribution of our product candidates is complex and subject to a multitude of risks. Additionally, the U.S. Food and Drug Administration (FDA) or foreign regulatory authorities may impose additional requirements on our manufacturing operations. These risks and requirements could substantially limit our supply of our product candidates and increase our costs, and the development and commercialization of our product candidates could be significantly delayed or restricted.
- Inadequate funding for the FDA, SEC, the National Institutes of Health and other government agencies, as well as changes in personnel at these agencies, could disrupt such agencies' operations and, in turn, hinder our ability to develop or commercialize new products in a timely manner or otherwise negatively impact our business.
- We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. Any failure to manufacture sufficient quantities of our product candidates consistently and at acceptable quality and costs may result in delays to our clinical development plans and impair our ability to obtain approval for, or commercialize, our product candidates and would materially and adversely affect our business.
- We depend on third-party suppliers, including sole source suppliers, for certain equipment and components used in the production of our product candidates, and the loss of suppliers could adversely impact our ability to conduct our clinical trials.
- We may face challenges recruiting and retaining key personnel due to labor market changes, availability of qualified candidates, and competition for employees from other companies.

- We may face cost fluctuations and inflationary pressures, including increases in prices of materials and costs of labor, which may adversely impact our operating performance, expenses, cash utilization and results.
- We depend on strategic partnerships and collaboration arrangements for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements are unsuccessful or are terminated, this could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and materially harm our results of operations.
- We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.
- If we are unable to protect our intellectual property or obtain and maintain patent protection for our technology and product candidates, other companies could develop products based on our technologies and discoveries, which may reduce demand for, or limit the commercial potential of, our products and harm our business.
- If we fail to comply with our obligations under our intellectual property license agreements, we could lose rights to our product candidates or key technologies.
- We may not be successful in obtaining or maintaining necessary rights to product components and processes for development or manufacture of our product candidates, which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.
- We do not have experience marketing any product candidates and do not have a sales force or distribution capabilities, and if our products are approved, we may be unable to commercialize them successfully.
- The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community and may require additional evidence to support the anticipated benefits, comparative risks, and costs.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business and adversely impact our operations.
- Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over our company.
- Our stock price is subject to fluctuation based on a variety of factors.
- We currently qualify as a “smaller reporting company” and a “non-accelerated filer,” and any decision on our part to comply with only certain reduced reporting and disclosure requirements applicable to such companies could make our stock less attractive to investors.
- Global economic and market conditions, any continued and prolonged public health emergency, global geopolitical tensions, including wars and other armed conflicts, or significant political, trade, economic or regulatory developments in the jurisdictions in which we may develop or commercialize our product candidates or conduct our operations, could adversely impact various aspects of our business, results of operations and financial condition, and could cause disruptions to our supply chain and the development and manufacture of our product candidates.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Fate Therapeutics, Inc.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 40,622	$ 36,056
Accounts receivable	682	3,539
Short-term investments	174,801	243,012
Prepaid expenses and other current assets	5,146	9,302
Total current assets	221,251	291,909
Long-term investments	10,305	27,657
Property and equipment, net	59,475	64,384
Operating lease right-of-use assets	42,413	46,508
Restricted cash	10,227	10,227
Other assets	—	9
Total assets	$ 343,671	$ 440,694
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,504	$ 9,365
Accrued expenses	17,571	21,348
CIRM award liability, current portion	2,280	—
Deferred revenue	5	393
Operating lease liabilities, current portion	4,751	7,416
Total current liabilities	28,111	38,522
CIRM award liability, net of current portion	6,590	5,070
Operating lease liabilities, net of current portion	74,494	77,849
Stock price appreciation milestones	410	527
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized shares— 5,000,000 at September 30, 2025 and December 31, 2024; Class A Convertible Preferred shares issued and outstanding— 2,755,086 at September 30, 2025 and December 31, 2024	3	3
Common stock, $0.001 par value; authorized shares— 350,000,000 at September 30, 2025 and 250,000,000 at December 31, 2024; issued and outstanding— 115,336,697 at September 30, 2025 and 113,928,279 at December 31, 2024	115	114
Additional paid-in capital	1,735,730	1,716,335
Accumulated other comprehensive income	153	268
Accumulated deficit	(1,501,935)	(1,397,994)
Total stockholders' equity	234,066	318,726
Total liabilities and stockholders' equity	$ 343,671	$ 440,694

See accompanying notes.

Fate Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(unaudited)		(unaudited)	
Collaboration revenue	$ 1,741	$ 3,074	$ 5,277	$ 11,771
Operating expenses:				
Research and development	25,838	34,650	82,404	101,392
General and administrative	10,638	20,801	35,856	58,907
Total operating expenses	36,476	55,451	118,260	160,299
Loss from operations	(34,735)	(52,377)	(112,983)	(148,528)
Other income (expense):				
Interest income	2,575	4,438	8,832	13,414
Change in fair value of stock price appreciation milestones	(90)	(13)	117	149
Other income	—	274	93	856
Total other income	2,485	4,699	9,042	14,419
Net loss	$ (32,250)	$ (47,678)	$ (103,941)	$ (134,109)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities, net	91	1,257	(115)	820
Comprehensive loss	$ (32,159)	$ (46,421)	$ (104,056)	$ (133,289)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.40)	$ (0.88)	$ (1.19)
Weighted-average common shares used to compute basic and diluted net loss per share	118,998,693	117,769,161	118,636,375	112,305,430

See accompanying notes.

Fate Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2025	2024
	(unaudited)	
Operating activities		
Net loss	$ (103,941)	(134,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,838	14,149
Stock-based compensation	19,396	32,376
Accretion and amortization of premiums and discounts on investments, net	(2,725)	(7,550)
Deferred revenue	(389)	(685)
Change in fair value of stock price appreciation milestones	(117)	(149)
(Gain) loss on disposal of property and equipment	(36)	942
Changes in operating assets and liabilities:		
Accounts receivable	2,857	(1,701)
Prepaid expenses and other assets	4,165	5,294
Accounts payable and accrued expenses	(9,892)	(2,316)
Right-of-use assets and lease liabilities, net	(1,926)	(1,326)
Net cash used in operating activities	(82,770)	(95,075)
Investing activities		
Proceeds from sale of property and equipment	125	—
Purchases of property and equipment	(4,761)	(632)
Purchases of investments	(157,412)	(279,745)
Maturities of investments	245,584	269,779
Net cash provided by (used in) investing activities	83,536	(10,598)
Financing activities		
Issuance of common stock from equity incentive plans, net of issuance costs	—	295
Proceeds from public offering of common stock, net of issuance costs	—	74,531
Proceeds from issuance of pre-funded warrants, net of issuance costs	—	19,996
Proceeds from FT819 CIRM award	—	1,940
Proceeds from FT836 CIRM award	3,800	—
Net cash provided by financing activities	3,800	96,762
Net change in cash, cash equivalents and restricted cash	4,566	(8,911)
Cash, cash equivalents and restricted cash at beginning of the period	46,283	57,047
Cash, cash equivalents and restricted cash at end of the period	$ 50,849	$ 48,136
Supplemental schedule of noncash investing and financing activities		
Purchases of property and equipment in accounts payable	$ 398	$ 16

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization

Fate Therapeutics, Inc. (the Company) was incorporated in the state of Delaware on April 27, 2007 and has its principal operations in San Diego, California. The Company is a clinical-stage biopharmaceutical company dedicated to bringing off-the-shelf, multiplexed-engineered, induced pluripotent stem cell (iPSC)-derived cellular immunotherapies to patients.

As of September 30, 2025, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated any revenues from any sales of its therapeutic product candidates. To date, the Company's revenues have been derived from collaboration agreements and government grants.

Corporate Restructuring

In August 2025, the Company implemented a corporate restructuring to streamline operations, reduce operating expenses, and extend cash runway. In connection with the restructuring, the Company committed to a reduction in total workforce. Affected employees were informed on August 12, 2025. The Company incurred charges of $1.1 million during the three months ended September 30, 2025 for severance and other employee termination-related costs. As of September 30, 2025, all restructuring and related expenses have been fully recognized and paid by the Company.

Use of Estimates

The Company's unaudited condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP). The preparation of the Company's unaudited condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's unaudited condensed consolidated financial statements and accompanying notes. The most significant estimates and assumptions in the Company's unaudited condensed consolidated financial statements relate to its stock price appreciation milestone obligations, contracts containing leases, and accrued expenses. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents include cash in readily available operating accounts, money market accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the unaudited condensed consolidated balance sheets that sum to the total of the same such amounts shown in the unaudited condensed consolidated statements of cash flows as of September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Cash and cash equivalents	$ 40,622	$ 37,909
Restricted cash	10,227	10,227
Total cash, cash equivalents, and restricted cash shown in the unaudited condensed consolidated statement of cash flows	$ 50,849	$ 48,136

For each of the nine months ended September 30, 2025 and 2024, the restricted cash balance includes a cash-collateralized irrevocable standby letter of credit for $10.2 million associated with the Company's facilities leases.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and following the requirements of the U.S. Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required can be condensed or omitted. The interim unaudited condensed consolidated financial statements should be read in conjunction with the Company's financial statements and accompanying notes for the fiscal year ended December 31, 2024, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, filed by the Company with the SEC on March 5, 2025. In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. The results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company assesses whether aspects of the arrangement between the Company and its collaboration partner are within the scope of other accounting literature, including ASC Topic 606, Revenue from Contracts with Customers (ASC 606). If it is concluded that some or all aspects of the arrangement represent a transaction with a customer, the Company will account for those aspects of the arrangement within the scope of ASC 606.

ASC 808 provides guidance for the presentation and disclosure of transactions in collaborative arrangements, but it does not provide recognition or measurement guidance. Therefore, if the Company concludes a counterparty to a transaction is not a customer or otherwise not within the scope of ASC 606, the Company considers the guidance in other accounting literature as applicable or by analogy to account for such transaction. The classification of transactions under the Company's arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants.

Revenue Recognition

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC 606.

For arrangements attributable to ASC 606, the Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service.

Leases

The Company determines if a contract contains a lease at the inception of the contract. The Company currently has leases related to its facilities leased for office and laboratory space, which are classified as operating leases. These leases result in operating right-of-use (ROU) assets, current operating lease liabilities, and non-current operating lease liabilities in the Company's consolidated balance sheets. The Company does not have any financing leases. Leases with a term of 12 months or less are considered short-term and ROU assets and lease obligations are not recognized. Payments associated with short-term leases are expensed on a straight-line basis over the lease term.

Lease liabilities represent an obligation to make lease payments arising from the lease and ROU assets represent the right to use the underlying asset identified in the lease for the lease term. Lease liabilities are measured at the present value of the lease payments not yet paid discounted using the discount rate for the lease established at the lease commencement date. To determine the present value, the implicit rate is used when readily determinable. For those leases where the implicit rate is not provided, the Company

determines an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. ROU assets are measured as the present value of the lease payments and also include any prepaid lease payments made and any other indirect costs incurred, and exclude any lease incentives received. Lease terms may include the impact of options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company aggregates all lease and non-lease components for each class of underlying assets into a single lease component.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. Performance-based stock units/awards represent a right to receive a certain number of shares of the Company's common stock based on the achievement of corporate performance goals and continued employment during the vesting period. At each reporting period, and to the extent achievement of one or any of the performance conditions is probable, the Company reassesses the probability of the achievement of such corporate performance goals and any increase or decrease in share-based compensation expense resulting from an adjustment in the estimated shares to be released is treated as a cumulative catch-up in the period of adjustment. For stock awards for which vesting is subject to both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, with the exception of option grants for which vesting is subject to both performance-based milestones and market conditions, which are valued using a lattice-based model. The fair value of restricted stock units, including performance-based restricted stock units, is based on the closing price of the Company's common stock as reported on the Nasdaq Global Market on the date of grant. The Company recognizes forfeitures for all awards as such forfeitures occur.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Other comprehensive loss includes unrealized gains and losses on available-for-sale securities.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. The pre-funded warrants associated with the January 2021 public equity offering and the private placement concurrent with the March 2024 public equity offering (see Note 8) are considered outstanding shares in the basic earnings per share calculation given their nominal exercise price. Dilutive common stock equivalents comprise convertible preferred stock, warrants for the purchase of common stock, and common stock options and restricted stock units outstanding under the Company's stock option plans. For all periods presented, there is no difference in the number of common shares used to calculate basic and diluted common shares outstanding due to the Company's net loss position.

Basic and diluted net loss per share attributable to stockholders for the three and nine months ended September 30, 2025 and 2024 are calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss	$ (32,250)	$ (47,678)	$ (103,941)	$ (134,109)
Denominator:				
Shares used to compute net loss per share, basic and diluted				
Weighted-average common shares outstanding	115,105,019	113,875,487	114,742,701	109,486,740
Weighted-average pre-funded warrants	3,893,674	3,893,674	3,893,674	2,818,690
Weighted-average common shares outstanding used to compute basic and diluted net loss per share	118,998,693	117,769,161	118,636,375	112,305,430
Net loss per share, basic and diluted				
Basic and diluted	$ (0.27)	$ (0.40)	$ (0.88)	$ (1.19)

The following weighted-average outstanding shares of potentially dilutive securities are excluded from the computation of diluted net loss per share for the periods presented because including them would have been anti-dilutive:

	As of September 30,	
	2025	2024
Convertible preferred stock	13,775,430	13,805,540
Outstanding options to purchase common stock	12,597,399	11,238,387
Outstanding restricted stock units	6,647,093	6,207,574
Total	33,019,922	31,251,501

2. Collaboration and License Agreements

Ono Collaboration and Option Agreement

On September 14, 2018, the Company entered into a Collaboration and Option Agreement (the Ono Agreement) with Ono Pharmaceutical Co., Ltd. (Ono) for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates (Candidate 1 and Candidate 2). Pursuant to the terms of the Ono Agreement, the Company received an upfront, non-refundable and non-creditable payment of $10.0 million. Additionally, the Company was entitled to receive funding for the conduct of research and preclinical development under a joint research plan, which fees were estimated to be $20.0 million in aggregate.

In December 2020, the Company entered into a letter agreement with Ono (the Ono Letter Agreement) pursuant to which Ono delivered proprietary antigen binding domains targeting an antigen expressed on certain solid tumors for incorporation into Candidate 2 and paid the Company a milestone fee of $10.0 million for further research and preclinical development of Candidate 2. In addition, Ono terminated all further research and preclinical development with respect to Candidate 1, and the Company retained all rights to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

In June 2022, the Company entered into an amendment with Ono to the Ono Agreement (the 2022 Ono Amendment). Pursuant to the 2022 Ono Amendment, the companies agreed to designate an additional antigen expressed on certain solid tumors for research and preclinical development, and Ono agreed to contribute proprietary antigen binding domains targeting such additional solid tumor antigen (Candidate 3). In addition, for both Candidate 2 and Candidate 3, Ono and the Company expanded the scope of the collaboration to include the research and preclinical development of iPSC-derived CAR NK cell product candidates (in addition to iPSC-derived CAR T-cell product candidates) targeting the designated solid tumor antigens. Similar to Candidate 2, the Company granted to Ono, during a specified period of time, a preclinical option (Candidate 3 Development Option) to obtain an exclusive license under certain intellectual property rights, subject to payment of an option exercise fee to the Company by Ono, to further develop and commercialize Candidate 3 in all territories of the world, where the Company retains rights to co-develop and co-commercialize Candidate 3 in the United States and Europe under a joint arrangement with Ono pursuant to which the Company is eligible to share at least 50% of the profits and losses. The Candidate 3 Development Option represents an option with no material right. Under the 2022 Ono Amendment, aggregate estimated research and preclinical development fees were increased by approximately $9.3 million, for a total estimated $29.3 million in aggregate research and preclinical development fees over the course of the joint research plan.

In November 2022, Ono exercised its option to obtain a license to develop and commercialize Candidate 2 (the Candidate 2 Development Option). The Company exercised its option (the CDCC Option) to co-develop and co-commercialize Candidate 2 in the United States and Europe. As a result, the Company received an Option Exercise Payment (as defined under the Ono Agreement) of $12.5 million. The Company and Ono are proceeding under a joint development plan for the ongoing development of Candidate 2. At the inception of the Ono Agreement, the Company determined the Candidate 2 Development Option represented an option with no material right that is distinct and separable from the ongoing development of Candidate 2 being performed by the parties. As such, the option exercise was treated as a separate contract with a single performance obligation of granting and delivering Ono a license to further develop and commercialize Candidate 2. The Company has completed its performance obligation with respect to the Candidate 2 Development Option and accordingly, recognized the Option Exercise Payment as revenue for the year ended December 31, 2022. The costs of this joint development plan are accounted for in accordance with ASC 808, and cost sharing payments to the Company from Ono are recorded net into research and development expenses. In addition, in connection with the ongoing joint development of Candidate 2, the Company is eligible to receive additional payments upon the achievement of certain clinical, regulatory, and commercial milestones (as further described below).

In November 2023, the Company entered into an amendment with Ono to the Ono Agreement (the 2023 Ono Amendment). Under the 2023 Ono Amendment, aggregate estimated research and preclinical development fees payable by Ono to the Company for Candidate 3 were increased by approximately $1.4 million, for a total estimated $30.7 million in aggregate research and preclinical development fees over the course of the joint research plan.

In May 2024, following Ono's exercise of the Candidate 2 Development Option and grant of the development and commercialization license, the Company achieved a $5.0 million clinical development milestone for Candidate 2 and recognized such amount as revenue during the nine months ended September 30, 2024.

In August 2024, the Company entered into an amendment with Ono to the Ono Agreement (the 2024 Ono Amendment). Under the 2024 Ono Amendment, aggregate estimated research and preclinical development fees payable by Ono to the Company for Candidate 3 were increased by approximately $7.3 million, for a total estimated $38.0 million in aggregate research and preclinical development fees over the course of the joint research plan.

In June 2025, the Company entered into an amendment with Ono to the Ono Agreement (the 2025 Ono Amendment, and collectively with the 2022 Ono Amendment, 2023 Ono Amendment, and 2024 Ono Amendment, the Ono Amendments). Under the 2025 Ono Amendment, aggregate estimated research and preclinical development fees payable by Ono to the Company for Candidate 3 were increased by approximately $6.5 million, for a total estimated $44.5 million in aggregate research and preclinical development fees over the course of the joint research plan. The Company will continue to receive committed funding under the joint research plan from Ono through June 2026. The Candidate 3 Development Option expires upon the achievement of the pre-defined preclinical milestone under the joint research plan.

Under the terms of the Ono Agreement (as amended by the Ono Amendments), for Candidate 2 and for Candidate 3 (subject to exercise by Ono of its Candidate 3 Development Option), the Company is eligible to receive additional payments upon the achievement of certain clinical, regulatory and commercial milestones (the Ono Milestones) with respect to each Candidate in an amount up to $843.0 million in aggregate, with the applicable milestone payments for the United States and Europe subject to reduction by 50% if the Company elects to co-develop and co-commercialize the Candidate in the United States and Europe as described above. In addition, in those territories where Ono has exclusive rights of commercialization, the Company is eligible to receive tiered royalties (Royalties) ranging from the mid-single digits to the low-double digits based on annual net sales by Ono for each Candidate in such territories, with the Royalties subject to certain reductions.

The Ono Agreement will terminate with respect to a Candidate if Ono does not exercise its development option for the applicable Candidate within the option period, or in its entirety if Ono does not exercise any of its development options for the Candidates within their respective option periods. In addition, either party may terminate the Ono Agreement in the event of breach, insolvency or patent challenges by the other party; provided, that Ono may terminate the Ono Agreement in its sole discretion (x) on a Candidate-by-Candidate basis at any time after the second anniversary of the effective date of the Ono Agreement or (y) on a Candidate-by-Candidate or country-by-country basis at any time after the expiration of the development option period, subject to certain limitations. The Ono Agreement will expire on a Candidate-by-Candidate and country-by-country basis upon the expiration of the applicable royalty term, or in its entirety upon the expiration of all applicable payment obligations under the agreement.

The Company determined that the Ono Agreement, Ono Letter Agreement, and Ono Amendments (collectively, the Ono Arrangement) were within the scope of ASC 808 and applicable to such guidance. The Company concluded that certain units of account, specifically the grant of a research license to certain intellectual property and the performance of research and preclinical development, within the Ono Arrangement represented a customer relationship and applied relevant guidance from ASC 606 to evaluate the appropriate accounting for those units of account. In accordance with this guidance, the Company identified its promised goods and services, including its grant of a research license to Ono to certain of its intellectual property subject to certain conditions, its conduct of research and preclinical development services, and its participation in a joint steering committee. The Company determined that its grant of a research license to Ono to certain of its intellectual property was not distinct from its conduct of research and preclinical development services and participation in a joint steering committee. Accordingly, the Company determined that the research license, the research and preclinical development services, and the participation in a joint steering committee during the development option period, should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and preclinical development services. The Company also determined that, subject to the guidance of ASC 606, the license to develop and commercialize Candidate 2 upon exercise of the Candidate 2 Development Option was distinct and separable from the development and commercialization activities, which are accounted for under ASC 808. The termination of the Ono Agreement with respect to Candidate 1 did not impact this assessment.

In accordance with ASC 606, the Company determined that the amended transaction price for research and preclinical development under the Ono Arrangement equaled $54.5 million, consisting of the upfront, non-refundable and non-creditable payment of $10.0 million and the aggregate estimated research and preclinical development fees of $44.5 million. The Company also concluded that the milestone fee of $10.0 million paid by Ono to the Company for further research and preclinical development of Candidate 2 represented a variable consideration that was previously constrained. Both the upfront payment of $10.0 million and the Candidate 2 milestone fee of $10.0 million were recorded as deferred revenue and were recognized as revenue over time in conjunction with the Company's conduct of research and preclinical development services based on actual costs incurred as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research and preclinical

development services. The Company recorded the $5.0 million prepayment of the first-year research and preclinical development fees as deferred revenue, and such fees were recognized as revenue as the research and preclinical development services were delivered.

The Company recognized revenue associated with research and preclinical development services of $1.7 million and $5.3 million under the Ono Arrangement for the three and nine months ended September 30, 2025, respectively. During the three and nine months ended September 30, 2024, the Company recognized revenue associated with research and preclinical development services of $3.1 million and $11.8 million, respectively.

The Company recognized contra-research and development expense of $1.3 million and $4.5 million associated with the joint development of Candidate 2 under the Ono Arrangement for the three and nine months ended September 30, 2025, respectively. During the three and nine months ended September 30, 2024, the Company recognized contra-research and development expense of $1.7 million and $3.6 million, respectively.

Memorial Sloan Kettering Cancer Center License Agreement

On May 15, 2018, the Company entered into an Amended and Restated Exclusive License Agreement (the Amended MSKCC License) with MSKCC. The Amended MSKCC License amends and restates the Exclusive License Agreement entered into between the Company and MSKCC on August 19, 2016 (the Original MSKCC License), pursuant to which the Company entered into an exclusive license agreement with MSKCC for rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T-cells and NK-cells derived from iPSCs engineered with chimeric antigen receptors (CARs).

Pursuant to the Amended MSKCC License, MSKCC granted to the Company additional licenses to certain patents and patent applications relating to new CAR constructs and off-the-shelf CAR T-cells, including the use of clustered regularly interspaced short palindromic repeat (CRISPR) and other innovative technologies for their production, in each case to research, develop, and commercialize licensed products in the field of all human therapeutic uses worldwide. The Company has the right to grant sublicenses to certain licensed rights in accordance with the terms of the Amended MSKCC License, in which case it is obligated to pay MSKCC a percentage of certain sublicense income received by the Company.

The Company is obligated to pay MSKCC an annual license maintenance fee during the term of the agreement, milestone payments upon the achievement of specified clinical, regulatory and commercial milestones for licensed products as well as royalty payments on net sales of licensed products.

In the event a licensed product achieves a specified clinical milestone, MSKCC is then eligible to receive certain milestone payments totaling up to $75.0 million based on the price of the Company’s common stock, where the amount of such payments owed to MSKCC is contingent upon certain increases in the price of the Company’s common stock following the date of achievement of such clinical milestone. These payments are based on common stock price multiples, with the numerator being the fair value of the ten-trading day trailing average closing price of the Company’s common stock and the denominator being the ten-trading day trailing average closing price of the Company’s common stock as of the effective date of the Amended MSKCC License, adjusted for any stock splits, cash dividends, stock dividends, other distributions, combinations, recapitalizations, or similar events. Under the terms of the Amended MSKCC License, upon a change of control of the Company, in certain circumstances, the Company may be required to pay a portion of these payments to MSKCC based on the price of the Company’s common stock in connection with such change of control.

The following table summarizes the common stock multiples and the stock price appreciation milestone payments under the terms of the Amended MSKCC License:

Common stock multiple		5.0x		10.0x	15.0x
Ten-trading day trailing average common stock price	$	50.18	$	100.36	$ 150.54
Stock price appreciation milestone payment (in millions)	$	20.0	$	30.0	$ 25.0

In July 2021, the Company achieved the specified clinical milestone for a licensed product under the Amended MSKCC License and the Company's ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, the Company remitted the first milestone payment of $20.0 million to MSKCC during the year ended December 31, 2021.

To determine the estimated fair value of the remaining stock price appreciation milestones, the Company uses a Monte Carlo simulation methodology which models future Company common stock prices based on the current stock price and several key variables.

The key inputs to the Monte Carlo simulation to determine the fair value of the stock price appreciation milestones include the Company's stock price as of the measurement date; the estimated term which is based in part on the last valid patent claim date; the expected volatility of the Company's common stock, estimated using the Company's historical common stock volatility as of the remeasurement date; and the risk-free rate based on the U.S. Treasury yield for the estimated term determined. Fair value measurements are highly sensitive to changes in these inputs and significant changes could result in a significantly higher or lower fair value and resulting expense or gain.

At each balance sheet date, the Company remeasures the fair value of the stock price appreciation milestones, with changes in fair value recognized as a component of other income (expense) in the unaudited condensed consolidated statements of operations and comprehensive loss. Amounts are included in current or non-current liabilities based on the estimated timeline associated with the individual potential payments. During the three and nine months ended September 30, 2025, the Company recorded other expense of $0.1 million and other income of $0.1 million, respectively, associated with the change in fair value of the stock price appreciation milestones. During the three and nine months ended September 30, 2024, the Company recorded expense of $0.1 million and other income of $0.1 million, respectively, associated with the change in fair value of the stock price appreciation milestone. As of September 30, 2025 and December 31, 2024, the Company recorded a liability of $0.4 million and $0.5 million, respectively, associated with the stock price appreciation milestones for the Amended MSKCC License.

3. California Institute for Regenerative Medicine Awards

FT819 CIRM Award

In February 2024, the Company was awarded $7.9 million from the California Institute for Regenerative Medicine (CIRM) to support the conduct of the Company's Phase 1 study of FT819 in patients with systemic lupus erythematosus and, in April 2024, the Company executed an award agreement with CIRM (the FT819 CIRM Award). Pursuant to the terms of the FT819 CIRM Award, the Company is eligible to receive five disbursements in varying amounts from CIRM, with one disbursement receivable upon the execution of the award and four disbursements receivable based upon the completion of certain development milestones throughout the period of the award, which is estimated to be from April 1, 2024 to March 31, 2028 (the Award Period). Under the FT819 CIRM Award, the Company has certain obligations of co-funding and is required to provide CIRM progress and financial update reports throughout the Award Period.

Following the conclusion of the Award Period, the Company, in its sole discretion, has the option to treat the FT819 CIRM Award either as a loan or as a grant. If the Company does not elect to treat the FT819 CIRM Award as a loan within 10 years of the award date, the award will be considered a grant and the Company will be obligated to pay CIRM, on a quarterly basis, a low single-digit royalty on commercial sales of FT819 until such aggregate royalty payments equal nine times the total amount awarded to the Company under the FT819 CIRM Award.

Since the Company may, at its election, repay some or all of the FT819 CIRM Award, the Company accounts for the award as a liability until the time of election. As of September 30, 2025, the Company has received two disbursements under the FT819 CIRM Award in the aggregate amount of $5.1 million, which is recorded as a liability on the accompanying consolidated balance sheets. As of September 30, 2025, the entire balance is classified as non-current as the Company does not expect any amount to be payable within the next 12 months.

FT836 CIRM Award

In January 2025, the Company was awarded $4.0 million from CIRM to support the conduct of preclinical and Investigational New Drug (IND)-enabling activities for FT836, and in May 2025, the Company executed an award agreement with CIRM (the FT836 CIRM Award). Pursuant to the terms of the FT836 CIRM Award, the Company is eligible to receive four disbursements in varying amounts from CIRM, with one disbursement receivable upon the execution of the award and three disbursements receivable based upon the completion of certain development milestones throughout the period of the award, which is estimated to be from May 1, 2025 to October 31, 2025 (the Award Period). Under the FT836 CIRM Award, the Company has certain obligations of co-funding and is required to provide CIRM progress and financial update reports throughout the Award Period.

Following the conclusion of the Award Period, the Company, in its sole discretion, has the option to treat the FT836 CIRM Award either as a loan or as a grant. If the Company does not elect to treat the FT836 CIRM Award as a loan within 10 years of the award date, the award will be considered a grant and the Company will be obligated to pay CIRM, on a quarterly basis, a low

single-digit royalty on commercial sales of FT836 until such aggregate royalty payments equal nine times the total amount awarded to the Company under the FT836 CIRM Award.

Since the Company may, at its election, repay some or all of the FT836 CIRM Award, the Company accounts for the award as a liability until the time of election. As of September 30, 2025, the Company has received three disbursements under the FT836 CIRM Award in the aggregate amount of $3.8 million. As of September 30, 2025, the total amount received is recorded as a CIRM liability in the consolidated balance sheets, with $2.3 million classified as current and the remaining $1.5 million as non-current, based on the portion expected to be payable within twelve months from the balance sheet date.

4. Investments

The Company invests portions of excess cash in United States treasuries, commercial paper, non-U.S. government securities, municipal securities, and corporate debt securities with maturities ranging from three to thirty-six months from the purchase date. These investments are accounted for as available-for-sale securities and are classified as short-term and long-term investments in the accompanying consolidated balance sheets based on each security's contractual maturity date. There were no significant realized losses on available-for-sale securities during the period ended September 30, 2025. As of September 30, 2025, the Company did not intend to sell the investments in an unrealized loss position and it was unlikely that the Company will be required to sell the investments before the recovery of their amortized cost basis.

The following table summarizes the Company's investments accounted for as available-for-sale securities as of September 30, 2025 and December 31, 2024 (in thousands, except for maturity in years):

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
September 30, 2025					
Classified as current assets:					
Money market fund	1 or less	$ 23,316	$ —	$ —	$ 23,316
U.S. Treasury debt securities	1 or less	41,672	—	33	41,705
Non-US government securities	1 or less	3,227	—	3	3,230
Corporate debt securities	1 or less	101,309	(13)	116	101,412
Commercial paper	1 or less	34,416	(3)	13	34,426
Total short-term investments		$ 203,940	$ (16)	$ 165	$ 204,089
Classified as non-current assets:					
Corporate debt securities	Greater than 1	10,301	—	4	10,305
Total long-term investments		$ 10,301	$ —	$ 4	$ 10,305
December 31, 2024					
Classified as current assets:					
Money market fund	1 or less	$ 29,491	$ —	$ —	$ 29,491
U.S. Treasury debt securities	1 or less	40,206	(6)	91	40,291
Non-US government securities	1 or less	2,994	—	1	2,995
Municipal securities	1 or less	2,490	—	2	2,492
Corporate debt securities	1 or less	170,169	(70)	228	170,327
Commercial paper	1 or less	26,903	(10)	14	26,907
Total short-term investments		$ 272,253	$ (86)	$ 336	$ 272,503
Classified as non-current assets:					
U.S. Treasury debt securities	Greater than 1	$ 9,752	$ (9)	$ 2	$ 9,745
Corporate debt securities	Greater than 1	17,887	(7)	32	17,912
Total long-term investments		$ 27,639	$ (16)	$ 34	$ 27,657

As of September 30, 2025 and December 31, 2024, the Company had $1.4 million and $2.1 million, respectively, of accrued interest on investments recorded in prepaid expenses and other assets on the unaudited condensed consolidated balance sheets.

5. Fair Value Measurements

The following table presents the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2025 and December 31, 2024 (in thousands):

	Total	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of September 30, 2025				
Financial assets:				
Money market funds	$ 23,316	$ 23,316	$ —	$ —
U.S. Treasury debt securities	41,705	41,705	—	—
Non-US government securities	3,230	—	3,230	—
Corporate debt securities	111,717	—	111,717	—
Commercial paper	34,426	—	34,426	—
Total financial assets measured at fair value on a recurring basis	$ 214,394	$ 65,021	$ 149,373	$ —
Financial liabilities:				
Stock price appreciation milestones	$ 410	$ —	$ —	$ 410
Total financial liabilities measured at fair value on a recurring basis	$ 410	$ —	$ —	$ 410
As of December 31, 2024				
Financial assets:				
Money market funds	$ 29,491	$ 29,491	$ —	$ —
U.S. Treasury debt securities	50,036	50,036	—	—
Non-U.S. government securities	2,995	—	2,995	—
Municipal securities	2,492	—	2,492	—
Corporate debt securities	188,239	—	188,239	—
Commercial paper	26,907	—	26,907	—
Total assets measured at fair value on a recurring basis	$ 300,160	$ 79,527	$ 220,633	$ —
Financial liabilities:				
Stock price appreciation milestones	$ 527	$ —	$ —	$ 527
Total financial liabilities measured at fair value on a recurring basis	$ 527	$ —	$ —	$ 527

Level 1 assets consisted of money market funds and U.S. Treasury securities measured at fair value based on quoted prices in active markets as provided by the Company's investment managers.

Level 2 assets consisted of corporate debt securities, commercial paper, municipal securities, and non-U.S. government securities measured at fair value using standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers. The Company validates the quoted market prices provided by its investment managers by comparing the investment managers' assessment of the fair values of the Company's investment portfolio balance against the fair values of the Company's investment portfolio balance obtained from an independent source.

There were no Level 3 assets held by the Company as of September 30, 2025.

Level 3 liabilities consisted of stock price appreciation milestones associated with the Amended MSKCC License as described in detail in Note 2.

The following table presents the changes in fair value of the Company's Level 3 stock price appreciation milestones liability for the nine months ended September 30, 2025 (in thousands):

Balance at December 31, 2024	$	527
Changes in fair value of stock price appreciation milestones liability		(280)
Balance at March 31, 2025	$	247
Changes in fair value of stock price appreciation milestones liability		73
Balance at June 30, 2025	$	320
Changes in fair value of stock price appreciation milestones liability		90
Balance at September 30, 2025	$	410

The following table presents the changes in fair value of the Company's Level 3 stock price appreciation milestones liability for the nine months ended September 30, 2024 (in thousands):

Balance at December 31, 2023	$	1,346
Changes in fair value of stock price appreciation milestones liability		1,394
Balance at March 31, 2024	$	2,740
Changes in fair value of stock price appreciation milestones liability		(1,556)
Balance at June 30, 2024	$	1,184
Changes in fair value of stock price appreciation milestones liability		13
Balance at September 30, 2024	$	1,197

6. Accrued Expenses

Accrued Expenses

Current accrued expenses consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Accrued payroll and other employee benefits	$ 7,395	$ 9,710
Accrued clinical trial related costs	6,319	5,279
Accrued other	3,857	6,359
Total current accrued expenses	$ 17,571	$ 21,348

7. Leases

The Company has lease agreements for office, laboratory and manufacturing spaces that are classified as operating leases on the consolidated balance sheets. These leases have terms varying from one to approximately sixteen years, with renewal options of up to ten years, as well as early termination options. Extension and termination options are included in the total lease term when the Company is reasonably certain to exercise them. The leases are subject to additional variable charges, including common area maintenance, property taxes, property insurance and other variable costs. Given the variable nature of such costs, they are recognized as expense as incurred. Additionally, some of the Company's leases are subject to certain fixed fees which the Company has determined to be non-lease components. The Company has elected to combine and account for lease and non-lease components as a single-lease component for purposes of determining the total future lease payments.

In October 2024, the Company exercised its right of early termination for its Torrey Pines operating lease, which consists of 72,000 square feet of office, laboratory, and Good Manufacturing Practice (GMP) space. In connection with such exercise, the Company paid $2.5 million to its landlord during the year ended December 31, 2024. Termination of the lease, which previously extended through December 31, 2028, took effect on October 31, 2025. The Company accounted for this transaction as a modification to the lease agreement, which reduced the ROU asset and corresponding lease liability balances as of December 31, 2024 in connection with such transaction.

As of September 30, 2025, future undiscounted minimum contractual payments under the Company's operating leases were $122.4 million, which will be paid over a remaining weighted-average lease term of 10.3 years. The weighted-average discount rate

for the operating lease liabilities was 8.4%, which was the Company's incremental borrowing rate at lease commencement, as the discount rates implicit in the leases could not be readily determined.

Future undiscounted minimum lease payments under the Company's operating leases as of September 30, 2025 are as follows (in thousands):

	Operating Lease Payments
Remaining 2025	$ 3,075
2026	11,050
2027	11,382
2028	10,293
2029	10,602
2030	10,920
Thereafter	65,056
Total undiscounted lease payments	$ 122,378
Less: imputed interest	(43,133)
Total lease liability	$ 79,245

8. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

In November 2016, the Company completed a private placement of stock in which investors, including investors affiliated with the directors and officers of the Company, purchased convertible preferred stock and common stock of the Company (the November 2016 Placement). The Company issued 2,819,549 shares of Class A Convertible Preferred Stock, $0.001 par value per share (the Class A Preferred), at $13.30 per share, each of which is convertible into five shares of common stock upon certain conditions defined in the Certificate of Designation of Preferences, Rights and Limitations of the Class A Preferred filed with the Delaware Secretary of State on November 22, 2016 (the CoD). The Class A Preferred were purchased exclusively by entities affiliated with Redmile Group, LLC (collectively, Redmile). The terms of the CoD prohibited Redmile from converting the Class A Preferred into shares of the Company's common stock if, as a result of conversion, Redmile, together with its affiliates, would own more than 9.99% of the Company's common stock then issued and outstanding (the Redmile Percentage Limitation), which percentage could change at Redmile's election upon 61 days' notice to the Company to (i) any other number less than or equal to 19.99% or (ii) subject to approval of the Company's stockholders to the extent required in accordance with the Nasdaq Global Market rules, any number in excess of 19.99%. On May 2, 2017, the Company's stockholders approved the issuance of up to an aggregate of 14,097,745 shares of common stock upon the conversion of the outstanding shares of Class A Preferred. As a result, Redmile has the right to increase the Redmile Percentage Limitation to any percentage in excess of 19.99% at its election. The Company also issued 7,236,837 shares of common stock at $2.66 per share as part of the November 2016 Placement. In April 2023, the Company filed with the office of the Secretary of State of the State of Delaware a Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock which amends the definition of Beneficial Ownership Limitation to be 14.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock pursuant to a Notice of Conversion. In April 2023, 33,441 shares of Class A Preferred were converted into 167,205 shares of the Company's common stock. In December 2024, 6,022 shares of the Class A Preferred were converted into 30,110 shares of the Company's common stock. In July 2025, Redmile provided the Company with notice of its intent to increase the Redmile Percentage Limitation from 9.99% to 14.99%, which became effective on August 31, 2025.

The Class A Preferred are non-voting shares and are convertible into five shares of the Company's common stock at a conversion price of $2.66 per share, which was the fair value of the Company's common stock on the date of issuance. Holders of the Class A Preferred have the same dividend rights as holders of the Company's common stock. Additionally, the liquidation preferences of the Class A Preferred are *pari passu* among holders of the Company's common stock and holders of the Class A Preferred, pro rata based on the number of shares held by each such holder (treated for this purpose as if the Class A Preferred had been converted to common stock).

Pre-Funded Warrants

In January 2021, in conjunction with a public offering, the Company issued pre-funded warrants, in lieu of common stock to certain investors, to purchase 257,310 shares of the Company's common stock (the 2021 Pre-Funded Warrants). The purchase price for the 2021 Pre-Funded Warrants was $85.499 per pre-funded warrant, which equals the per share public offering price for the shares

of common stock less the $0.001 exercise price for each such pre-funded warrant. Given that the 2021 Pre-Funded Warrants are indexed to the Company's own shares of common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the warrants as additional paid-in capital on the Company's consolidated balance sheets.

In March 2024, in conjunction with a public offering, the Company issued in a private placement, in lieu of common stock to certain investors, pre-funded warrants to purchase 3,636,364 shares of the Company's common stock (2024 Pre-Funded Warrants, and collectively with the 2021 Pre-Funded Warrants, the Pre-Funded Warrants). The purchase price for the 2024 Pre-Funded Warrants was $5.499 per pre-funded warrant, which equals the per share public offering price for the shares of common stock issued in the March 2024 public offering, less the $0.001 exercise price for each such pre-funded warrant. Given that the 2024 Pre-Funded Warrants are indexed to the Company's own shares of common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the warrants as additional paid-in capital on the Company's unaudited condensed consolidated balance sheets.

The Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of Pre-Funded Warrants may not exercise the Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

As of September 30, 2025, there were 3,893,674 Pre-Funded Warrants outstanding.

Stock Options and Restricted Stock Unit Awards

The following table summarizes stock option activity and related information under all equity plans for the period ended September 30, 2025:

	Number of Options	Weighted-Average Price
Balance at December 31, 2024	10,722,674	$ 10.99
Granted	3,690,400	1.29
Exercised	(832)	1.32
Cancelled	(1,814,843)	7.45
Balance at September 30, 2025	12,597,399	$ 8.66

Restricted stock unit activity under all equity and stock option plans is summarized as follows:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value per Share
Balance at December 31, 2024	6,214,064	$ 15.50
Granted	3,395,020	1.20
Vested	(1,407,586)	15.79
Cancelled	(1,554,405)	7.59
Balance at September 30, 2025	6,647,093	$ 9.98

The allocation of stock-based compensation for all stock awards is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 2,448	$ 5,295	$ 10,146	$ 16,248
General and administrative	2,413	6,470	9,250	16,128
Total	$ 4,861	$ 11,765	$ 19,396	$ 32,376

As of September 30, 2025, the unrecognized compensation cost related to outstanding options was $6.8 million and is expected to be recognized as expense over a weighted-average period of approximately 1.5 years.

As of September 30, 2025, the unrecognized compensation cost related to restricted stock units was $14.9 million which is expected to be recognized as expense over a weighted-average period of approximately 1.6 years.

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants were as follows:

	Nine Months Ended September 30,	
	2025	2024
Risk-free interest rate	4.4%	3.9%
Expected volatility	90.4%	87.1%
Expected term (in years)	6.2	6.4
Expected dividend yield	0.0%	0.0%

Reconciliation of Consolidated Stockholders' Equity Accounts

The following table summarizes the Company's changes in stockholders' equity accounts for the three and nine months ended September 30, 2025 (in thousands, except share data):

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	2,755,086	$ 3	113,928,279	$ 114	$ 1,716,335	$ 268	$ (1,397,994)	$ 318,726
Issuance of common stock upon vesting of restricted stock units	—	—	675,631	1	(1)	—	—	—
Stock-based compensation	—	—	—	—	7,381	—	—	7,381
Unrealized loss on investments	—	—	—	—	—	(77)	—	(77)
Net loss	—	—	—	—	—	—	(37,621)	(37,621)
Balance at March 31, 2025	2,755,086	$ 3	114,603,910	$ 115	$ 1,723,715	$ 191	$ (1,435,615)	$ 288,409
Exercise of stock options, net of issuance costs	—	—	832	—	—	—	—	832
Issuance of common stock upon vesting of restricted stock units	—	—	50,325	—	—	—	—	50,325
Stock-based compensation	—	—	—	—	7,154	—	—	7,154
Unrealized loss on investments	—	—	—	—	—	(129)	—	(129)
Net loss	—	—	—	—	—	—	(34,070)	(34,070)
Balance at June 30, 2025	2,755,086	$ 3	114,655,067	$ 115	$ 1,730,869	$ 62	$ (1,469,685)	$ 261,364
Issuance of common stock upon vesting of restricted stock units	—	—	681,630	—	—	—	—	681,630
Stock-based compensation	—	—	—	—	4,861	—	—	4,861
Unrealized gain on investments	—	—	—	—	—	91	—	91
Net loss	—	—	—	—	—	—	(32,250)	(32,250)
Balance at September 30, 2025	2,755,086	$ 3	115,336,697	$ 115	$ 1,735,730	$ 153	$ (1,501,935)	$ 234,066

The following table summarizes the Company's changes in stockholders' equity accounts for the three and nine months ended September 30, 2024 (in thousands, except share data):

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	2,761,108	$ 3	98,627,076	$ 99	$ 1,580,032	$ 15	$ (1,211,732)	$ 368,417
Exercise of stock options, net of issuance costs	—	—	45,438	—	299	—	—	299
Issuance of common stock upon vesting of restricted stock units	—	—	580,974	—	—	—	—	—
Stock-based compensation	—	—	—	—	10,981	—	—	10,981
Public offering of common stock, net of issuance costs	—	—	14,545,454	15	74,620	—	—	74,635
Private placement of pre-funded warrants, net of issuance costs	—	—	—	—	19,996	—	—	19,996
Unrealized loss on investments	—	—	—	—	—	(209)	—	(209)
Net loss	—	—	—	—	—	—	(48,004)	(48,004)
Balance at March 31, 2024	2,761,108	$ 3	113,798,942	$ 114	$ 1,685,928	$ (194)	$ (1,259,736)	$ 426,115
Exercise of stock options, net of issuance costs	—	—	—	—	(4)	—	—	(4)
Issuance of common stock upon vesting of restricted stock units	—	—	50,615	—	—	—	—	—
Stock-based compensation	—	—	—	—	9,630	—	—	9,630
Public offering of common stock, net of issuance costs	—	—	—	—	(104)	—	—	(104)
Unrealized loss on investments	—	—	—	—	—	(228)	—	(228)
Net loss	—	—	—	—	—	—	(38,427)	(38,427)
Balance at June 30, 2024	2,761,108	$ 3	113,849,557	$ 114	$ 1,695,450	$ (422)	$ (1,298,163)	$ 396,982
Issuance of common stock upon vesting of restricted stock units	—	—	35,327	—	—	—	—	—
Stock-based compensation	—	—	—	—	11,765	—	—	11,765
Unrealized gain on investments	—	—	—	—	—	1,257	—	1,257
Net loss	—	—	—	—	—	—	(47,678)	(47,678)
Balance at September 30, 2024	2,761,108	$ 3	113,884,884	$ 114	$ 1,707,215	$ 835	$ (1,345,841)	$ 362,326

9. Segment Reporting

The Company has one reportable segment relating to its operations. The segment derives its current revenues from research and development collaborations.

The Company's Chief Operating Decision Maker (the CODM), our Chief Executive Officer, manages the Company's operations on an integrated basis for the purposes of allocating resources. When evaluating the Company's financial performance, the CODM reviews total revenues, total expenses and expenses by certain categories and makes decisions using this information.

The table below is a summary of the segment profit or loss, including significant segment expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 1,741	$ 3,074	$ 5,277	$ 11,771
Less:				
Personnel costs	10,997	10,420	33,383	33,378
Clinical programs	6,065	7,343	18,126	19,041
Research activities	1,100	4,596	5,406	11,125
Facilities costs	6,113	6,785	18,078	20,446
Other segment expenses (1)	12,201	26,307	43,267	76,309
Total operating expenses	36,476	55,451	118,260	160,299
Loss from operations	(34,735)	(52,377)	(112,983)	(148,528)
Other income (expense):				
Interest income	2,575	4,438	8,832	13,414
Change in fair value of stock price appreciation milestones	(90)	(13)	117	149
Other income	—	274	93	856
Total other income	2,485	4,699	9,042	14,419
Net loss	$ (32,250)	$ (47,678)	$ (103,941)	$ (134,109)

(1) Other segment expenses include stock compensation expense, depreciation, legal fees, general & administrative expenses, and corporate expenses.

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2024 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2025.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Such forward-looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terms such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions. Factors that could cause or contribute to differences in results include, but are not limited to, those set forth under "Risk Factors" under Item 1A of Part II below. Except as required by law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline of off-the shelf cellular immunotherapies to patients.

We have pioneered a therapeutic approach that we generally refer to as cell programming: we create and engineer human induced pluripotent stem cells (iPSCs) to incorporate novel synthetic controls of cell function; we generate a clonal master iPSC line for use as a renewable source of cell manufacture; and we direct the fate of the clonal master iPSC line to produce our cell therapy product candidates. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe our proprietary clonal master iPSC lines can be used to mass produce multiplexed-engineered. cellular immunotherapies which have off-the-shelf availability, can be administered alone or in combination with standard-of-care therapies, and enable significant patient reach.

Utilizing our iPSC product platform, we are developing off-the-shelf, multiplexed-engineered T-cell and natural killer (NK) cell product candidates which are selectively designed, incorporate novel synthetic controls of cell function, and are intended to deliver multiple therapeutic mechanisms to patients. We have a pipeline of iPSC-derived, chimeric antigen receptor (CAR)-targeted T-cell and NK cell product candidates currently under development. In addition, we have entered into research collaborations and license agreements with academic institutions to support the development of our iPSC product platform and our off-the-shelf product candidates.

We have also entered into collaborations with pharmaceutical companies to research, develop and commercialize off-the-shelf, multiplexed-engineered, iPSC-derived CAR T-cell CAR NK cell product candidates for the treatment of cancer. In September 2018, we entered into a collaboration and option agreement (Ono Agreement) with Ono Pharmaceutical Co., Ltd. (Ono), under which we are currently researching and developing iPSC-derived CAR T-cell and CAR NK cell product candidates for the treatment of solid tumors.

We were incorporated in Delaware in 2007 and are headquartered in San Diego, California. Since our inception in 2007, we have devoted substantially all of our resources to our cell programming approach and the research and development of our product candidates, the creation, licensing and protection of related intellectual property, and the provision of general and administrative support for these activities. To date, we have funded our operations primarily through the public and private sale of common stock and warrants, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants.

We have never been profitable and have incurred net losses in each year since inception. 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 operating losses for at least the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will remain significant in connection with our ongoing and planned activities as we:

- conduct our ongoing and planned preclinical studies and clinical trials of our product candidates, which may include higher clinical trial expenses associated with arrangements we may enter into with clinical research organizations (CROs) for the execution and management of certain clinical trials, including trials outside of the United States;
- conduct Good Manufacturing Practice (GMP) production, including through the use of contract manufacturing organizations (CMOs) for the conduct of some or all of the activities required for manufacturing our iPSC-derived cell product candidates, process and scale-up development and technology transfer activities for the manufacture of our

product candidates, including those undergoing clinical investigation and Investigational New Drug (IND) application-enabling preclinical development;

- procure laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- conduct preclinical and clinical research to investigate the therapeutic activity of our product candidates;
- continue our research, development and manufacturing activities, including under our sponsored research and collaboration agreement with Ono;
- maintain, prosecute, protect, expand and enforce our intellectual property portfolio;
- engage with regulatory authorities for the development of, and seek regulatory approvals for, our product candidates;
- continue our business operations at our corporate headquarters, including maintaining internal GMP production capabilities; and
- continue operating as a public company and support our operations.

We do not expect to generate any meaningful revenues from product sales, royalties, or sales milestones unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings, collaboration arrangements, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative effect on our financial condition and ability to develop our product candidates.

Financial Operations Overview

We conduct substantially all of our activities through Fate Therapeutics, Inc., a Delaware corporation, at our facilities headquartered in San Diego, California. Our results of operations include the operations of the Company and its subsidiaries. To date, the aggregate operations of our subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

Collaboration Revenue

To date, we have not generated any revenues from therapeutic product sales or royalties. Our revenues have been derived from collaboration agreements and government grants.

Agreement with Ono Pharmaceutical Co., Ltd.

On September 14, 2018, we entered into the Ono Agreement for the joint development and commercialization of two iPSC-derived CAR T-cell product candidates (Candidate 1 and Candidate 2). Pursuant to the terms of the Ono Agreement, we received an upfront, non-refundable and non-creditable payment of $10.0 million. Additionally, we are entitled to receive fees for the conduct of research and development under a joint development plan, which fees were estimated to be $20.0 million in aggregate.

In December 2020, we entered into a letter agreement with Ono pursuant to which Ono delivered proprietary antigen binding domains targeting an antigen expressed on certain solid tumors for incorporation into Candidate 2 and paid the Company a milestone fee of $10.0 million for further research and development of Candidate 2. In addition, Ono terminated all further research and development with respect to Candidate 1, and we retained all rights to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

In June 2022, we entered into an amendment with Ono to the Ono Agreement (the 2022 Ono Amendment). Pursuant to the 2022 Ono Amendment, the companies agreed to designate an additional antigen expressed on certain solid tumors for research and preclinical development, and Ono agreed to contribute proprietary antigen binding domains targeting such additional solid tumor antigen (Candidate 3). In addition, for both Candidate 2 and Candidate 3, the companies expanded the scope of the collaboration to include the research and development of iPSC-derived CAR NK cell product candidates (in addition to iPSC-derived CAR T-cell product candidates) targeting the designated solid tumor antigens. Similar to Candidate 2, we granted to Ono, during a specified period of time, a preclinical option to obtain an exclusive license under certain intellectual property rights, subject to payment of an option exercise fee to us by Ono, to develop and commercialize Candidate 3 in all territories of the world, where we retain rights to co-develop and co-commercialize Candidate 3 in the United States and Europe under a joint arrangement with Ono under which we are eligible to share at least 50% of the profits and losses. We maintained worldwide rights of manufacture for Candidate 3. Under the

2022 Ono Amendment, aggregate estimated research and development fees were increased by approximately $9.3 million, for a total estimated $29.3 million in aggregate research and development fees over the course of the joint development plan.

In November 2022, Ono exercised its preclinical option to Candidate 2, and we exercised our preclinical option to co-develop and co-commercialize (CDCC Option) in the United States and Europe under a joint arrangement with Ono. As a result, we recognized an option exercise fee of $12.5 million from Ono during the year ended December 31, 2022. We received the option exercise fee payment during the year ended December 31, 2023.

In November 2023, we entered into an amendment with Ono to the Ono Agreement (the 2023 Ono Amendment). Under the 2023 Ono Amendment, aggregate estimated research and development fees payable to us by Ono were increased by approximately $1.4 million, for a total estimated $30.7 million in aggregate research and development fees over the course of the joint development plan.

In August 2024, we entered into an amendment with Ono to the Ono Agreement (the 2024 Ono Amendment). Under the 2024 Ono Amendment, aggregate estimated research and preclinical development fees payable to us by Ono were increased by approximately $7.3 million, for a total estimated $38.0 million in aggregate research and preclinical development fees over the course of the joint research plan.

In June 2025, we entered into an amendment with Ono to the Ono Agreement (the 2025 Ono Amendment and collectively with the 2024 Ono Amendment, 2023 Ono Amendment, and 2022 Ono Amendment, the Ono Amendments). Under the 2025 Ono Amendment, aggregate estimated research and preclinical development fees payable to us by Ono were increased by approximately $6.5 million, for a total estimated $44.5 million in aggregate research and preclinical development fees over the course of the joint research plan.

We account for the Ono Agreement, Ono Letter Agreement, and Ono Amendments (collectively, the Ono Arrangement) as a revenue contract under ASC 606. The amended transaction price under the Ono Arrangement was determined to be $54.5 million, consisting of the upfront, non-refundable and non-creditable payment of $10.0 million and the aggregate estimated research and development fees of $44.5 million. We identified our promised goods and services under the Ono Arrangement to include our grant to Ono of a license to certain of our intellectual property subject to certain conditions, our conduct of research services, and our participation in a joint steering committee. We determined that the promised goods and services should be accounted for as one combined performance obligation. We recognize revenue for the combined performance obligation over time as the research services are performed.

During the three and nine months ended September 30, 2025, we recognized $1.7 million and $5.3 million of collaboration revenue, respectively, and $1.3 million and $4.5 million of contra-research and development expense, respectively, under the Ono Arrangement. During the three and nine months ended September 30, 2024, we recognized $3.1 million and $11.8 million of collaboration revenue, respectively, and $1.7 million and $3.6 million of contra-research and development expense, respectively, under the Ono Arrangement.

Research and Development Expenses

Research and development expenses consist of costs associated with the research, preclinical development, process and scale-up development, manufacture and clinical development of our product candidates, the research and development of our cell programming technology including our iPSC product platform, and the performance of research and development activities under our collaboration agreements. These costs are expensed as incurred and include:

- salaries and employee-related costs, including stock-based compensation;
- costs incurred under clinical trial agreements with investigative sites;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials, including our product candidates;
- costs associated with conducting our preclinical, process and scale-up development, manufacturing, clinical and regulatory activities, including fees paid to third-party professional consultants, service providers and suppliers;
- costs incurred for our research, development and manufacturing activities, including under our collaboration agreements;
- costs for laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- costs incurred to license and maintain intellectual property; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

We plan to continue to significantly invest in our current level of research and development activities for the foreseeable future as we continue the clinical and preclinical development and manufacture of our product candidates, research and develop our iPSC product platform, and perform our obligations under collaboration agreements including under our agreements with Ono and University of Minnesota. Our current planned research and development activities over the next twelve months consist primarily of the following:

- conducting clinical trials of our product candidates, including through the engagement of CROs to manage various aspects of our clinical trials;
- conducting GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;
- procuring laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- conducting preclinical and clinical research to investigate the therapeutic activity of our product candidates; and
- conducting research, development and manufacturing activities, including under our sponsored research and collaboration agreement with Ono.

Due to the inherently unpredictable nature of preclinical and clinical development and manufacture, and given our novel therapeutic approach and the current stage of development of our product candidates, we cannot determine and are unable to estimate with certainty the timelines we will require and the costs we will incur for the development and manufacture of our product candidates. Clinical and preclinical development and manufacturing timelines and costs, and the potential of development and manufacturing success, can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development and manufacturing plans and capital requirements. We cannot predict the effects of the impact of global economic and market conditions, a continued and prolonged public health emergency, and global geopolitical tensions, including wars and other armed conflicts on our business and operations, and our expenditures may be increased by delays or disruptions due to these or other factors, including as a result of actions we take in the near term to ensure business continuity and protect against possible supply chain shortages.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for our employees in executive, operational, finance and human resource functions; professional fees for accounting, legal and tax services; costs for obtaining, prosecuting, maintaining, and enforcing our intellectual property; and other costs and fees, including director and officer insurance premiums, to support our operations as a public company. We anticipate that our general and administrative expenses will remain significant in the future as we maintain our focus on innovation, and research and development activities, maintain compliance with exchange listing and SEC requirements, protect and enforce our intellectual property, and continue to operate as a public company.

Other Income (Expense)

Other income (expense) consists of changes in the fair value of stock price appreciation milestones associated with the Amended MSKCC License with MSKCC, interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

California Institute for Regenerative Medicine Awards

FT819 CIRM Award

In February 2024, we were awarded $7.9 million from the California Institute for Regenerative Medicine (CIRM) to support the conduct of the Company's Phase 1 study of FT819 in patients with systemic lupus erythematosus and, in April 2024, we executed an award agreement with CIRM (the FT819 CIRM Award). Pursuant to the terms of the FT819 CIRM Award, we are eligible to receive five disbursements in varying amounts from CIRM, with one disbursement receivable upon the execution of the award and four disbursements receivable based upon the completion of certain development milestones throughout the period of the award, which is estimated to be from April 1, 2024 to March 31, 2028 (the Award Period). Under the FT819 CIRM Award, we have certain obligations of co-funding and are required to provide CIRM progress and financial update reports throughout the Award Period.

Following the conclusion of the Award Period, we, in our sole discretion, have the option to treat the FT819 CIRM Award either as a loan or as a grant. If we do not elect to treat the FT819 CIRM Award as a loan within 10 years of the award date, the award will

be considered a grant and we will be obligated to pay CIRM, on a quarterly basis, a low single-digit royalty on commercial sales of FT819 until such aggregate royalty payments equal nine times the total amount awarded to us under the FT819 CIRM Award.

Since we may, at our election, repay some or all of the FT819 CIRM Award, we account for the award as a liability until the time of election. As of September 30, 2025, we have received two disbursements under the award in the aggregate amount of $5.1 million, which is recorded as a liability on the accompanying consolidated balance sheets. As of September 30, 2025, the entire balance is classified as non-current as we do not expect any amount to be payable within the next 12 months.

FT836 CIRM Award

In January 2025, we were awarded $4.0 million from the California Institute for Regenerative Medicine (CIRM) to support the conduct of pre-clinical and Investigational New Drug (IND)-enabling activities for FT836, and in May 2025, we executed an award agreement with CIRM (the FT836 CIRM Award). Pursuant to the terms of the FT836 CIRM Award, we are eligible to receive four disbursements in varying amounts from CIRM, with one disbursement receivable upon the execution of the award and three disbursements receivable based upon the completion of certain development milestones throughout the period of the award, which is estimated to be from May 1, 2025 to October 31, 2025 (the Award Period). Under the FT836 CIRM Award, we have certain obligations of co-funding and are required to provide CIRM progress and financial update reports throughout the Award Period.

Following the conclusion of the Award Period, we, in our sole discretion, have the option to treat the FT836 CIRM Award either as a loan or as a grant. If we do not elect to treat the FT836 CIRM Award as a loan within 10 years of the award date, the award will be considered a grant and we will be obligated to pay CIRM, on a quarterly basis, a low single-digit royalty on commercial sales of FT836 until such aggregate royalty payments equal nine times the total amount awarded to us under the FT836 CIRM Award.

Since we may, at our election, repay some or all of the FT836 CIRM Award, we account for the award as a liability until the time of election. As of September 30, 2025, we have received three disbursements under the FT836 CIRM Award in the aggregate amount of $3.8 million. As of September 30, 2025, the total amount received is recorded as a CIRM liability in the consolidated balance sheets, with $2.3 million classified as current and the remaining $1.5 million as non-current, based on the portion we expect to be payable within twelve months from the balance sheet date.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to the fair value of the stock price appreciation milestones for the Amended MSKCC License, contracts containing leases, accrued expenses, stock-based compensation, and the estimated total costs expected to be incurred under our collaboration agreements. We base our estimates on historical experience, known trends and events, financial models, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The estimates and judgments involved in our accounting policies, as described in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2024, continue to be our critical accounting policies and there have been no other material changes to our critical accounting policies during the nine months ended September 30, 2025.

See Note 1 to the unaudited condensed consolidated financial statements for a summary of critical accounting policies and information related to recent accounting pronouncements.

Results of Operations

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

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

	Three Months Ended September 30,		Increase/ (Decrease)
	2025	2024	
Collaboration revenue	$ 1,741	$ 3,074	$ (1,333)
Research and development expense	25,838	34,650	(8,812)
General and administrative expense	10,638	20,801	(10,163)
Total other income	2,485	4,699	(2,214)

Collaboration Revenue. During the three months ended September 30, 2025 and 2024, we recognized revenue of $1.7 million and $3.1 million, respectively, under our collaboration agreement with Ono. The decrease in collaboration revenue was primarily driven by an increase in research and preclinical development fees during the three months ended September 30, 2024 payable by Ono under the 2024 Ono Amendment, which did not occur during the three months ended September 30, 2025.

Research and development expenses. Research and development expenses were $25.8 million for the three months ended September 30, 2025, compared to $34.7 million for the three months ended September 30, 2024. The decrease in research and development expenses was attributable primarily to the following:

- $2.8 million decrease in third-party professional consultant and advisory fees;
- $2.8 million decrease in employee stock-based compensation expense;
- $1.6 million decrease in clinical trial related expense; and
- $1.4 million decrease in depreciation expense.

General and administrative expenses. General and administrative expenses were $10.7 million for the three months ended September 30, 2025, compared to $20.8 million for the three months ended September 30, 2024. The decrease in general and administrative expenses was attributable primarily to a $5.9 million decrease in patent and legal expenses and a $4.1 million decrease in employee stock-based compensation expense.

Other income (expense), net. Other income (expense), net was $2.5 million and $4.7 million for the three months ended September 30, 2025 and 2024, respectively. During the three months ended September 30, 2025, we recorded $0.1 million in other expense attributable to the change in fair value of the stock price appreciation milestones under the Amended MSKCC License. Other income (expense), net for the three months ended September 30, 2025 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

During the three months ended September 30, 2024, we recorded $0.1 million in other expense attributable to the change in fair value of the stock price appreciation milestones under the Amended MSKCC License. Other income (expense), net for the three months ended September 30, 2024 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

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

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

	Nine Months Ended September 30,		Increase/ (Decrease)
	2025	2024	
Collaboration revenue	$ 5,277	$ 11,771	$ (6,494)
Research and development expense	82,404	101,392	(18,988)
General and administrative expense	35,856	58,907	(23,051)
Total other income	9,042	14,419	(5,377)

Collaboration Revenue. During the nine months ended September 30, 2025 and 2024, we recognized revenue of $5.3 million and $11.8 million, respectively, under our collaboration agreement with Ono. The decrease in collaboration revenue was primarily due to our achievement of a clinical development milestone during the nine months ended September 30, 2024, resulting in the recognition of $5.0 million in revenue during that period.

Research and development expenses. Research and development expenses were $82.4 million for the nine months ended September 30, 2025, compared to $101.4 million for the nine months ended September 30, 2024. The decrease in research and development expenses was attributable primarily to the following:

- $6.1 million decrease in employee stock-based compensation expense;
- $4.3 million decrease in depreciation expense;
- $3.2 million decrease in third-party professional consultant and advisory fees;
- $1.9 million decrease in laboratory materials and supplies expenses relating to the manufacture of our product candidates; and

- $1.1 million decrease in sub-licensing fees.

General and administrative expenses. General and administrative expenses were $35.9 million for the nine months ended September 30, 2025, compared to $58.9 million for the nine months ended September 30, 2024. The decrease in general and administrative expenses was attributable primarily to a $15.7 million decrease in patent and legal expenses and a $7.3 million decrease in employee compensation and benefits expense, including a $6.9 million decrease in employee stock-based compensation expense.

Other income (expense), net. Other income (expense), net was $9.0 million and $14.4 million for the nine months ended September 30, 2025 and 2024, respectively. During the nine months ended September 30, 2025, we recorded $0.1 million in other income attributable to the change in fair value of the stock price appreciation milestones under the Amended MSKCC License. Other income (expense), net for the nine months ended September 30, 2025 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

During the nine months ended September 30, 2024, we recorded $0.1 million in other income attributable to the change in fair value of the stock price appreciation milestones under the Amended MSKCC License. Other income (expense), net for the nine months ended September 30, 2024 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of September 30, 2025, we had an accumulated deficit of $1.5 billion and we anticipate that we will continue to incur net losses for the foreseeable future.

Operating Activities

During the nine months ended September 30, 2025, cash used in operating activities was $82.8 million and primarily consisted of a net loss of $103.9 million adjusted for non-cash items including stock-based compensation of $19.4 million and depreciation and amortization of $9.8 million.

During the nine months ended September 30, 2024, cash used in operating activities was $95.1 million and primarily consisted of a net loss of $134.1 million adjusted for non-cash items including stock-based compensation of $32.4 million and depreciation and amortization of $14.1 million.

Investing Activities

During the nine months ended September 30, 2025, investing activities provided cash of $83.5 million compared to cash used by investing activities of $10.6 million during the nine months ended September 30, 2024. During the nine months ended September 30, 2025, we purchased $157.4 million of investments, which were offset by $245.6 million in maturities of investments. The remaining investing activities for the periods presented were primarily attributable to the purchase of $4.8 million in property and equipment. During the nine months ended September 30, 2024, we purchased $279.7 million of investments, which were offset by $269.8 million in maturities of investments. The remaining investing activities for the periods presented were primarily attributable to the purchase of property and equipment.

Financing Activities

For the nine months ended September 30, 2025, financing activities provided cash of $3.8 million from proceeds of the FT836 CIRM award.

For the nine months ended September 30, 2024, financing activities provided cash of $96.8 million, which primarily consisted of (i) the issuance of 14,545,454 shares of common stock at a purchase price of $5.50 per share in an underwritten offering of common stock in March 2024, (ii) the issuance of pre-funded warrants to purchase an aggregate of 3,636,364 shares of common stock at a purchase price of $5.499 per pre-funded warrant, which represents the offering price per share of common stock in the underwritten offering less the $0.001 exercise price per share of each pre-funded warrant, in a private placement concurrent with the underwritten offering, and (iii) the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

From our inception through September 30, 2025, we have funded our consolidated operations primarily through the public and private sale of common stock, the issuance of warrants, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of September 30, 2025, we had aggregate cash and cash equivalents and investments of $225.7 million.

Offerings Pursuant to Registration Statement on Form S-3 and Private Placement of Pre-Funded Warrants

In November 2023, the SEC declared effective a shelf registration statement on Form S-3 filed by us in November 2023 (File No. 333-275402). The shelf registration statement allows us to issue certain securities, including shares of our common stock, from time to time. The specific terms of any offering under the shelf registration statement would be established at the time of such offering. We were initially eligible to issue an aggregate of $300.0 million in securities under the shelf registration statement. Additionally, we entered into a sales agreement with Jefferies Group LLC (Jefferies) with respect to an at-the-market offering program, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $100.0 million (which is included in the $300.0 million registered under the shelf registration statement) through Jefferies as the sales agent.

In March 2024, we entered into an underwriting agreement with BofA Securities, Inc., Jefferies, and Leerink Partners LLC with respect to an underwritten public offering, under which we sold 14,545,454 shares of our common stock at a purchase price of $5.50 per share pursuant to the shelf registration statement. To date, we have not sold any securities pursuant to the sales agreement with Jefferies and are eligible to issue an aggregate of approximately $220.0 million under the shelf registration statement (including the $100.0 million issuable pursuant to the sales agreement with Jefferies).

In March 2024, concurrent with the underwritten public offering, we entered into a securities purchase agreement with a fund affiliated with Redmile Group, LLC under which we sold pre-funded warrants to purchase up to 3,636,364 shares of our common stock, at a purchase price of $5.499 per pre-funded warrant, in a private placement exempt from the registration requirements pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act). Pursuant to the terms of the purchase agreement, we agreed to register for resale the shares of common stock issuable upon the exercise of the pre-funded warrants (Warrant Shares). On April 18, 2024, we filed a resale registration statement on Form S-3 (File No. 333-278792), registering the Warrant Shares. The resale registration statement on Form S-3 was declared effective on April 29, 2024.

Operating Capital Requirements

We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to remain significant as we continue the research, manufacture and development of, and seek regulatory approvals for, our product candidates and conduct additional research, manufacturing and development activities pursuant to our collaboration agreement with Ono. Our product candidates have not yet achieved regulatory approval and we may not be successful in achieving commercialization of our product candidates.

We are also subject to all the risks and uncertainties incident in the research, manufacture and development of therapeutic products, and cell therapy product candidates in particular. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies, manufacturing activities, or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research, manufacturing and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research, manufacturing and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

We will require additional capital for the research, manufacture and development of our product candidates and to perform our obligations under our collaboration agreements, and we may need to seek additional funds sooner than expected due to any changes in our business, operations, financial condition or prospects, including any impacts of inflation rates and global economic conditions, and wars or other armed conflicts. We expect to finance our capital requirements in the foreseeable future through the sale of public or private equity, debt securities, or through existing or future potential collaborations. However, additional capital may not be available to us on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the research, manufacture or development of one or more of our product candidates. If we do raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. Additionally, if we incur indebtedness, we may become subject to financial or other covenants that could adversely restrict, impair or affect our ability to conduct our business, such as requiring us to relinquish rights to certain of our product candidates or technologies or limiting our ability to acquire, sell or license intellectual property rights or incur additional debt. Any of these events could significantly harm our business, operations, financial condition and prospects. In addition, the full impact of inflation rates, global political and economic instability, a continued and prolonged public health emergency, and wars and other armed conflicts, on our business, operations, financial condition and prospects, and on the global economy, are currently unknown and difficult to predict, and these events could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

Our forecast of the period of time through which our existing cash, cash equivalents, and investments will be adequate to support our operations is a forward-looking statement and involves significant risks and uncertainties. We have based this forecast on assumptions that may prove to be wrong, and actual results could vary materially from our expectations, which may adversely affect our capital resources and liquidity. We could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, timing, progress, size, duration, costs and results of our clinical trials and preclinical studies for our product candidates, including the timing and costs of manufacturing activities to support such clinical trials and preclinical studies;
- the number and the nature of product candidates that we pursue;
- the cost of maintaining internal GMP production capabilities to support the clinical and potential commercial manufacture of our product candidates at our corporate headquarters;
- the cost of GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including the cost of laboratory equipment, materials and supplies to support these activities;
- the time, cost and outcome of seeking and obtaining regulatory approvals;
- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments, including payments owed to MSKCC in connection with the stock price appreciation milestones;
- the extent to which milestones are achieved under our collaboration agreement with Ono, and any other strategic partnership or collaboration agreements that we may enter into in the future, and the time to achievement of such milestones and our receipt of any associated milestone payments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of enforcing any of our other contractual rights;
- the cost of our research and development activities, including our need and ability to hire additional employees and procure additional equipment, materials and supplies;
- the establishment and continuation of collaborations and strategic alliances;
- the timing and terms of future in-licensing and out-licensing transactions; and
- the cost of establishing sales, marketing, manufacturing and distribution capabilities for, and the pricing and reimbursement of, any products for which we may receive regulatory approval.

In addition, we are closely monitoring inflation rates and global political and economic conditions, including wars and other armed conflicts, and evaluating adjustments to our business and operations, which may negatively impact our financial condition and prospects and our operating results. We will continue to assess our operating capital requirements and may make adjustments to our business and operations if circumstances warrant. If we cannot continue or expand our research, manufacturing and development operations, or otherwise capitalize on our business opportunities, because we lack sufficient capital, our business, operations, financial condition and prospects could be materially adversely affected.

Contractual Obligations and Commitments

We lease certain office, laboratory, and manufacturing space under non-cancelable operating leases. In addition to rent, our leases are subject to certain fixed amenities fees. These leases are also subject to additional variable charges for common area maintenance, property taxes, property insurance and other variable costs. See Note 7 to the unaudited condensed consolidated financial statements for additional detail.

We entered into a license agreement with MSKCC under which we obtained rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T-cells and NK-cells derived from iPSCs engineered with CARs. In the event a licensed product achieves a specified clinical milestone, MSKCC is then eligible to receive certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSKCC are contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. In July 2021, we achieved the specified clinical milestone for a licensed product under the Amended MSKCC License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, we remitted payment to MSKCC for the first milestone payment of $20.0 million. See Note 2 to the unaudited condensed consolidated financial statements for additional detail surrounding our stock price appreciation milestone obligations.

We have no material contractual obligations not fully recorded on our unaudited condensed consolidated balance sheets or fully disclosed in the notes to the financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not required for smaller reporting companies.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2025.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On January 20, 2023, a purported stockholder of the Company filed a securities class action lawsuit against the Company and certain of its officers captioned Hadian v. Fate Therapeutics, Inc. et al. in the U.S. District Court for the Southern District of California (the Securities Action). On May 4, 2023, the court appointed a different purported stockholder of the Company to serve as lead plaintiff in the Securities Action. On July 24, 2023, the lead plaintiff filed an amended complaint. The amended complaint alleged that the Company violated the federal securities laws by making allegedly false and/or misleading statements and/or omissions in its public disclosures dating back to August 2020 relating to our collaboration agreement with Janssen Biotech, Inc. (the Janssen Agreement), potential product candidates subject to the Janssen Agreement, and the termination of the Janssen Agreement. On September 22, 2023, we filed a motion to dismiss the amended complaint. On September 19, 2024, the court granted our motion to dismiss the amended complaint, with leave for plaintiff to file a second amended complaint. On October 18, 2024, the lead plaintiff filed a second amended complaint alleging substantially similar facts and claims as in the prior amended complaint. We filed a motion to dismiss the second amended complaint on November 18, 2024, and briefing on the motion was completed on January 21, 2025. On September 22, 2025, the court granted our motion to dismiss the second amended complaint, with leave for plaintiff to file a third amended complaint. On October 17, 2025, the plaintiff filed a third amended complaint. The Company intends to file a motion to dismiss by November 17, 2025. Plaintiff must file any opposition brief by December 18, 2025, and if filed, the Company will file its reply in support of its motion to dismiss by January 15, 2026. We intend to continue to vigorously defend against this action.

On June 2, 2023, a derivative complaint, captioned Guarino v. Wolchko, et al., was filed by a purported stockholder of the Company in the U.S. District Court for the Southern District of California (the Guarino Action). On June 12, 2024, an additional derivative complaint, captioned Horrobin v. Wolchko, et al., was filed by a purported stockholder of the Company in the same district (the Horrobin Action). On December 2, 2024, the court entered an order consolidating the Guarino Action and the Horrobin Action under the caption In re Fate Therapeutics, Inc. Derivative Litigation (the Derivative Action) and staying the Derivative Action pending the court's decision on our motion to dismiss the second amended complaint in the Securities Action. On September 22, 2025, the stay of the consolidated case automatically expired when the decision dismissing the second amended complaint in the Securities Action was issued. On October 24, 2025, the court extended the stay pending the court's decision on our anticipated motion to dismiss the third amended complaint. The court's ruling on the motion is pending. The Derivative Action names members of our board of directors and certain officers as defendants. The Company is also named as a nominal defendant. The plaintiffs in the Derivative Actions assert derivative claims arising out of substantially the same alleged facts and circumstances as the Securities Action. The Guarino complaint asserts claims for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violation of federal securities laws. The Horrobin complaint asserts substantially similar claims in addition to a claim of breach of fiduciary duty for insider trading. We intend to vigorously defend against the Derivative Action.

From time to time, we may be subject to various other legal proceedings and claims that arise in the ordinary course of our business activities.

Item 1A. Risk Factors

RISK FACTORS

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

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

If we fail to complete the preclinical or clinical development of, or to obtain regulatory approval for, our product candidates, our business would be significantly harmed.

All of our product candidates are currently in research or early clinical development. We have not completed clinical development of or obtained regulatory approval for any of our product candidates. Only a small percentage of research and development programs ultimately result in commercially successful products, and we cannot assure you that any of our product candidates will demonstrate the safety, purity and potency, or efficacy profiles necessary to support further preclinical study, clinical development or regulatory approval. In addition, we have historically focused on the development of cell therapies for cancer. We

have limited prior experience in developing treatments for autoimmune diseases, and there are no cell therapies approved in the United States to treat autoimmune diseases.

We may experience delays in, or cancel our ongoing and planned clinical development activities or research and development activities for any of our product candidates for a variety of reasons, including:

- difficulties in optimizing the right dose and dosing schedule for our product candidates, which might result in a determination that a product candidate is ineffective, causes harmful side effects, or otherwise presents unacceptable safety risks during clinical trials or has an unfavorable toxicity profile in preclinical studies or early clinical trials to support initiating or continuing clinical investigation;
- difficulties in manufacturing or distributing a product candidate, including the inability to manufacture and distribute a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under protocols and processes and with materials and facilities acceptable to the U.S. Food and Drug Administration (FDA) or comparable foreign regulatory authorities for the conduct of clinical trials or for marketing approval;
- challenges in making arrangements with various medical divisions across hospitals or with other treatment centers for administration of our product candidates, including with treatment centers and relevant hospital divisions to perform infusion of our product candidates;
- our prioritization of certain of our product candidates for advancement or the emergence of competing product candidates developed by others, including a decision to cease research and development of any existing product candidate due to the potential obsolescence of our product candidate by a competing product or product candidate or our determination that another of our existing or future product candidates has greater potential for clinical development, regulatory approval, or commercialization, including potentially greater therapeutic benefit, a more favorable safety or efficacy profile, a more consistent or more cost effective manufacturing process, or a more favorable commercial profile, including greater market acceptance or commercial potential, or more advantageous intellectual property position;
- challenges and delays in trial execution which may result from our testing of multiple product candidates in the same indication in different clinical trials, as well as competition from biotechnology and pharmaceutical companies, universities, and other research institutions for patients, qualified investigators and clinical trial sites;
- the proprietary rights of third parties, which may preclude us from developing, manufacturing or commercializing a product candidate;
- determining that a product candidate may be uneconomical to develop, manufacture, or commercialize;
- our inability to obtain market acceptance or third-party coverage and an adequate pricing and reimbursement profile;
- our inability to secure or maintain relationships with strategic partners that may be necessary for advancement of a product candidate into or through clinical development, regulatory approval and commercialization in any particular indication(s) or geographic territory(ies); and
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development.

Additionally, we will only be able to obtain regulatory approval to market a product candidate if we can demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, in well-designed and conducted clinical trials that such product candidate is manufactured in accordance with applicable regulatory requirements, is safe, pure and potent, or effective, and otherwise meets the appropriate standards required for approval for a particular indication. Our ability to obtain regulatory approval of our product candidates depends on, among other things, completion of additional preclinical studies, process development and manufacturing activities, and clinical trials, whether our clinical trials demonstrate statistically significant efficacy with safety profiles that do not potentially outweigh the therapeutic benefit, and whether regulatory agencies agree that the data from our clinical trials and our manufacturing operations are sufficient to support approval. In addition, the approval by the FDA of new products in the same indications that we are studying may change the standard of care, and this may result in the FDA or other regulatory agencies requesting that we conduct additional studies to show that our product candidate is superior to the new standard of care. Securing regulatory approval also requires the submission of information about product manufacturing operations to, and inspection of manufacturing facilities by, the relevant regulatory authority. The results of our current and future clinical trials may not meet the FDA's or other regulatory agencies' requirements to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing operations are insufficient to support approval. We may need to conduct preclinical studies and clinical trials that we currently do not anticipate, including as a result of changes in the standard of care. If we fail to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates, we will not be able to generate any revenues from product sales and our ability to receive milestone or other payments under any collaboration agreements may be impaired, which will harm our business, prospects, financial condition and results of operations.

We may face delays in initiating, conducting or completing our clinical trials, and we may not be able to initiate, conduct or complete them at all.

We are heavily dependent on our ability to complete the clinical development of, and obtain regulatory approval for, our product candidates. We have not completed the clinical trials necessary to support an application for approval to market any of our product candidates. We, or any investigators who initiate or conduct clinical trials of our product candidates, may experience delays in our current or future clinical trials, and we do not know whether we or our investigators will be able to initiate, enroll patients in, or complete, clinical trials of our product candidates on time, if at all. Current and future clinical trials of our product candidates may be delayed, unsuccessful or terminated, or not initiated at all, as a result of many factors, including factors related to:

- difficulties in recruiting eligible patients for participation in clinical trials of our product candidates, including pediatric patients who need parental consent;
- difficulties enrolling a sufficient number of suitable patients to conduct clinical trials of our product candidates, including difficulties resulting from patients enrolling in studies of therapeutic product candidates sponsored by us or our competitors and difficulties resulting from patient availability as a result of any measures taken by governmental authorities, hospitals, or clinical trial sites in response to any future public health crises or other serious disasters or similar events;
- difficulties determining suitable doses and schedules of our novel cell product candidates for evaluation in clinical trials;
- difficulties in obtaining agreement from regulatory authorities on study endpoints and/or study duration, achieving study endpoints, the amount and sufficiency of data demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product candidates;
- delays in filing an Investigational New Drug (IND) application or IND amendment with the FDA to initiate or amend clinical trials of our current product candidates and any other product candidates that we may identify;
- difficulties in obtaining agreement with regulatory authorities on the preclinical safety and efficacy data, the manufacturing requirements, and the clinical trial design and parameters necessary for an IND application to go into effect to initiate and conduct clinical trials for any of our current product candidates and any other product candidates that we may develop;
- the occurrence of unexpected safety issues or adverse events in any ongoing or future clinical trials of our product candidates, including in trials of our product candidates conducted by investigator-sponsors;
- securing and maintaining the support of clinical investigators and investigational sites, including investigators and sites who may conduct clinical trials under an investigator-sponsored IND with our financial support, and obtaining institutional review board (IRB) approval at each site for the conduct of our clinical trials;
- reaching agreement on acceptable terms with third-party service providers and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different service providers and clinical trial sites;
- failure to manufacture certain of our product candidates consistently, and at acceptable quality levels and costs, in accordance with our protocol-specified manufacturing requirements and applicable regulatory requirements;
- failure or delays in obtaining sufficient quantities of suitable raw materials, components, and equipment necessary for the conduct of our clinical trials or the manufacture of any product candidate, including any inability to obtain materials as a result of supply chain issues related to any future public health crises or other serious disasters or ongoing or emerging global geopolitical tensions, including wars and other armed conflicts, or other factors;
- failure or delays by us or by our clinical sites to obtain sufficient quantities of components and supplies necessary for the conduct of our clinical trials, including any inability to obtain agents such as cyclophosphamide or fludarabine which may be required to condition patients for treatment with our product candidates, or certain monoclonal antibodies which are intended for administration to patients in combination with many of our product candidates in certain of our clinical trials;
- challenges in distributing our product candidates to clinical trial sites, or failure to establish effective protocols for the supply and transport of our product candidates;
- the costs of conducting clinical trials or manufacturing of our product candidates being greater than we anticipate, including due to rising inflation rates, or the timelines for these activities being longer than we anticipate;
- our failure, or the failure of investigators, third-party service providers, or clinical trial sites, to ensure the proper and timely conduct of and analysis of data from clinical trials of our product candidates;
- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators, and IRBs;

- imposition of a temporary or permanent clinical hold by data monitoring committees or regulatory agencies for a number of reasons, including after review of an IND submission or amendment, or equivalent application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants, a negative finding from an inspection of our clinical trial operations or trial sites, developments in trials conducted by us or our competitors that raise concerns about the safety risk to patients of novel therapeutics derived from pluripotent or genome edited therapies and/or negative public perception of the same, or if the FDA or other foreign regulatory authorities find that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- with respect to our clinical trials of product candidates in oncology indications, the serious, life-threatening diseases of the patients in our oncology clinical trials, who may die or suffer adverse medical events during the course of the trials for reasons that may not be related to our product candidates;
- failure of patients to complete participation in a clinical trial or adhere to study protocols;
- approval of competitive agents or changes in the standard of care or treatment landscape on which a clinical development plan was based, which may require new or additional trials, or render our product candidates or clinical trial designs obsolete;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- governmental or regulatory delays, including any delays due to limitations on the availability of governmental and regulatory agency personnel to review regulatory filings, conduct site inspections or engage in discussions with us as a result of government shutdowns or other events related to the 2025 change in the U.S. presidential administration, any future public health crisis or other serious disaster or similar events, failure to obtain regulatory approval, or uncertainty or changes in U.S. or foreign regulatory requirements, policy or guidelines;
- insufficient staffing and resources at our clinical trial sites to support our trials on a timely basis; and
- limitations on clinical trial conduct at our clinical trial sites resulting from prioritization of hospital and other medical resources toward other efforts, such as any future public health crisis or other serious disaster or similar events, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials including those relating to site initiation, study monitoring, and data collection and analysis, and other precautionary measures taken in treating patients or in practicing medicine in response to various public health concerns.

If there are delays in initiating or conducting any clinical trials of our product candidates or any of these clinical trials are suspended or terminated before completion, the commercial prospects of our product candidates will be harmed. In addition, any delays in initiating, conducting or completing our clinical trials or adjustments to certain of our study protocols and procedures, including as a result of any shortage of materials or agents necessary to conduct our studies or as a result of any future public health crisis or other public health concerns or other factors, will increase our costs, slow down our product candidate development and regulatory approval process, and jeopardize our ability to gain regulatory approval, commence product sales and generate revenues. Furthermore, many of the factors that cause, or lead to, a delay in the initiation, conduct or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these occurrences would significantly harm our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

In addition, from time to time, we may announce the expected timing of various scientific, clinical, regulatory, or other product development milestones. These milestones may include the filing or submission of regulatory filings, such as an IND or equivalent application, the commencement or expansion of clinical trials, or the development or release of data from our clinical trials. These milestones are and will be based on a variety of assumptions. If any of the foregoing factors impairs our ability to meet the announced timing of these milestones, we may experience significant harm to our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

The manufacture and distribution of our cell product candidates, particularly our induced pluripotent stem cell (iPSC)-derived cell product candidates, is complex and subject to a multitude of risks. These risks could substantially increase our costs and limit the clinical and commercial supply of our product candidates, and the development and commercialization of our product candidates could be substantially delayed or restricted if the FDA or other regulatory authorities impose additional requirements on our manufacturing operations or if we are required to change our manufacturing operations to comply with regulatory requirements.

The manufacture and supply of our cell product candidates involves novel processes that are more complex than those required for most small molecule drugs and other cellular immunotherapies, and accordingly present significant challenges and are subject to multiple risks. For our iPSC-derived product candidates, these complex processes include reprogramming human fibroblasts to obtain iPSCs, genetically engineering these iPSCs, and differentiating the iPSCs to obtain the desired cell product candidate. As a result of the complexities in manufacturing biologics and distributing cell therapies, the cost to manufacture and distribute biologics and cell

therapies in general, and our cell product candidates in particular, is generally higher than for traditional small molecule chemical compounds. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect our clinical trials and the commercial viability of our product candidates.

We have limited experience in the manufacture of cell-based therapies. We are still developing optimized and reproducible manufacturing processes for clinical and commercial-scale manufacturing of our product candidates, and none of our manufacturing processes have been validated for commercial production of our product candidates. We may face multiple challenges as we scale our manufacturing for large-scale clinical trials or commercial-scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. In addition, we are continuing to optimize our protocols for the supply and transport of our product candidates for distribution to clinical trial sites. Although we are working to develop reproducible and commercially viable manufacturing processes for our product candidates, and effective protocols for the supply and transport of our product candidates, doing so is a difficult and uncertain task.

We may make changes or be required by the FDA or other regulatory authorities to make changes to our manufacturing processes, including materials and equipment used in manufacturing our product candidates, as we continue to develop and refine the manufacturing and distribution processes for our product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes, materials, and equipment will not cause our product candidates to perform differently and affect the results of our ongoing and planned clinical trials or the performance of the product once commercialized. In some circumstances, changes in our manufacturing operations, including to our protocols, processes, materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our product candidates, and may increase our development costs substantially.

The manufacturing processes for any products that we may develop are subject to FDA and foreign regulatory authority approval requirements, and we and any contract manufacturing organizations (CMOs) or other third-party manufacturers that we may engage for manufacturing our product candidates will need to meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. Our existing product candidates are currently manufactured by us and our current manufacturing operations, including protocols, processes, materials, and facilities, may not support regulatory approval of our existing product candidates. We may be required to identify alternative protocols, processes, materials or facilities for the manufacture of any of these product candidates in compliance with applicable regulatory requirements. In addition, we may be required to make changes to our protocols for the supply and transport of our product candidates to enable effective distribution of our product candidates. Any modifications to our manufacturing and supply protocols, processes, materials or facilities, and any delays in, or inability to, establish acceptable manufacturing and supply operations for our product candidates could require us to incur additional development costs or result in delays to our clinical development. If we or any CMOs or other third-party manufacturers that we may engage for manufacturing our product candidates are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the regulatory approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or any CMOs or other third-party manufacturers that we may engage for manufacturing our product candidates will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities and on the requisite timelines to meet the requirements for the potential launch of the product, or to meet potential future demand. Additionally, changes in regulatory requirements may require us or any third-party manufacturers that we may engage for manufacturing our product candidates to perform additional studies or to modify protocols, processes, materials or facilities for the manufacture of our product candidates or any components thereof. Any of these challenges could delay initiation or completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

A disruption to our manufacturing operations, or the inability by us or our third-party suppliers or manufacturers to manufacture sufficient quantities of our product candidates at acceptable quality levels or costs, or at all, would materially and adversely affect our business.

Developing manufacturing processes to support clinical studies and commercialization requirements is a difficult and uncertain task, and there are risks associated with scaling to the level required for clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability and purity issues, lot consistency, and timely availability of acceptable reagents and raw materials. If we are unable to scale to the level required for the conduct of clinical trials or commercialization, we may not be able to produce our product candidates in a sufficient quantity to conduct our ongoing and planned clinical trials, or to meet demand if any product candidates are approved for commercialization. We have not yet caused any

of our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

We are substantially dependent on our own internal manufacturing facilities in San Diego, California for the production of our product candidates, and we rely, and expect to continue to rely, on third parties for the manufacture of certain components to manufacture our product candidates for use in conducting clinical trials. The facilities used to manufacture our product candidates, including our own facilities, must be evaluated by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it later finds deficiencies or withdraws any such approval in the future, we may not be able to locate additional or replacement facilities to produce such product candidates or materials in a timely manner and on commercially reasonable terms, or at all. This would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Because we rely on our own manufacturing facilities to produce our product candidates and on third parties for the manufacture of certain components, we are required to transfer certain manufacturing process know-how and certain intermediates to third parties, including larger-scale facilities operated by a CMO or by us, to facilitate manufacture of our product candidates for clinical trials and commercialization. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We and any CMOs or third parties that we engage to manufacture our product candidates will need to conduct significant development work to transfer these processes and manufacture each of our product candidates for clinical trials and commercialization. In addition, we may be required to demonstrate the comparability of material generated by any CMO or third parties that we engage for manufacturing our product candidates with material previously produced and used in testing. Any inability to manufacture comparable drug product by us or any CMOs or third parties that we engage to manufacture our product candidates could delay the continued development of our product candidates.

In addition to relying on third parties for the manufacture of certain components used in the manufacture of our product candidates, we manufacture our product candidates ourselves, including all of the clinical supply of our iPSC-derived NK-cell and T-cell product candidates for our ongoing and planned clinical trials. We will need to scale up our own manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient quantities of each of our product candidates to support commercialization of each of our product candidates, if approved. Accordingly, we will be required to make significant investments to maintain and expand our existing Good Manufacturing Practice (GMP) manufacturing capabilities and facilities, establish additional GMP manufacturing facilities, conduct GMP production, and process and scale up development and technology transfer activities for the manufacture of our product candidates, and our efforts to scale our own manufacturing operations may not succeed.

Even if we are successful in developing manufacturing capabilities sufficient for clinical and commercial supply, problems with our manufacturing operations or those of the third-party manufacturers upon which we rely, including difficulties with production costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, shortages of materials and supplies, facility shutdowns, global pandemics or other public health concerns, global geopolitical tensions, including wars and other armed conflicts, natural disasters (including due to the effects of climate change) or other reasons, as well as compliance with strictly enforced federal, state and foreign regulations, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient supplies of our product candidates for our ongoing and planned clinical trials or eventual commercialization. Further, delays in regulatory inspections, commissioning and receiving regulatory approvals for our manufacturing capabilities or facilities, including any new facilities could delay our development plans, including the initiation and conduct of our ongoing and planned clinical trials. In addition, we and our third-party manufacturers may have limited manufacturing capacity for certain product candidates or components used in manufacturing our product candidates, and we may fail to locate suitable additional or replacement manufacturing capacity, including for the manufacture of our product candidates in compliance with current GMP (cGMP) or current Good Tissue Practice (cGTP), on a reasonable basis or at all. Any such failure could be the basis for the FDA or other regulatory authorities to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

Furthermore, certain of the components currently used in manufacturing our product candidates are research-grade only, and we may encounter problems obtaining or achieving adequate quantities and quality of clinical grade materials that meet FDA, European Medicines Agency, or other standards or specifications applicable in the United States or in other countries with consistent and acceptable production yields and costs. In addition, if contaminants are discovered in our supply of product candidates or in our

manufacturing facilities or those of our third-party suppliers and manufacturers, such manufacturing facilities may be closed for an extended period of time to investigate and remedy the contamination. Any such events could delay or prevent our ability to obtain regulatory approval for or commercialize our product candidates, which would adversely affect our business, prospects, financial condition and results of operations.

Because our approach to the development of product candidates is based on novel and unproven technologies, it is subject to a substantial degree of technological uncertainty and we may not succeed in developing any of our product candidates.

All of our current product candidates are based on our novel iPSC platform, and some of our product candidates utilize novel genome editing technologies. To date, no iPSC-derived therapeutic product candidates have been approved in the United States or worldwide, and there have been only a limited number of regulatory approvals of genome edited therapeutics, and similarly a limited number of clinical trials involving the use of a therapeutic product candidate manufactured using a master iPSC line or genome edited cells. The development of such complex cell therapies is a relatively new and emerging field, and the scientific research that forms the basis of our efforts to discover and develop iPSC-derived and genome edited cellular immunotherapies is ongoing; this is particularly true in relation to the development of cell therapies for the treatment of autoimmune diseases where there is limited clinical data available and where we have limited prior experience. We may determine to incorporate information learned from this research into the design of our ongoing Phase 1 clinical trials of our iPSC product candidates, as well as our planned future clinical trials, which could delay or impair our clinical development activities. We may ultimately discover that our product candidates do not possess certain properties required for therapeutic effectiveness or protection from toxicity in our target patient populations, or they may exhibit undesirable side effects as more patient data become available. In addition, our product candidates may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. It may take many years before we develop a full understanding of the pharmacological properties of our product candidates, and we may never know precisely how they function in vivo. As with any new biologic or product developed using novel technologies, our product candidates have an unknown immunogenicity profile. As a result, our cellular immunotherapy product candidates may trigger immune responses that inhibit their therapeutic effects or cause adverse side effects. In addition, one or more of our product candidates may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

Any such problems that affect one of our product candidates may have an unfavorable impact on all of our product candidates. As a result, we may never succeed in developing a marketable product and we may never become profitable, which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

We anticipate that our current product candidates and any future product candidates may be used in combination with third-party drugs or biologics, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.

Certain of our product candidates are being developed for use in combination with one or more other cancer therapies, such as monoclonal antibodies, and other current or future product candidates may be used in combination with other biologics or drugs, both approved and unapproved, such as fludarabine. Our ability to develop and ultimately commercialize our current product candidates and any future product candidates used in combination with another drug or biologic will depend on our ability, or the ability of third-party clinical trial sites on which we rely, to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that we, or third-party clinical trial sites on which we rely, will be able to secure a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure by us, or by third-party clinical trial sites on which we rely, to secure a steady supply of such drugs or biologics may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to

the combination therapy and not our current product candidates or any of our future product candidates. Moreover, following product approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, quality, manufacturing and supply issues, and changes to the standard of care.

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

In addition, to the extent a third-party clinical trial site on which we rely sources a combination therapy itself and does not submit the costs of such therapy to government programs or patients' insurance, the costs of such therapy may be passed on to us, which could harm our business, financial condition, results of operations, stock price and prospects.

If we encounter difficulties enrolling patients in our clinical trials, including as a result of challenges in identifying and recruiting eligible patients to participate in our trials or competition for patients, our clinical development activities could be delayed or otherwise adversely affected.

We are required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of our product candidates, and we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and who meet certain criteria, in a timely manner. In addition, we will be competing with other clinical trials of product candidates being developed by our competitors in the same therapeutic areas, and potential patients who might be eligible for enrollment in one of our clinical trials may instead choose to enroll in a trial being conducted by one of our competitors. We may also face an unwillingness of sites to participate in our clinical trials. A number of cell therapy companies have recently commenced clinical trials for the treatment of autoimmune diseases, which has increased competition for investigators and for patients for our ongoing and any future clinical trials that we may initiate for the treatment of autoimmune diseases.

Our ability, and the ability of investigators, to enroll patients in our ongoing and planned clinical trials of our product candidates is affected by factors including:

- our ability to identify clinical trial sites and recruit clinical trial investigators with the appropriate capabilities, competencies and experience;
- our ability to open clinical trial sites;
- the ability to identify, solicit and recruit a sufficient number of patients;
- severity of the disease under investigation;
- the design of the clinical trial and whether the FDA and other foreign regulatory agencies agree to the design and implementation of the trial;
- the relatively small size and nature of the patient populations for certain of our clinical trials;
- eligibility criteria for the clinical trials in question;
- clinicians' and patients' and parents' (for juvenile patients) perceptions as to the potential risks and benefits of the product candidate under study in relation to other available therapies, including any perceived risks associated with our iPSC-derived product candidates, which we believe are the first ever iPSC-derived cell therapies cleared by the FDA for clinical investigation in the United States, or with our chimeric antigen receptor (CAR) T-cell therapies broadly following FDA's investigation into reports of T-cell malignancies for B-cell maturation antigen (BCMA)- and CD19-directed autologous CAR T-cell therapies, and perceived risks associated with the novel use of cell therapies for the treatment of autoimmune diseases, where there are no FDA-approved cell therapies and limited clinical precedent;
- changing medical practice patterns or guidelines related to the indications we are investigating;
- the availability of competing therapies and clinical trials;

- efforts to facilitate timely enrollment in clinical trials;
- the availability of time and resources at the limited number of institutions at which our clinical trials are or will be conducted, including any constraints on resources, or policies and procedures implemented, at hospitals and clinical trial sites as a result of any natural disaster or public health crisis;
- the availability of components and agents necessary to enroll and treat prospective patients in our clinical trials, including agents which may be required to condition patients or monoclonal antibodies which are intended for administration to patients in combination with our product candidates, in certain of our clinical trials;
- the ability to monitor patients adequately during and after treatment, including through remote monitoring if required as a result of precautionary changes implemented at clinical trial sites as a result of any public health crisis; and
- the proximity and availability of clinical trial sites for prospective patients.

Moreover, development of certain of our product candidates as treatment for autoimmune diseases represents a novel approach, and no cell therapies have been approved for commercial use for the treatment of autoimmune diseases. As a consequence, use of cell therapies such as our product candidates for the treatment of autoimmune diseases may not gain the acceptance of the public or medical community. Our ability to enroll patients in our clinical trials for treatment of autoimmune diseases will depend upon the treatment practices of physicians who specialize in the treatment of autoimmune diseases targeted by our product candidates, and enrollment in our clinical trials may be impaired if physicians are reluctant to enroll patients into our clinical trials in lieu of, or in addition to, using existing treatments with which they are more familiar and for which more clinical data may be available. In addition, patient populations targeted for autoimmune diseases by our product candidates are typically not at risk of near-term death, even if they may suffer life-threatening symptoms, so these patients will need to deem the potential benefits of our cell therapy product candidates to be worth the risk of unknown potential adverse side effects. Furthermore, autoimmune disease patients and their physicians may choose to use conventional therapies, such as corticosteroids or systemic immunosuppressive medications, rather than participate in our clinical trials.

In addition, our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates. This competition will reduce the number of clinical trial sites and patients available to us because some clinical trial sites and patients may opt to participate in a trial being conducted by a competitor rather than participate in our clinical trials. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

The clinical development of our product candidates could be substantially delayed if we are required to conduct unanticipated studies, including preclinical studies or clinical trials, or if the FDA imposes other requirements or restrictions including on the manufacture, of our product candidates.

The FDA may require us to generate additional preclinical, product, manufacturing, or clinical data as a condition to continuing our current clinical trials, or initiating and conducting any future clinical trials of our current product candidates or other cell product candidates that we may identify. Additionally, the FDA may in the future have comments, or impose requirements, on the conduct of our clinical trials or the initiation of clinical trials or any of our other iPSC-derived cell product candidates, including the protocols, processes, materials and facilities we use to manufacture our product candidates and potential future product candidates in support of clinical trials. Any requirements to generate additional data, or redesign or modify our protocols, processes, materials or facilities, or other additional comments, requirements or impositions by the FDA, may cause delays in the initiation or conduct of the current or future clinical trials for our product candidates and subsequent development activities for our product candidates, and could require us to incur additional development or manufacturing costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our preclinical or clinical development activities for our product candidates, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for our product candidates.

Further, if the results of our clinical trials are inconclusive, or if there are safety concerns or adverse events associated with our existing product candidates or any other product candidates we may identify, we may:

- be delayed in obtaining, or unable to obtain, regulatory approval for such product candidates;
- be required to amend the protocols for our clinical trials, perform additional nonclinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings or contraindications; or
- in the event a product candidate is approved, have regulatory authorities withdraw their approval of the product or impose restrictions on its use.

Even if our current and planned clinical trials are successful, we will need to conduct additional clinical trials, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing protocols, processes, materials or facilities or under different manufacturing conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. In addition, changes in regulatory policies under the current U.S. presidential administration may result in delays in the regulatory review and approval process and cause uncertainty regarding approval pathways. If we fail to meet the requirements to support continued clinical development, our clinical development activities for any of our product candidates are delayed or suspended, or we fail to obtain or maintain regulatory approvals with an acceptable scope, our business, prospects, financial condition and results of operations will be harmed.

We are pursuing multiple programs and product candidates in our novel cell therapy development pipeline using an approach that is designed to enable rapid incorporation of new product features. If we elect to incorporate these new features into next-generation product candidates, this may render our existing product candidates obsolete, and we may devote our limited resources in pursuit of a particular program for which there is a greater potential for success and fail to capitalize on development opportunities or product candidates including those which may be more advanced in development.

We focus on the development of programmed cellular immunotherapies for patients, including off-the-shelf NK- and T-cell product candidates derived from clonal master engineered iPSC lines. Because our iPSC product platform is designed to enable rapid incorporation of novel functional product features in an evolving clinical setting, we may elect to incorporate these discoveries into next-generation product candidates that render our existing product candidates, including product candidates under clinical development, obsolete. Additionally, because we have limited financial and personnel resources, we may elect or be required to abandon or delay the pursuit of opportunities with existing or future product candidates, including those that may be more advanced in development than those we ultimately elect to pursue. We have also expanded our research and development efforts into areas outside of our initial focus in oncology, such as autoimmune diseases, where we have limited experience. Due to these factors, our spending on current and future research and development programs and product candidates and the scientific innovation arising from these expenditures, may not yield commercially viable product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients may report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions and may require us to pause our clinical trials or require additional testing to confirm these determinations, if they occur. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects or patients. Many times, drug-related side effects are only detectable after investigational products are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval.

Currently approved CAR T-cell therapies and those under development have shown frequent rates of adverse events, including infection, cytokine release syndrome (CRS), and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), and some adverse events have resulted in patient deaths. In clinical trials of our current product candidates, adverse events have occurred and there is a possibility that our current or future product candidates could cause similarly life threatening serious adverse events such as CRS and ICANS. Additionally, preconditioning regimens, such as those currently implemented in certain regimens of our clinical trials, may increase the risk of occurrence and severity of adverse side effects including infection, prolonged or persistent cytopenias, and ICANS. Patients in our clinical trials receiving preconditioning treatment may experience increased or more severe adverse effects specifically related to the preconditioning regimen, including allergic reactions, shortness of breath, fevers, infections, low blood counts, development of certain cancers, loss of fertility, temporary hair loss, and organ dysfunction. Furthermore, because certain autoimmune diseases we seek to treat may be less serious than the later stage cancers traditionally being treated with cell therapies or

other immunotherapy products, we believe the FDA and other regulatory authorities will apply a different benefit-risk threshold such that any potential harmful side effects may outweigh the benefits of our product candidates and require us to cease clinical trials or result in denial of regulatory approval of our product candidates in autoimmune disease indications. Tolerance for adverse events in the autoimmune disease patient populations being pursued with cell-based therapies, such as in patients in our FT819 clinical trial for the treatment of SLE and other autoimmune disease indications, is expected to be lower than it is in oncology, and the risks of negative impacts from these toxicities may therefore be greater for our autoimmune programs than for our oncology programs or the oncology programs of others. Medical personnel using our product candidates may also need additional training to understand the potential side effect profile and potential toxicities associated with treatment with cellular immunotherapies, including FT819, and to appropriately recognize and manage any side effects that may occur in our clinical trials. Inadequate management of the potential side effects could result in patient deaths. Undesirable side effects, whether associated with our product candidate or with a preconditioning regimen, may delay patient enrollment in our clinical trials, and cause us or regulatory authorities to interrupt, delay, or halt clinical trials. Any undesirable side effects could result in changes to our clinical trial design and development strategy, a more restrictive label, or the delay, denial, or revocation of regulatory approval by the FDA or foreign regulatory authorities. Any such delay or failure as a result of undesirable side effects would harm our business, financial condition, results of operations and prospects.

Certain of our product candidates are being developed for the treatment of patient populations with significant comorbidities, particularly in the case of oncology patients, that may result in deaths or serious adverse events or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients treated with our current product candidates, particularly in our clinical trials in oncology indications, may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. In particular, the oncology diseases we are studying have complex comorbidities and the patients enrolled in those studies are often critically ill. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our existing product candidates or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

Because our product candidates are based on novel technologies, it is difficult to predict the regulatory approval process and the time, the cost and our ability to successfully initiate, conduct and complete clinical development, and obtain the necessary regulatory and reimbursement approvals, required for commercialization of our product candidates, if approved.

Our cell programming technology and platform for generating cell therapy products using iPSCs represent novel therapeutic approaches, and to our knowledge there are currently no iPSC-derived cell products approved anywhere in the world for commercial sale. As such, it is difficult to accurately predict the type and scope of challenges we may incur during development of our product candidates, and we face uncertainties associated with the preclinical and clinical development, manufacture and regulatory requirements for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of these product candidates. In addition, because our iPSC-derived cell product candidates are all in the early clinical or preclinical stage, we are currently assessing safety in humans and have not yet been able to assess the long-term effects of treatment. Animal models and assays may not accurately predict the safety and efficacy of our product candidates in our target patient populations, and appropriate models and assays may not exist for demonstrating the safety and purity of our product candidates, as required by the FDA and other regulatory authorities for ongoing clinical development and regulatory approval.

The preclinical and clinical development, manufacture, and regulatory requirements for approval of novel product candidates such as ours can be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the preclinical and clinical development, manufacture, and regulatory requirements for approval of our product candidates, we may be required to modify or change our preclinical and clinical development plans or our manufacturing activities and plans, or be required to meet stricter regulatory requirements for approval. Any such modifications or changes could delay or prevent our ability to develop, manufacture, obtain regulatory approval or commercialize our product candidates, which would adversely affect our business, financial condition and results of operations.

Cellular immunotherapies, and iPSC-derived cell therapies in particular, represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with cell therapies. For example, in January 2024, the FDA determined that new safety information related to T-cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies. To date, there are relatively few approved cell therapies as treatments for cancer, and no cell-based therapies have been approved for commercial use for

the treatment of an autoimmune disease. Currently, all approved CAR T-cell immunotherapies are in oncology indications, and there can be no assurance that the FDA will find the risks of treatment with cell therapy acceptable in other indications, such as autoimmune diseases. The development of any cell therapy may be placed on hold by the FDA upon the detection of any unexpected safety event to evaluate the potential relevance of such novel technology to the occurrence of such safety event, highlighting the technical and regulatory risk of working with new technology. As a result, the regulatory approval process for product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for cell therapy product candidates based on other, better known or more extensively studied technologies and therapeutic approaches.

Regulatory requirements in the United States and in other countries governing the development of cell therapy products and therapeutic products created with gene editing technology have changed frequently and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, as regulatory expectations regarding cell therapy products and products created with gene editing technology continue to evolve, the FDA could require additional testing or new testing of products created with gene editing technology, including our product candidates, and any such additional FDA requirements for approval for any of our product candidates may adversely impact or slow development of our product candidates. The FDA previously established the Office of Tissues and Advanced Therapies (OTAT) within the Center for Biologics Evaluation and Research (CBER) to consolidate the review of cell therapy and related products, and to advise CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products (OTP) and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload and new commitments under the Prescription Drug User Fee Act agreement for fiscal years 2023-2027. It is possible that over time and with new leadership direction at the FDA that new or different divisions may be established or be granted the responsibility for regulating cell and/or gene therapy products, including iPSC-derived cell products made with gene editing technology, such as ours. The regulatory review divisions and committees, and any new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies or clinical trials, and delay or prevent development, approval, and commercialization of our product candidates.

In addition, to market any product outside of the United States, we must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant must obtain the necessary approvals by the comparable foreign regulatory authorities before commencing clinical trials or marketing of the product in those countries or jurisdictions. For example, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States but can differ in significant ways. It entails the satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission of a marketing authorization application to the relevant competent authorities and the granting of a marketing authorization by those authorities before the product can be marketed and sold in the European Union.

As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our product candidates will likely be reviewed by an FDA advisory committee. Any guidance we receive from the FDA or other foreign regulatory authorities is subject to change. These regulatory authorities could change their position, including on the acceptability of our clinical trial designs or the clinical endpoints selected in our clinical trials, which may require us to complete additional clinical trials or result in stricter conditions for obtaining regulatory approval for our product candidates. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

Preliminary data and interim results we disclose may change as more patient data becomes available or as we make changes to our protocols or manufacturing processes, and such interim results and results from earlier studies may not be predictive of the final results, or of later studies or future clinical trials.

We may from time to time disclose results from preclinical testing or preliminary data or interim results from clinical studies of our product candidates. Such results from preclinical testing, process development and manufacturing activities, and clinical studies, including interim clinical trial results as of specified data cutoff dates and results of earlier clinical studies with similar product candidates, are not necessarily predictive of future results, including later clinical trial results.

The results of our current and future clinical trials may differ from results achieved in earlier preclinical and clinical studies for a variety of reasons, including:

- we may not demonstrate the potency and efficacy benefits observed in previous studies;
- our efforts to improve, standardize and automate the manufacture and supply of our product candidates and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency, stability, or efficacy of such product candidates;
- differences in study design, including differences in conditioning regimens, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve study endpoints in our current or future clinical trials; and
- safety issues or adverse events in patients who enroll in our current or future clinical trials.

Additionally, some of the data from clinical trials of our product candidates performed to date were generated from open-label studies, and these studies are being conducted at a limited number of clinical sites on a limited number of patients. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which treatment regimen patients have received and may interpret the information of the treated group more favorably given this knowledge. Accordingly, the preliminary data from our Phase 1 clinical trials of certain of our product candidates may not be predictive of future clinical trial results for these or other product candidates when studied in a controlled environment or larger patient populations.

From time to time, we also publish interim, "top-line," or preliminary data from our clinical studies based on a preliminary analysis of then-available data. Preliminary or interim data from clinical trials that we are conducting are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, the duration of treatment increases and more patient data become available. For example, although we have, from time to time, reported positive interim clinical data for certain of our clinical programs, we may encounter dose-limiting toxicities or unacceptable side effects for these product candidates as dose escalation and expansion progresses in our clinical trials and additional patient data become available. Our preliminary or interim results and related conclusions also are subject to change following a more comprehensive review of the data related to the particular study or trial. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary, "top-line," or interim data and final data could significantly harm our business prospects, financial condition and results of operations.

Results of clinical testing of any of our existing or future product candidates may fail to show the necessary safety and efficacy required for regulatory approval.

Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans of any such product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our product candidates have a limited history of being evaluated in human clinical trials. Any of our product candidates may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical trials.

There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

If our product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected. In addition, the standard of care may change with the approval of new products for the same indications that we are studying.

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

Any product candidate for which we obtain marketing approval, along with the manufacturing protocols, processes, materials and facilities, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, requirements relating to cGMP, applicable product tracking and tracing requirements, quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Additionally, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Later discovery of previously unknown problems with our product candidates, manufacturing operations, or failure to comply with regulatory requirements, may lead to various adverse conditions, including significant delays in bringing our product candidates to market and/or being precluded from manufacturing or selling our product candidates, any of which could significantly harm our business.

We have received and may in the future seek regenerative medicine advanced therapy (RMAT) designation for certain of our product candidates, but such designation may not actually lead to a faster development or regulatory review or approval process and we may be unable to obtain or maintain the benefits associated with such designation.

We have received RMAT designation from the FDA for FT819 for the treatment of active moderate to severe systemic lupus erythematosus (SLE), including lupus nephritis, and may seek additional RMAT designations in the future for current or future product candidates. A product candidate is eligible for RMAT designation if: (1) it is a cell therapy, therapeutic tissue engineering product, human cell or tissue product, or a combination product using any such therapies or products; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) there is preliminary clinical evidence that indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. This program is intended to facilitate efficient development and expedite review of RMATs. A Biologics License Application (BLA) for a product candidate with RMAT designation may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate that has RMAT designation and is subsequently granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. Even though we obtained RMAT designation for FT819 in April 2025, such designation does not change the standards for product approval, and there is no assurance that this designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. In addition, even if one or more of our product candidates qualifies for RMAT designation, the FDA may rescind RMAT designation if it believes the product no longer meets the conditions for qualification.

We may rely on orphan drug status to develop and commercialize certain of our product candidates, but orphan drug designations may not confer marketing exclusivity or other expected commercial benefits and we may not be able to obtain orphan drug designations for our other product candidates.

We may rely on orphan drug exclusivity for product candidates that we may develop. Orphan drug status confers seven years of marketing exclusivity in the United States under the Federal Food Drug, and Cosmetic Act, and up to ten years of marketing exclusivity in Europe for a particular product in a specified indication, subject to certain conditions. However, we may be unable to obtain orphan drug designations for any of our product candidates that we are currently developing or may pursue. Even if we do obtain orphan drug designations and are the first to obtain marketing approval of our product candidates for the applicable indications,

we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these time frames. Furthermore, any marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product.

For any product candidate for which we may be granted orphan drug designation in a particular indication, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication in the United States, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to our orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

We may seek designation for our cell programming technology as a designated platform technology, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek designation for our cell programming technology as designated platform technology. Under FDORA, a platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under a BLA or New Drug Application (NDA); (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA or NDA for a drug that uses or incorporates the platform technology. Even if we believe our cell programming technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that a drug will be developed more quickly or lead to a faster FDA review or approval process and does not assure ultimate FDA approval of a drug. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

We may seek approval of one or more of our product candidates into real-time oncology review (RTOR). This program may not lead to a faster regulatory review or approval process and does not increase the likelihood that our product candidate(s) will receive marketing approval.

Participation in RTOR is voluntary. Our acceptance into RTOR does not guarantee or influence approval of our application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application even if it is selected for RTOR. If at any time the FDA determines our participation in RTOR, if selected, is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

We may be subject to certain regulations, including federal and state healthcare fraud and abuse laws, physician payment transparency laws, anti-bribery and anti-corruption laws and health information privacy and security laws. Any actual or perceived failure to comply with these regulations could have a material adverse effect on our business and financial condition.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state healthcare laws, including, without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may impact, among other things, our proposed sales, marketing and education programs. Additionally, we may be subject to state and foreign equivalents of such healthcare laws and regulations, some of which may be broader in scope and may apply regardless of the payor, as well as patient privacy regulation by both the federal government and the states in which we conduct our business. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse

laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. For more information, please see "Business—Government Regulation—Other Healthcare Laws and Compliance Requirements" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2025.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement 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.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union (EU). The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and individual imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or individual imprisonment.

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

We plan to develop and potentially commercialize our product candidates worldwide. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with data privacy regulations in foreign countries;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act or comparable foreign regulations;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from ongoing and emerging geopolitical tensions, including wars, armed conflicts or acts of terrorism.

These and other risks associated with our potential international operations may materially adversely affect our ability to attain or maintain profitable operations, which could have a material adverse effect on our business and results of operations.

We may decide to conduct clinical trials for our product candidates outside the United States, and the FDA may not accept data from trials conducted in such locations.

To date, we have only conducted clinical trials in the United States. However, we may in the future choose to conduct one or more of our clinical trials or include sites in current or future clinical trials outside the United States.

Although the FDA may accept data from sites or clinical trials outside the United States, acceptance of these data is subject to conditions imposed by the FDA. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND unless (i) the trial was well-designed and well-conducted in accordance with Good Clinical Practice (GCP) requirements, including requirements for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected, and (ii) the FDA is able to validate the data from the trial through an onsite inspection, if necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering must be met. Many foreign regulatory authorities have similar approval requirements. In addition, while these clinical trials or trial sites are subject to the applicable local laws where the trials are conducted, FDA acceptance of the data will depend on its determination that the trials or trial sites also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial or trial site outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or halt our development of the applicable product candidates.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

In June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This decision may result in more lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Risks Related to Our Financial Condition

Our ongoing and planned operations, including the development of our product candidates, will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, or commercialization of our product candidates.

We are currently advancing multiple product candidates through clinical development, and conducting preclinical research and development activities in other programs. Drug development is expensive, and we expect our research and development expenses to remain significant in connection with our ongoing activities, particularly as we advance our current product candidates in clinical trials and seek to initiate clinical development for additional product candidates.

As of September 30, 2025, our cash, cash equivalents, and investments were $225.7 million. We intend to use our cash, cash equivalents, investments primarily to fund the advancement and clinical development of our current product candidates and our ongoing preclinical, discovery and research programs, and for working capital and general corporate purposes. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize our existing product candidates and any other product candidates we may identify and develop. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, size, timing and costs of our ongoing and planned clinical trials, and any additional clinical trials we may initiate, conduct or support for our product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to initiate and conduct clinical trials for our product candidates and to establish and maintain manufacturing capabilities necessary to support such trials;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing and other research activities that may be necessary in order for an IND application to go into effect for a prospective clinical development candidate, as well as potential future clinical trials of any additional product candidates we may identify for development;
- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments, including payments owed to Memorial Sloan Kettering Cancer Center (MSKCC) in connection with the stock price appreciation milestones;
- our ability and the ability of our investigators to initiate and conduct, and the progress, results, size, timing and costs of, clinical trials of our product candidates that will be necessary to support any application for regulatory approval;
- our ability to manufacture, or enter into arrangements with third parties for the manufacture of our existing product candidates, as well as potential future clinical development candidates, both for clinical development and commercialization, and the timing and costs associated with such manufacture;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, or other costs we may incur, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of manufacturing, distribution, and commercialization activities and arrangements, including the manufacturing of our product candidates, establishment of effective protocols for the supply and transport of our product candidates, and the establishment of a sales and marketing organization either internally or in partnership with a third party; and
- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators including our existing collaborations with Ono Pharmaceutical Co., Ltd. (Ono), and the University of Minnesota to advance the research, development and commercialization of therapeutic products.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment and interest obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at a different stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, while the overall impacts of the ongoing and emerging geopolitical tensions, including wars and other armed conflicts, on the global economy remain unknown and difficult to predict, these events caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of these and other similar global events could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

If we cannot raise additional capital or obtain adequate funds, we may be required to curtail significantly our research and clinical programs or may not be able to continue our research or clinical development of our product candidates. Our failure to raise

additional capital, or obtain adequate funds, will have a material adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company formed in 2007 with a limited operating history. We have not yet obtained regulatory approval for any of our product candidates or generated any revenues from therapeutic product sales. Since inception, we have incurred significant net losses in each year and, as of September 30, 2025, we had an accumulated deficit of $1.5 billion. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of our product candidates and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our research and development of, and seek regulatory approval for, our product candidates, in-license or acquire new product candidates for development, implement additional infrastructure and internal systems, and hire additional scientific, clinical, and administrative personnel. We anticipate that our net losses for the next several years could be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with pharmaceutical, biological, and cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials, preclinical studies, process development, manufacturing activities, or the research and development of any of our product candidates. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We have broad discretion over the use of our cash, cash equivalents, and investments and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents, investments and any additional funds that we may raise to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline or delay the development of our product candidates. We may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Risks Related to Our Reliance on Third Parties

We are, and expect to continue to be, dependent on third parties to conduct some or all aspects of manufacturing of our product candidates for use in clinical trials and for commercial sale, if approved. Our business could be harmed if those third parties fail to perform satisfactorily.

While we currently manufacture clinical supplies of our iPSC-derived cell product candidates at our cGMP facilities located in San Diego, California, we also rely on third parties to manufacture certain components required for the manufacture of our product candidates, and we may rely on third parties to conduct some or all aspects of manufacturing of our product candidates for use in conducting later stage clinical trials and for commercial sale upon approval of any of our product candidates.

Reliance on third parties for manufacture of our product candidates and components utilized in manufacturing our product candidates entails certain risks, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial, personnel or other resources to meet its obligations, the possibility that the third party fails to manufacture such components, or our product candidates or any products we may eventually commercialize, in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination of our manufacturing relationship by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards.

In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to a particular 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 if needed, or we may be unable to transfer such skills at all. In addition, if we are required to change contract

manufacturers for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies produced by different manufacturers, which could require the conduct of additional clinical trials.

Further, we depend in some instances on third party suppliers, including sole source suppliers, for the provision of reagents, materials, devices and equipment that are used by us and our third-party contract manufacturers in the production of our product candidates, including certain of our iPSC-derived cell therapy product candidates. Any disruption to or loss of supply from any of these suppliers could delay our clinical development and commercialization efforts, which would adversely affect our business, prospects, results of operations and financial condition.

We depend on strategic partnerships and collaboration arrangements for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements are terminated or are unsuccessful, this could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and materially harm our results of operations.

Our strategy for fully developing and commercializing our product candidates is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and other third parties. We currently have a corporate collaboration agreement with Ono. Our collaboration agreement with Ono provides for, among other things, research funding and significant future payments should certain development, regulatory and commercial milestones be achieved. Under our arrangement with Ono and any future corporate arrangements that we may form, our corporate collaborators may be 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 such corporate collaborations in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations.

Our lack of control over the research funding for, and the development and commercialization of, certain of our product candidates being developed under the collaboration and option agreement we entered into with Ono on September 14, 2018 (as amended to date, the Ono Agreement) and any other product candidates that we may develop under a future arrangement could cause delays or other difficulties in the development and commercialization of any of our product candidates, which may prevent completion of research and development activities and intended regulatory filings in a timely fashion, if at all. Because we expect to continue to rely on our current collaborator and to enter into new collaborations in the future, the development and commercialization of any of our product candidates could be substantially delayed, and our ability to receive future funding could be substantially impaired, if one or more of our current or future 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 or delays development of one or more product candidates under the collaboration;
- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of 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 the Ono Agreement 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.

Cell-based therapies depend on the availability of reagents and specialized materials and equipment which in each case are required to be acceptable to the FDA and foreign regulatory agencies, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We rely on third-party suppliers for various components, materials and equipment required for the conduct of our clinical trials and the manufacture of our product candidates and do not have supply arrangements for certain of these components.

The development and manufacturing of our product candidates requires many reagents and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. To date, we and our CMOs have purchased equipment, materials and disposables used for the manufacture of our existing product candidates from third-party suppliers. 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 rely on the general commercial availability of materials and equipment required for the manufacture of our product candidates, and 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. Even if we are able to enter into such contracts, we may be limited to a sole third-party for the supply of certain required components and equipment.

In addition, the clinical development of our product candidates depends on the availability of certain materials and agents used in our clinical trials. For example, we intend to develop certain of our product candidates as a combination therapy with other cancer therapies, such as monoclonal antibodies, requiring availability and use of these monoclonal antibodies in certain of our clinical trial protocols. Any failure or delays by us or by our clinical sites to obtain sufficient quantities of materials and agents required under our protocols, or other components and agents necessary for the conduct of our clinical trials, may delay our ability to enroll and treat patients in, or complete, our current or future clinical trials of our product candidates on time, if at all.

As a result of any public health crises, the business and operations of our suppliers and other third parties which produce agents and materials used in our clinical trials or manufacturing of our product candidates may be disrupted or delayed, and we in turn may experience disruptions or delays in our supply chain. A delay or inability to continue to source product or materials from any of these suppliers or third parties, which could be due to the impacts of any public health crises, natural disasters (including due to the effects of climate change), ongoing and emerging global geopolitical tensions, including wars and other armed conflicts, 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 manufacture our product candidates and our ability to conduct clinical trials, which could significantly harm our business.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect our clinical development of our product candidates and harm our business.

We currently rely on third parties to conduct certain research and development activities and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to timely develop, manufacture, obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely upon third parties, including medical institutions, clinical investigators, and clinical research organizations (CROs) for the conduct of certain research and preclinical development activities, process development and manufacturing activities, and for the conduct, management, and supervision of clinical trials of our product candidates. We do not have direct control over the activities of these third parties, and may have limited influence over their actual performance. Our reliance on these third parties and CROs does not relieve us of our responsibilities to ensure that our clinical studies are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards.

We are responsible for complying, and we are responsible for ensuring that our third-party service providers and CROs comply, with applicable GCP for conducting activities for all of our product candidates in clinical development, including conducting our clinical trials, and recording and reporting data from these trials. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with applicable GCP requirements. In addition, our registrational clinical trials must be conducted with product produced under applicable regulatory requirements.

If these third parties and CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines or successfully complete activities as planned, or if the quality or accuracy of the research, preclinical development, process development, manufacturing, or clinical data they obtain is compromised due to the failure to adhere to applicable regulatory and manufacturing requirements or for other reasons, our research, preclinical development, process development and manufacturing activities, and clinical trials, and the development of our product candidates, may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Further, if our agreements with third parties or CROs are terminated for any reason, the development of our product candidates may be delayed or impaired, and we may be unable to advance our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or impaired.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of our collaborators' or partners' support for our product candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of our product candidates. Any of these developments could harm our product development efforts.

We may also rely on certain third-party vendors located in China or who are owned by or are associated with certain Chinese companies to assist in non-clinical or clinical trials or provide laboratory services. It is unknown how current or future geopolitical relationships with China or specific Chinese-owned or associated vendors may affect our ability to complete our non-clinical or clinical trials.

We currently, and may in the future, do business with one or more companies located in China, or that are owned or operated by Chinese companies to provide non-clinical or clinical trial support services. The process of changing these vendors could have an adverse impact on our current clinical development programs if they were no longer permitted to provide services or products due to geopolitical pressures, including legislative activities or executive orders aimed at prohibiting certain Chinese or Chinese-owned biotechnology companies from engaging in biotechnology or biopharmaceutical research activities. We could experience delays in finding suitable replacement service providers located outside China or not otherwise owned by or associated with Chinese companies, which could have a material adverse effect on our development activities and our business. We are unable to predict whether or when proposed legislative or executive actions would be effective, and whether such changes would materially and

adversely affect our liquidity, access to capital and our ability to conduct business. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to manufacture and develop our product candidates.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property, or obtain and maintain patent protection for our technology and product candidates, other companies could develop products based on our discoveries, which may reduce demand for our products and harm our business.

Our commercial success will depend in part on our ability to obtain and maintain intellectual property protection for our product candidates, the operations used to manufacture them and the methods for using them, and also for our cell programming technology in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates or otherwise exploiting our cell programming approach. The scope of patent protection in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. We own and have exclusive licenses to patent portfolios for our product candidates and cell programming technology, although we cannot be certain that our existing patents and patent applications provide adequate protection or that any additional patents will issue to us with claims that provide adequate protection of our other product candidates. Further, we cannot predict the breadth of claims that may be enforced in our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. If we are unable to secure and maintain protection for our product candidates and cell programming technology, or if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices. The scope, validity or enforceability of our patents or the patents of our licensors may be challenged in such proceedings in either the courts or patent offices in the United States and abroad, and our business may be harmed if the coverage of our patents or the patents of our licensors is narrowed, or if a patent of ours or our licensors is judged invalid or unenforceable, in any such proceedings.

Furthermore, our intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of the patent rights and technology that we own or have licensed was funded in part by the U.S. government. As a result, the government has certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. These rights may permit the government to disclose our information to third parties and to exercise march-in rights to use or allow third parties to use our technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights or by any third party of its reserved rights could harm our competitive position, business, financial condition, results of operations, and prospects.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely affect our business and operations.

Certain rights to our key technologies and product candidates, including intellectual property relating to our iPSC technology, are licensed from third parties. As a licensee of third-party intellectual property, we rely on our licensors to file and prosecute patent

applications and maintain patents, and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our licensed patents, patent applications and other intellectual property rights, and we cannot be certain that such activities will result in valid and enforceable patents and other intellectual property rights. Additionally, our licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and we cannot be certain that our licensors will allocate sufficient resources or prioritize enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

We have obtained rights to develop, market and sell some of our product candidates through intellectual property license agreements with third parties. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. In particular, under our Amended MSKCC License with MSKCC, in the event a licensed product achieves a specified clinical milestone, MSKCC is eligible to receive from us certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSKCC is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. If we fail to comply with our obligations under our license agreements, including any payment obligations, we could lose some or all of our rights to develop, market and sell products covered by these licenses, and our ability to form collaborations or partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

We have in the past and may in the future become involved in litigation or other proceedings relating to the enforcement or defense of patent and other intellectual property rights, which could cause us to divert our resources and could put our intellectual property at risk.

To prevent infringement or unauthorized use of our intellectual property, we have in the past, and may in the future, need to file infringement claims. When we pursue litigation to stop another party from using the inventions claimed in any patents we own or control, that party has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. In addition to patent infringement lawsuits, we may decide to file interferences, oppositions, *ex parte* reexaminations, post-grant review, or *inter partes* review proceedings before the U.S. Patent and Trademark Office (the USPTO) and corresponding foreign patent offices. Litigation and other proceedings relating to intellectual property are unpredictable and expensive and may consume time and resources and divert the attention of managerial and scientific personnel. Such litigations and proceedings could substantially increase our operating losses and reduce the resources available for research, development, and other activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings or may be required to divert such resources from our ongoing and planned research and development activities. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There also is a risk that a court or patent office in such proceeding will decide that our patents or the patents of our licensors are not valid or are not enforceable, and that we do not have the right to stop the other party from using the inventions. Additionally, even if the validity of such patents is upheld, the court may refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we are not successful in enforcing or defending our intellectual property, our competitors could develop and market products based on our discoveries and technologies, which may reduce the commercial viability of, and demand for, our product candidates and any future products.

We or our strategic partners may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing, or increase the costs of commercializing, our product candidates.

Our success will depend, in part, on our ability to operate without infringing the proprietary 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, *ex parte* reexaminations, post-grant review, and *inter partes* review proceedings before the USPTO and corresponding foreign patent offices. 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 developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued,

the risk increases that our product candidates may be subject to claims of infringement of the patent rights or misappropriation of other intellectual property rights of third parties.

We cannot be certain that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. 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, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or intellectual property rights or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot guarantee that the manufacture, use or marketing of our existing product candidates or any other product candidates that we develop, or the use of our cell programming technology, will not infringe third-party patents. There may be third-party patents or patent applications with claims to materials, cell compositions, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for development or manufacture of our product candidates which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We own or license from third parties certain intellectual property rights necessary to develop and manufacture our product candidates. The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights, including to advance our research or allow commercialization of our product candidates. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical or biotechnology companies and academic institutions may also have filed or may be planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches or technology that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license

within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. In addition, it may be more costly for us to secure and maintain the necessary patent protection to block third parties from using our technology than to negotiate out-licenses or similar agreements with these parties to provide them with limited rights to use our technology. There can be no assurance that we will be able to successfully complete any such negotiations and ultimately acquire or maintain, on commercially viable terms, the rights to the intellectual property required for the successful development and commercialization of our product candidates.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we have initiated, and may from time to time initiate, litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

In conducting our business operations, we have obtained confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. If we fail in defending any such claims, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. We may also be subject to monetary damages, and any of these outcomes could have a material adverse impact on our business.

Proprietary information and invention assignment agreements with our employees and third parties may not prevent unauthorized disclosure of our trade secrets and other proprietary information.

In addition to the protection afforded by patents, we also rely upon unpatented trade secrets and improvements, proprietary know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our collaborators and consultants. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets, however, may be difficult to protect, and any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Although we use reasonable efforts to protect our trade secrets, our employees or former employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

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

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

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

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The term of our patents may not be sufficient to effectively protect our market position and products.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if we obtain patents covering our product candidates, once the patent life has expired for a product, we may be open to competition from other products. If the lives of our patents are not sufficient to effectively protect our products and business, our business and results of operations will be adversely affected.

Risks Related to the Commercialization of Our Product Candidates

We do not have experience marketing any product candidates and do not have a sales force or distribution capabilities, and if our products are approved, we may be unable to commercialize them successfully.

We currently have no experience in marketing and selling therapeutic products, including obtaining and maintaining adequate pricing and reimbursements. If any of our product candidates are approved for marketing, we intend to establish marketing and sales capabilities internally or we may selectively seek to enter into partnerships with other entities to utilize their marketing and distribution capabilities. If we are unable to develop adequate marketing and sales capabilities on our own or effectively partner with third parties, our ability to generate product revenues will suffer.

Even if we obtain regulatory approval of our product candidates, the commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

The commercial success of our products, if approved for marketing, will depend in part on the medical community, patients and third-party payers accepting our product candidates as effective and safe. The use of cellular immunotherapies for the potential treatment of autoimmune diseases is a recent development, and may not become widely accepted by patients, physicians, treatment centers, and third-party payors. If any of our products obtains regulatory approval but does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. For example, in January 2024, the FDA determined that new safety information related to T-cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies. FDA's investigation into CAR T-cell therapies and other similar actions could result in increased government regulation, unfavorable public perception and publicity, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. The degree of market acceptance of our products, if approved for marketing, will depend on a number of factors, including:

- the safety and efficacy of the products, and advantages over alternative treatments;

- the labeling of any approved product;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which any product candidate is approved;
- the emergence, and timing of market introduction, of competitive products;
- the effectiveness of our marketing strategy;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the cost of treatment in relation to alternative treatments;
- obtaining and maintaining adequate pricing and reimbursement; and
- sufficient third-party insurance coverage or governmental reimbursement, which may depend on our ability to provide compelling evidence that a product meaningfully improves health outcomes to support such insurance coverage or reimbursement.

The patient populations targeted by our autoimmune product candidates are also typically not at risk of near-term death, even if they may suffer life-threatening symptoms, so those patients will need to deem the benefits of cell therapy to be worth the risk of unknown potential adverse side effects. Our success in this space will depend upon physicians who specialize in the treatment of autoimmune diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. In addition, the target populations may be relatively small, resulting in a high degree of uncertainty regarding long-term demand for our product candidates. Even if we obtain marketing approval for a product, demand for our product may not be adequate to support commercialization.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Any failure to achieve market acceptance for our product candidates will harm our business, results and financial condition.

We expect to face uncertainty regarding the pricing of our existing product candidates and any other product candidates that we may develop. If pricing policies for our product candidates are unfavorable, our commercial success will be impaired.

Due to the novel nature of our cellular immunotherapy product candidates, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for any cellular immunotherapy product candidates that we develop will be relatively high due to their anticipated use in the prevention or treatment of life-threatening diseases where therapeutic options are limited, the biopharmaceutical industry has recently experienced significant pricing pressures. In particular, drug pricing and other healthcare costs continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility and adversely affect results of operations and our ability to raise funds.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the availability of coverage and reimbursement for these products from third-party payors, including government health administration authorities, private health insurers, and other managed care organizations. The availability and extent of reimbursement by governmental and private payors is essential for most patients who generally rely on third-party payors to reimburse all or part of the costs of their care, including treatments such as cellular immunotherapy. Because our product candidates represent new approaches to the treatment of cancer and autoimmune diseases, there is significant uncertainty as to the insurance coverage and reimbursement status of any product candidates for which we may receive regulatory approval. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS determinations to a substantial degree. If reimbursement or insurance coverage is not available for our product candidates, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv)

cost-effective; and (v) neither experimental nor investigational. For more information, please see "Business—Government Regulation—Coverage and Reimbursement" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2025.

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

If the market opportunities for our product candidates are restricted or smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidates may be small and variable, we must be able to successfully identify patients and capture a significant market share to achieve and maintain profitability.

We focus our research and development on product candidates for rare diseases. The FDA often approves new therapies initially for use in patients with relapsed or refractory disease. We expect to initially seek approval of our product candidates in these settings. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment. There is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials, including potentially comparative trials against approved therapies. Certain of our product candidates also target similar patient populations as autologous cell therapy product candidates, including approved autologous CAR T products. Our therapies may not be as safe and effective as approved autologous CAR T therapies and as a result, such product candidates may only be approved for patients who are ineligible for autologous CAR T therapy.

Our projections of the number of people who have or will have the diseases we may be targeting, as well as the subset of patients with these cancers in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, or the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates, all of which would adversely affect our results of operations and our business. Additionally, because our target patient populations may be small and variable, we may never achieve profitability without capturing a significant market share or obtaining regulatory approval for additional indications for our products.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. Additional changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the Affordable Care Act (ACA) and the passage of additional laws and regulations may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program. For more information regarding the risks related to recently enacted and future legislation please see "Business—Government Regulation—Healthcare Reform and Other Regulatory Changes" our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2025.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

The growing legislative and enforcement interest in the United States with respect to drug pricing practices has resulted in several U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (the IRA), for example, 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 to $2,000 starting in 2025, eliminating the prescription drug 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 an HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program; however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

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

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

On April 15, 2025, the Trump Administration published Executive Order 14273, “Lowering Drug Prices by Once Again Putting Americans First,” which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called “pill penalty” under the IRA that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients” which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to “take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries.” Notably, a similar “Most Favored Nation” pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

In addition, the U.S. Supreme Court’s 2024 decision in Loper Bright Enterprises v. Raimondo overruled the Chevron doctrine, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a

particular topic. In Loper Bright, the Supreme Court held that the U.S. Administrative Procedure Act requires courts to exercise their independent judgment when deciding whether an agency has acted within its statutory authority, and that courts may not defer to an agency interpretation solely because a statute is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. Any such challenges, if successful, could have an impact on our business, and any such impact could be material. In addition to potential changes to regulations and agency guidance as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays in and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations.

Risks Related to Our Business and Industry

The success of our existing product candidates is substantially dependent on developments within the field of cellular immunotherapy, and specifically developments relating to the use of pluripotent or genome edited cells for the manufacture of cellular therapeutics, the majority of which are beyond our control.

Our product candidates are designed and are being developed as therapeutic entities for use as cellular immunotherapies, and all of our current product candidates are based on our novel iPSC product platform. Additionally, some of our product candidates utilize novel genome editing technologies. To date, there is limited clinical trial experience testing iPSC-derived therapeutic product candidates using genome edited cells. The fields of cellular and genome edited therapies are evolving, and as more therapeutic product candidates derived from pluripotent and genome edited cells are reviewed by regulatory authorities, regulatory authorities may impose additional requirements for approval that were not previously anticipated. There have also been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. Additionally, in January 2024, the FDA determined that new safety information related to T-cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies. There can be no assurance that any product candidates developed from or related to our iPSC product platform or any of our research programs will not cause severe or undesirable side effects or result in significant delays or unanticipated costs, or that such development problems can be solved. Any adverse developments in the fields of cellular immunotherapy or genome edited therapy, such as the FDA's investigation into CAR T-cell therapies and other similar actions, could negatively affect our ability to develop and commercialize our product candidates.

We face intense competition in an environment of rapid technological and scientific progress from other biotechnology and pharmaceutical companies that are commercializing, 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 product candidates or platform technologies more rapidly than we do, if their commercialized products or product candidates are more effective, more cost effective, or have fewer side effects, or if they compete in various other aspects of our business, our ability to develop and successfully commercialize product candidates and to execute on our business plans will be adversely affected.

The biotechnology and pharmaceutical industries are intensely competitive and characterized by rapid and significant innovation, particularly in the areas of immune-oncology and the development and commercialization of cell therapies. 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. Many of our competitors have greater financial and other resources, such as larger research and development staff, more experienced manufacturing organizations and facilities and greater sales and marketing organizations. Third parties are commercializing, have developed, are developing or may develop product candidates, platform technologies and processes that compete with ours. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community, as well as novel treatments that are currently in preclinical or clinical development or may otherwise enter the market. We believe that a significant number of product candidates are currently under development, including various cellular immunotherapies as well as multifunctional targeted antibodies, such as bi-specific and tri-specific T-cell engagers, which may become commercially available in the future for the treatment of indications, including a variety of cancers, for which we are developing or may try to develop our product candidates. Additionally, several companies with experience and knowledge in the development of CAR T-cell therapies for oncology indications have now commenced the development of cell therapies for the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease affected populations, and the product candidates these companies develop may be competitive with product candidates that we are developing for autoimmune diseases. Should one or more of these competing product candidates or other competing product candidates of which we are not aware receive regulatory approval or

otherwise achieve clinical or commercial success, our regulatory strategy could be impaired, our ability to obtain regulatory approval could be delayed or prevented, or the market for our products may be reduced or eliminated, thereby harming or preventing our commercial success.

Even if we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the relative safety and efficacy of our product candidates, the actual or perceived quality of patient life while undergoing treatment with 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, pricing, reimbursement coverage and patent positions, and the relative prioritization of our product candidates by physicians and healthcare providers among available therapies. 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 also make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such product. We could also face competition from other companies for collaboration partners, employees, advisors and service providers, which could negatively impact our ability to execute our business plans.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive or more commercially viable than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our product candidates uneconomical or obsolete and we may not be successful in marketing those product candidates, once approved, against competitors.

Our ability to compete effectively with other biotechnology and pharmaceutical companies depends on our ability to distinguish our company and our product candidates from our competitors and their product candidates.

Some of our competitors may have, and new competitors or alliances may emerge that have, greater name and brand recognition, greater market share, a larger customer base, more widely adopted proprietary technologies, greater marketing expertise, larger sales forces, and/or significantly greater resources than we do and may be able to offer solutions competitive with ours at a more attractive price. Further, our current or potential competitors may be acquired by third parties with greater available resources. As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements and may have the ability to initiate or withstand substantial price competition. In addition, our competitors may in the future establish cooperative relationships with vendors of complementary products, technologies or services to increase the availability of their solutions in the marketplace. Our competitors could also be better positioned to serve certain segments of our market, which could create additional price pressure. In light of these factors, even if any products that we may develop are more effective than those of our competitors, current or potential customers may accept competitive products in lieu of purchasing our products. If we are unable to successfully compete, our business, financial condition, and results of operations could be materially and adversely affected.

The loss of any member of our senior management team or our inability to attract and retain key personnel and consultants could adversely affect our business.

We are highly dependent upon the efforts of our senior management team and other key personnel. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed offer letters with each member of our senior management team, these agreements are terminable at will without notice and, therefore, we may not be able to retain their services as expected. Our former Chief Executive Officer (CEO) retired on December 31, 2024, transitioning to an advisory role, and our former President of Research and Development assumed the role of CEO effective January 1, 2025. Management transitions may create uncertainty and involve a diversion of resources and management attention, be disruptive to our daily operations or impact public or market perception, any of which could negatively impact our ability to operate effectively or execute our strategies.

In addition, on August 12, 2025, we announced a reduction in force affecting approximately 12% of our workforce. This reduction was part of a tactical operations plan intended to reduce our costs and extend funding of our operations through the end of 2027. However, this reduction may increase our dependence on the remaining key members of our senior management and executive teams and could result in other unintended consequences, such as the loss of institutional knowledge and expertise, decreased morale or attrition among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force.

We may not be able to retain or attract qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for a limited number of qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. We may also experience difficulties in attracting or retaining personnel with sufficient experience and skills in the complex and emerging field of cellular therapeutic development and manufacture to support our ongoing and planned clinical development activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. We may also be subject to penalties or other liabilities if we misclassify employees as consultants. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. Further, some of the qualified personnel that we hire and recruit are not U.S. citizens. Changes to U.S. immigration policies, particularly to H-1B and other visa programs, could restrain the flow of technical and professional talent into the United States and may inhibit our ability to hire qualified personnel.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock unit (RSU) awards that vest over time. The value to employees of stock options and RSU awards that vest over time has been significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. A significant number of our employee options remain underwater and may not provide the intended incentive for employees to remain at our company.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources and different risk profiles than we do. We may be required to provide compensation in excess of historical levels in order to recruit and retain personnel in the current market. If we are not able to retain and attract necessary personnel and consultants to perform the requisite operational roles and accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we have considered, and we will consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into business combinations with other companies. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

We face potential product liability exposure far in excess of our limited insurance coverage.

The use of our product candidates in clinical trials, and the sale of any products for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by participants in clinical trials, hospitals, medical centers, healthcare providers, pharmaceutical companies, and consumers, or by others selling, manufacturing or otherwise coming into contact with our product candidates. We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs. In addition, if and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain insurance coverage for any approved products on commercially reasonable terms or in sufficient amounts to protect us against losses due to liability.

On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. In addition, under some of our agreements with clinical trial sites, we are required to indemnify the sites and their personnel against product liability and other claims. A successful product liability claim, or a series of claims, brought against us or any third parties whom we are required to indemnify could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for a variety of reasons. Such events, whether or not resulting from our product candidates, could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively affect or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Our insurance policies are expensive and protect us from only some risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk to which our business is or may be exposed. Some of the policies we maintain include general liability, product liability, property, employee benefits liability, employment practices, workers' compensation, cybersecurity, directors' and officers' insurance, and umbrella. We do not know, however, if we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Even if we obtain insurance, a claim could exceed the amount of our insurance coverage or it may be excluded from coverage under the terms of the policy. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Our employees or third party service providers may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee or third party service provider fraud or other misconduct. Misconduct by employees or third party service providers could include intentional failures to comply with the regulations of the FDA or foreign regulators, to provide accurate information to the FDA or foreign regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to 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, misconduct, kickbacks, self-dealing and other abusive practices. Employee or third party service provider misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. If any actions alleging such conduct are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business, including the imposition of significant fines or other sanctions.

We face risks of potential liability related to the privacy of personal information, including health information we utilize in the development of our products, as well as information we obtain from clinical trials sponsored by us from research institutions and directly from individuals.

We and our partners and vendors may be subject to various federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations,

including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators, including the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly 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. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act. In addition, certain of the materials we use as starting material in our iPSC-derived product candidates are derived from human sources, which potentially contain sensitive identifiable personal information regarding the donor. In addition, in conducting our clinical trials, we may maintain sensitive identifiable personal information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our clinical trials. As such, we may become subject to further obligations under HIPAA. Our collection of personal information generally (e.g., of employees currently and/or of patients in the future) may subject us to state data privacy laws governing the processing of personal information and requiring notification of affected individuals and state regulators in the event of a breach of such personal information. These state laws include the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the CCPA), which establishes data privacy rights for residents of the State of California, with corresponding obligations on businesses related to transparency, deletion rights, and opt-out of the selling or sharing of personal information, and grants a private right of action for individuals in the event of certain security breaches. Similar laws relating to data privacy and security have passed in numerous other states, which may have potentially conflicting requirements that would make compliance challenging, require us to expend significant resources to come into compliance, and restrict our ability to process certain personal information. Moreover, some states have advanced privacy laws focused on protecting consumer health information, such as Washington's My Health My Data Act, and this remains a rapidly changing legislative and regulatory environment.

Certain state laws may be more stringent or broader in scope than the CCPA, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

An increasing number of foreign data protection laws, regulations and industry standards may also apply to personal information we obtain from individuals outside of the United States. For example, the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's General Data Protection Regulation (UK GDPR) impose strict requirements for processing the personal data of individuals within the EEA and UK, including health-related data, and on the transfer of personal data out of the European Economic Area (EEA) and United Kingdom (UK) to non-adequate territories such as the United States; any inability to transfer personal data from the EEA and UK to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position. Failure to comply with the requirements of the EU GDPR may result in potential fines for companies of up to the greater of €20 million (£17.5 million for the UK GDPR) or 4% of annual global revenue and other administrative penalties. In addition, under the EU GDPR and UK GDPR, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to protect their interests. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR, particularly with the introduction of the new Data Reform Bill into the UK legislative process. In addition, EEA Member States have adopted national laws to supplement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EEA Member States may interpret EU GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance, and could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA.

In December 2024, the U.S. Department of Justice issued regulations implementing Executive Order (EO) 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United Stated Government-Related Data by Countries of Concern," which became effective on April 8, 2025. These regulations prohibit transactions involving access to bulk sensitive data by countries of concern, such as China (including Hong Kong). In the life sciences sector, the regulations prohibit investment agreements, employment agreements, vendor agreements, and other transactions involving human genomic data and biospecimens, except where necessary for specified exempt activities. Tracking and complying with these regulations may require significant time and expense.

We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable data privacy and security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity that could harm our business. Moreover, even if we take all necessary action to comply with legal and regulatory requirements, we could be subject to a data breach or other unauthorized access of personal information, which could subject us to fines and penalties, as well as litigation and reputational damage. If we fail to keep apprised of and comply with applicable international, federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action or litigation could also generate adverse publicity, damage our reputation, result in liabilities, fines and loss of business, and require that we devote substantial resources that could otherwise be used in other aspects of our business.

We make public statements about our use and disclosure of personal information through our privacy policy information provided on our internet platform and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractual partners fail to comply with our published policies, certifications and documentation. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policies or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our prospective customers to reduce their use of our products and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify customers or other counterparties of a security breach. Although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach or security incident. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded in a manner that requires changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with contract partners and the physician and patient community and have a material and adverse impact on our business.

The increasing use of artificial intelligence-based software (including machine learning) may result in reputational harm or liability or could otherwise adversely affect our business.

The use of artificial intelligence (AI)-based software is increasingly being used in the biopharmaceutical and global healthcare industries. As with many developing technologies, artificial intelligence-based software presents risks and challenges that could affect its further development, adoption, and use, and therefore our business. For example, algorithms may be flawed; data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end-users could impair results. If the analyses that AI applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability, and reputational harm. Furthermore, use of AI-based software may

lead to the inadvertent release of confidential information which may impact our ability to realize the benefit of our intellectual property rights.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. For example, the EU's Artificial Intelligence Act (AI Act) imposes significant obligations on providers and deployers of AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. Likewise, in the United States, several states, including Colorado and California, passed laws to regulate various uses of AI, including to make consequential decisions. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued guidance on the use of AI in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to apply significant resources to design, develop, test and maintain such systems in accordance with applicable law and regulation, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

The use of social media platforms presents risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat. We also work with third parties, including patient advocacy organizations and patient recruitment firms, to raise awareness of our clinical trials, and these third parties often use social media to communicate with patients. Social media use in the biotechnology and biopharmaceutical industry continues to evolve, and applicable regulations and guidance are not always clear. This creates uncertainty and risk of noncompliance with laws governing marketing, communications, and clinical trial disclosures, which could result in regulatory actions, litigation, or heightened scrutiny by the FDA, SEC, and other regulators. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social media website, or a risk that a post on a social media website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

In addition, our employees have been impersonated by bad actors, who are believed to have drawn on publicly available information from our social media, such as LinkedIn, to make fraudulent job offers. While these incidents have not been material to date, similar activity could occur in the future. Misinformation disseminated from fraudulent accounts impersonating our employees or our business could harm our business and reputation.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors, vendors, and consultants may be vulnerable to damage from cybersecurity risks, including attempts to gain unauthorized access to and to harm sensitive or confidential information and networks, insider threats, and ransomware. These vulnerabilities may be heightened as a result of flexible work arrangements, including hybrid or remote work policies implemented by us and our third-party contractors, that were first adopted in response to the COVID-19 pandemic and have continued by many businesses in an effort to attract and retain talent.

Like other companies in our industry, we, and our third party vendors, have from time to time experienced, and will continue to experience in the future, cyberattacks on our information technology systems, including malware and computer virus attacks, despite our best efforts to prevent them. Although such incidents have been immaterial to our business to date, investigations into and remedial efforts in connection with any security incidents, even those with immaterial impact, can be costly and time-consuming, and any future incidents could be material, or cause significant disruption, to our business. Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers and other business partners, may become the target of cyberattacks or data breaches that could result in the unauthorized release, gathering, monitoring, misuse, loss, or destruction of proprietary and other information, or could otherwise lead to the disruption of our business operations. For example, the loss of clinical trial data from

completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials. We depend on these third parties to implement adequate controls and safeguards to protect against and report cybersecurity incidents. If they fail to do so, we may suffer financial and other harm, including to our information, operations, performance, and reputation. To the extent that any cybersecurity incident or data breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we may have an obligation to provide legal notifications and disclosures, and we could incur liability and the further development and commercialization of our product candidates could be delayed.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. Cybersecurity threats, both on premises and in the cloud, are evolving and could occur and result in information theft, data corruption, operational disruption, damage to our reputation, or financial loss. Such threats include, but are not limited to: malicious software, destructive malware, ransomware attacks, denial-of-service attacks, business email compromises, viruses, wrongful intrusions, social engineering (including phishing attacks), attempts to gain unauthorized access to systems or data, data breaches, the unauthorized release of confidential, personal or otherwise protected information, data corruption, the breakdown or damage or interruption of networks or systems from, among other things, natural disasters, terrorism, war, telecommunication and electrical failures, and harm to individuals. In addition, we could be impacted by cybersecurity threats or other disruptions or vulnerabilities found in products or services we use that are provided to us by third-parties. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, cyber criminals, hacktivists, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. These events, if not prevented or effectively mitigated, could damage our reputation, require remedial actions and lead to loss of business, regulatory actions, potential liability and other financial losses.

Certain data breaches must also be reported to affected individuals and various government and/or regulatory agencies, and in some cases to the media, under provisions of HIPAA, as amended by HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive, and financial penalties may also apply.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or data breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention.

Inadequate funding for the FDA, the Securities Exchange Commission (SEC), the National Institutes of Health (NIH) and other government agencies, including from government shut downs, or other disruptions to these agencies' staffing and operations, could hinder their ability to hire, retain or deploy personnel, and substantial leadership, personnel, and policy changes or otherwise could prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result of these factors. Disruptions at the FDA and other agencies, including substantial leadership departures, personnel cuts and policy changes, may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing have been reported by some in the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Currently, federal agencies in the U.S. are operating under a federal government shutdown due to expiration of the continuing resolution on September 30, 2025. The duration of the current government shutdown is unknown. If a prolonged government

shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Additionally, disruptions at the NIH or changes to the NIH's budget may negatively impact our operations and ongoing clinical trials. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

With the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to whether and how the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

Risks Related to the Ownership of Our Common Stock

Our stock price has been and may continue to be volatile or may decline regardless of our operating performance.

The market price of shares of our common stock has fluctuated in the past and could be subject to wide fluctuations in the future as a result of many risks listed in this section, and other risks beyond our control, including:

- the timing of the initiation of, and progress in, our current and planned clinical trials and preclinical studies;
- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others for product candidates or indications similar to ours;
- developments related to the FDA or to regulations applicable to cellular immunotherapies generally or our product candidates in particular including, but not limited to, regulatory pathways and clinical trial requirements for approvals;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments, such as our announcement in January 2023 of the termination of our collaboration with Janssen;
- developments related to proprietary rights including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- actual or anticipated changes in our research and development activities and our business prospects, including in relation to our competitors;
- developments of technological innovations or new therapeutic products by us or others in the field of immunotherapy;
- announcements or expectations of additional equity or debt financing efforts;
- sales of our common stock by us or by our insiders or our other stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- comments by securities analysts;
- fluctuations in our operating results (including changes related to stock-based compensation from performance-based awards);
- acts of war or periods of widespread civil unrest, including the increasingly volatile global economic conditions resulting from the ongoing global geopolitical tensions, including wars and other armed conflicts; and
- general economic and market conditions, including inflationary pressures and stock market volatility.

These and other market and industry factors, including the effects of any future public health crises or other public health concerns, wars or other armed conflicts, changes in the regulatory landscape and governmental agency personnel in the United States or similar events resulting from the change in the U.S. presidential administration, and global economic conditions, may cause the market price and demand for our common stock to fluctuate substantially regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

Changes in our stock price may also trigger financial obligations under our licensing arrangements. For example, pursuant to the terms of the Amended MSKCC License, MSKCC is eligible to receive from us certain milestone payments totaling up to $75.0

million based on the price of our common stock, where the amount of such payments owed to MSKCC is contingent upon certain increases in the price of our common stock following the date of achievement of a specified clinical milestone. In July 2021, we achieved the specified clinical milestone for a licensed product under the Amended MSKCC License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. Accordingly, MSKCC received the first milestone payment of $20.0 million in November 2021; however, uncertainty of the price of our common stock results in an inability to ascertain the precise timing of any remaining future milestone payments in advance.

If our common stock is delisted from the Nasdaq Global Market, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease.

Our common stock is currently listed on the Nasdaq Global Market (Nasdaq), which has minimum requirements that a company must meet in order to remain listed such market, including that we maintain a minimum closing bid price of $1.00 per share. If we fail to maintain such minimum requirements and a final determination is made by Nasdaq that our common stock must be delisted, our ability to raise additional funds and the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease. Our failure to be listed on Nasdaq or another national securities exchange would have a material adverse effect on the value of your investment in us.

Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over our company.

As of November 6, 2025, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 39.8% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 8 of the notes to the consolidated financial statements herewith) relating to the Class A Convertible Preferred Stock, Redmile (as such term is defined in Note 8 of the notes to the consolidated financial statements herewith) elects to remove certain limitations on the percentage of our outstanding common stock that it may own such that the 2,755,086 shares of Class A Convertible Preferred Stock currently held by Redmile become fully convertible at Redmile's option into 13,775,430 shares of common stock, the beneficial ownership of our executive officers, directors and entities affiliated with our five percent stockholders would increase to 43.7%. Although we are not aware of any voting arrangements in place among these stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that our other stockholders may believe are in their best interests, or adversely affecting the liquidity, volatility, and market price of our common stock. For example, if any of our directors, executive officers or other entities affiliated with our five percent stockholders elect to sell, transfer or otherwise dispose of a significant amount of shares of our common stock, this could result in a decrease in our stock price. Furthermore, any transferees or successors of all or a significant portion of our existing stockholders' ownership in us will be able to exert a similar amount of control over us through their ownership position.

We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business. Issuances of common stock or rights to purchase common stock under our equity incentive plans could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, and we may seek additional funding through a combination of equity offerings, debt financings, state or government grants, strategic alliances, licensing and collaboration arrangements, or other third-party business arrangements. These financing activities may have an adverse effect on our stockholders' rights, the market price of our common stock and on our operations and may require us to relinquish rights to some of our technologies, intellectual property or product candidates, issue additional equity or debt securities, or otherwise agree to terms unfavorable to us. Further, in November 2023, we filed a registration statement on Form S-3 pursuant to which we were initially eligible to issue and sell up to $300.0 million in common stock, preferred stock, debt securities, warrants and/or units, in one or more series or classes, including up to $100.0 million in shares of common stock that may be issued in sales deemed to be an "at the market offering" as defined by the Securities Act of 1933, as amended (the Securities Act). In March 2024, we issued and sold 14,545,454 shares of our common stock at a purchase price of $5.50 per share in an underwritten offering pursuant to the shelf registration statement for aggregate gross proceeds of approximately $80.0 million. Accordingly, we are currently eligible to issue an aggregate of approximately $220.0 million under the shelf registration statement (including the $100.0 million issuable in "at the market offerings"). Any sale or issuance of securities pursuant to a registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline, and new investors could gain rights superior to our existing stockholders. In addition, any debt financings that we may enter into in the future may subject us to unfavorable repayment terms, including increased interest rates, impose restrictive covenants or otherwise adversely affect the holdings or the rights of our

stockholders, and any additional equity financings will be dilutive to our stockholders. Furthermore, additional equity or debt financing might not be available to us on reasonable terms, if at all.

Pursuant to our 2022 Stock Option and Incentive Plan (as amended and restated, the 2022 Plan) we are authorized to grant stock options and other equity-based awards to our employees, officers, directors and consultants. The 2022 Plan currently authorizes the issuance of up to 24.5 million shares following stockholder approval of an increase in the number of shares authorized for issuance under the 2022 Plan in May 2025. We also make equity grants to new employees joining our company pursuant to our inducement plan, and our board of directors may elect to increase the number of shares available for future grants under the inducement plan without stockholder approval. If our board of directors elects in the future to increase the number of shares available for future grant and, in the case of the 2022 Plan, if our stockholders approve of any such future increase, our stockholders may experience additional dilution, and our stock price may fall.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. A significant portion of our outstanding shares of common stock are held by a small number of stockholders, including our directors, officers and significant stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

For example, we registered all of the 5,250,000 shares of common stock issued by us in our August 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in September 2016. We also registered all of the 6,766,915 shares of common stock issued by us and all 14,097,745 shares of common stock issuable upon the conversion of an aggregate of 2,819,549 shares of Class A Convertible Preferred Stock issued by us in our November 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in January 2017. Additionally, we have registered the shares of common stock issued to Johnson & Johnson Innovation – JJDC, Inc. under the stock purchase agreement entered into in June 2020 in connection with the Janssen Agreement pursuant to a registration statement on Form S-3. Moreover, we registered all of the 5,380,117 shares of common stock issued by us and all of the 257,310 prefunded warrants to purchase common stock in our public offering in January 2021. We registered all of the 14,545,454 shares of common stock issued by us in our underwritten offering in March 2024. In addition, we registered for resale all of the 3,636,364 shares of common stock issuable upon exercise of the pre-funded warrants sold in the concurrent private placement in March 2024.

We have also registered or intend to register all shares of our common stock subject to options, restricted stock units or other equity awards issued or reserved for future issuance under our equity incentive plans. As a result, these shares will be available for sale in the public market subject to vesting arrangements and exercise of options, and restrictions under applicable securities laws. In addition, certain of our executive officers, directors, employees and affiliates have established and may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the Exchange Act), for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, and could make it more difficult for you to change management.

Provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or delay attempts by stockholders to replace or remove our current management or members of our board of directors. These provisions include:

- a classified board of directors with limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our board of directors to make, alter or repeal our amended and restated bylaws; and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge

or combine with us. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or discouraging a potential acquisition proposal or tender offer could limit the opportunity for our stockholders to achieve liquidity for their shares of our common stock, even if the acquisition proposal or tender offer is at a premium over the then-current market price for our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware and the U.S. federal district courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Pursuant to our amended and restated 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 or other wrongdoing by any of our directors, officers, or employees to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our amended and restated bylaws; 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. Unless we consent in writing to the selection of an alternate forum, the U.S. federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The forum selection clause in our amended and restated bylaws may limit our stockholders' ability to litigate disputes with us in a different judicial forum. While the Delaware courts have determined that these types of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we may incur significant additional costs associated with resolving the dispute in other jurisdictions, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

A sustained decline in our stock price may result in an impairment indication which could have an adverse impact on our results of operations.

Any significant change in market conditions, including a sustained decline in our stock price, that indicate a reduction in carrying value may give rise to indicators of impairment in the period that the change becomes known. For example, during the year ended December 31, 2024, we identified an indicator of impairment of our long-lived assets due to a sustained decline in the trading price of our common stock over the preceding year, resulting in our market capitalization being below its net asset value. As a result of the fair value analysis, we recorded a $13.4 million impairment charge against property and equipment and a $1.3 million impairment charge against the right-of-use asset in the statement of operations during the year ended December 31, 2024.

We currently qualify as a "smaller reporting company" and a "non-accelerated filer," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to such companies could make shares of our common stock less attractive to investors.

We qualify as a "smaller reporting company," as defined under the Exchange Act. In addition, we are a "non-accelerated filer" as defined under the Exchange Act. For as long as we continue to be a smaller reporting company or a non-accelerated filer, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies or non-accelerated filers, as applicable, including, but not limited to, an exemption from the requirement that our independent registered public accounting firm attest to the design and operating effectiveness of our internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act.

If we choose to rely on any of these reporting and disclosure exemptions, the information we provide stockholders will be different than the information that is available with respect to many other public companies. Moreover, if some investors find our common stock less attractive as a result of any choices to reduce future disclosure or have an independent review and attestation of our internal control over financial reporting, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Our ability to use our net operating loss carryforwards and certain other tax benefits may be limited and, as a result, our future tax liability may increase.

As of December 31, 2024, we had federal and state net operating loss carryforwards of $689.2 million and $644.2 million, respectively, some of which begin to expire in various amounts in 2027 and 2028, respectively. As of December 31, 2024, we also had federal and California research and development tax credit carryforwards of $45.6 million and $37.8 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2035 unless previously utilized, while the California

carryforwards will carry forward indefinitely. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) or tax credits, or NOLs or credits, to offset future taxable income or taxes. Generally, a change of more than 50 percentage points in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. We have determined that we triggered an ownership change limitation in November 2009 and again in May 2015. We have determined that we do not believe there were any ownership changes from May 2015 through December 2024. We have not analyzed periods subsequent to December 2024. We may experience additional ownership changes as a result of shifts in our stock ownership in the future. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. The amount of NOLs generated in taxable periods beginning after December 31, 2024, that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. U.S. federal and certain state NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration.

General Risk Factors

We are and could be further subject to securities class action litigation and other types of stockholder litigation.

The stock market in general, and Nasdaq and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. For example, in January 2023, a purported stockholder filed a lawsuit against us and certain of our officers captioned Hadian v. Fate Therapeutics, Inc. et al. in the U.S. District Court for the Southern District of California and two derivative actions were filed in the same court in June 2023 and June 2024, respectively (see *"Item 1. Legal Proceedings"* for a more detailed description of this matter). We could also be subject to other types of litigation, which may involve claims of breach of fiduciary duties by our directors or officers for misuse/mismanagement of company assets/resources or conflicts of interest. Any such 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. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

Our business operations may subject us to disputes, claims and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.

From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. For example, we have in the past and we may, from time to time, face or initiate claims related to intellectual property matters, employment matters, or commercial disputes. Any dispute, claim or lawsuit may divert management's attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. Litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business, regulatory and other factors beyond our control, such as the rate of unemployment, rate of inflation, the number of uninsured persons in the United States, political influences and inflationary pressures, and fluctuations in costs, particularly due to changes in labor costs and material costs. For example, an overall decrease in or loss of insurance coverage among individuals in the United States due to high levels of unemployment, underemployment or the repeal of certain provisions of the ACA and changes to other federal healthcare programs may decrease the demand for healthcare services and pharmaceuticals. These changes could adversely impact our clinical trial recruitment, particularly in underserved populations. In addition, if fewer patients are seeking medical care because they do not have insurance coverage or are unable to obtain medical care for their conditions due to resource constraints on the healthcare system, we may experience difficulties in any eventual commercialization of our product candidates and our business, results of operations, financial condition and cash flows could be adversely affected. In addition, if we are unable to manage cost fluctuations and

inflationary pressures, including prices of materials, costs of labor, it may adversely impact our operating performance, expenses and results.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such as us are dependent for sources of capital. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, ongoing and emerging global geopolitical tensions, including wars or other armed conflicts, interest rate fluctuations, rising inflation rates or recession, could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, and weakened demand for our product candidates. A weak or declining economy, and rising inflation could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which ongoing wars and other armed conflicts, current economic climate and financial market conditions could adversely impact our business.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We intend to expand our clinical operations to countries other than the U.S., and are developing products for regulatory approval and sale in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may conduct clinical trials, develop, or sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape, such as supply chain disruptions and delays as a result of any new tariff policies or trade restrictions, could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, in early 2025, the U.S. imposed and adjusted a series of tariffs on imports from key trading partners, including Canada, Mexico, China and the European Union. Since then, tariff activity has continued to escalate, with new rounds of increases, expanded coverage to additional goods and materials, pauses, and shifting implementation timelines. In response to tariffs, other countries have implemented retaliatory tariffs on imports from the United States. Historically, tariffs have led to increased trade and political tensions. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. The current U.S. presidential administration has threatened to impose additional significant tariffs on pharmaceutical products, which could lead to corresponding punitive actions by countries outside the United States. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

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 product candidates, retain or expand our current levels of personnel, improve our existing products, 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;
- continue the research and development or our existing product candidates and develop or enhance our technological infrastructure;
- pursue acquisitions, in-licenses or other strategic relationships; and
- respond to competitive pressures.

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.

Recent volatility in interest rates could affect our ability to obtain working capital through borrowings such as bank credit lines and public or private sales of debt securities, which may result in lower liquidity, reduced working capital and other adverse impacts on our business.

To meet our liquidity needs, we have previously relied, in part, on borrowed funds, and may do so again in the future. Continued volatility in interest rates will impact the cost of new indebtedness and could materially and adversely affect our results of operations, financial condition, liquidity and cash flows.

Increasing scrutiny and changing expectations from governments and third-parties relating to environmental, social and governance (ESG) policies and practices may cause us to incur additional costs, expose us to additional risks or impact our reputation.

In recent years, there has been increasing public focus and scrutiny from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to ESG factors. In addition to the changing rules and regulations related to ESG matters imposed by governmental and self-regulatory organizations, a variety of third-party organizations, institutional investors and customers evaluate the performance of companies on ESG topics, and the results of these assessments are widely publicized. These changing rules, regulations and stakeholder expectations have resulted in, and are likely to continue to result in, increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. Reduced access to or increased cost of capital may occur as financial institutions and investors increase expectations related to ESG matters. Third-party providers of ESG ratings and reports on companies have increased in number, resulting in varied and, in some cases, inconsistent standards and frameworks. Topics taken into account in such assessments include, among others, our efforts and impacts with respect to climate change and the role of our board of directors in supervising various sustainability issues.

Developing and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG-related information and metrics can be costly, difficult, and time consuming and is subject to evolving reporting standards. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, social investments and other ESG-related matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Furthermore, statements about our ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If our ESG-related data, processes and reporting are incomplete or inaccurate, or if we fail to achieve progress with respect to our goals, including our previously announced commitments to reduce greenhouse gas emissions, within the scope of ESG on a timely basis, or at all, our reputation, business, financial performance and growth could be adversely affected. In addition, in recent years “anti-ESG” sentiment has gained momentum across the U.S., with several states and Congress having proposed or enacted “anti-ESG” policies, legislation, or initiatives or issued related legal opinions, and the current U.S. presidential administration having recently issued an executive order opposing diversity equity and inclusion (DEI) initiatives in the private sector. Such anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, legal opinions, and scrutiny could result in our facing additional compliance obligations, becoming the subject of investigations and enforcement actions, or sustaining reputational harm.

If our business practices do not meet evolving investor, government agency or other stakeholder expectations and standards with respect to ESG, then our reputation, our ability to attract or retain employees and the market price of our securities could be negatively impacted. New governmental regulations could result in new directives and new or more stringent forms of ESG oversight and disclosures which may lead to increased expenditures for sustainability initiatives, which in turn could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline.

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 our 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, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In these cases 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. We currently use deposit accounts to fund our operations and other financial instruments such as cash-collateralized letters of credit associated with our facilities leases. Our excess cash is invested according to a restrictive investment policy within custodial accounts at various financial institutions. If any of the financial institutions that hold our deposit accounts were to be placed into receivership, we may be unable to access the funds in those accounts, which could result in liquidity constraints or failures. In addition, if any of our collaboration partners, 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 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, or the sale of its assets, 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. 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 and other business 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 us, the financial institutions with which we have 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 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; or
- Delayed or lost access to, or reductions in borrowings available under working capital sources and/or delays, inability or reductions in our ability to refund, roll over or extend the maturity of, or enter into new working capital resources.

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.

Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our collaboration partners, suppliers or other parties with whom we do business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any bankruptcy or insolvency of a collaboration partner, supplier or other party with whom we do business, or the failure of any such party to make payments when due, or any breach or default by any such party, or the loss of any significant commercial relationships, could result in material losses to us and may have a material adverse impact on our business.

Geopolitical risks associated with ongoing wars and armed conflicts could have an adverse impact on our business, financial condition and results of operations, including our clinical trials.

There are ongoing and emerging geopolitical tensions, including wars and other armed conflicts, and although the conflicts have had little direct impact on our business to date, the uncertainty and ripple effects created by these conflicts may have unknown indirect impacts. For instance, the ongoing conflicts have resulted in significant volatility in certain equity, debt and currency markets, material increases in certain commodity prices, and economic uncertainty. Global conflicts, including Russia's invasion of Ukraine, conflicts in the Middle East, and heightened tensions in the Pacific region, have significantly elevated global geopolitical tensions and security concerns. It is not possible to predict the broader or longer-term consequences of these conflicts, although a prolonged conflict may result in adverse effects on microeconomic conditions including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cybersecurity-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; our exposure to foreign currency fluctuations; and constraints, volatility, or disruption in the capital markets, any of which could negatively impact our business, financial performance and financial condition. Economic sanctions imposed by the United States, Canada, EU, and other countries in response to the ongoing conflicts and the potential response to such sanctions may also have an adverse impact our business, including our clinical trials and supply chain, the financial markets and the global economy.

We continue to monitor any adverse impact that the outbreak of war and the subsequent institution of sanctions by the United States and other countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and third parties with whom we conduct business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, wildfires, power outages, or other natural disasters, including public health crises, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our facilities are located in San Diego, California, which is a seismically active region, and historically has been subject to wildfires and electrical blackouts. Earthquakes, wildfires, power outages, or other natural disasters (including due to the effects of climate change or any public health crises) could severely disrupt our operations, or the operations of third parties upon whom we depend, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities or those of our CMOs, 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. For example, clinical supplies of our NK and T-cell therapeutic product candidates, as well as the working and master cell banks from which these product candidates are manufactured, are maintained in freezers at our manufacturing facility and at third-party biorepositories. If these materials are damaged at our facility or at the facilities of our third-party repositories, including as a result of a power outage or natural disaster, clinical supply of our product candidates may be impacted and our clinical trials may be delayed. Further, any measures taken by governmental authorities or businesses in response to any public health crisis, such as quarantines, stay-at-home orders or travel restrictions, could adversely affect our business, operations, financial condition, prospects or results of operations by restricting our ability to conduct our clinical trials and research and development activities, and limiting our and our third-party manufacturers' ability to manufacture product and forcing temporary closure of our facilities and facilities that we rely upon. The disaster recovery and business continuity plans we and our third-party biorepositories have in place currently may be limited and may not prove adequate for protecting and continuing our business in the event that our business is disrupted as a result of a public health crisis or other 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. Any insurance we maintain against such risks may not be adequate to cover losses in any particular case.

If we fail to maintain an effective system of disclosure controls and procedures and internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We cannot assure that we will not have material weaknesses or significant deficiencies in our internal control over financial reporting. If we are unable to successfully remediate any material weakness or significant deficiency in our internal control over financial reporting, or identify any material weaknesses or significant deficiencies that may exist, the accuracy and timing of our financial reporting may be adversely affected, 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, and our stock price may decline materially as a result.

If we fail to comply with environmental, health, and safety laws and regulations, including regulations governing the handling, storage or disposal of hazardous materials, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals, biological materials and infectious agents. Our operations also may produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (IRS) and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes to tax laws have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses to 80% of current year taxable income and the elimination of net operating loss carrybacks (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. In addition, the One Big Beautiful Bill Act (OBBBA) was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. The OBBBA further provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' 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.

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

The Company made no unregistered sales of securities during the quarter covered by this report that have not previously been disclosed on Form 8-K.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

a) None.

b) None.

c) Rule 10b5-1 Trading Plans

During the period covered by this Quarterly Report on Form 10-Q, none of the Company's directors or officers adopted, materially modified, or terminated any contract, instruction, or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any non-Rule 10b5-1 trading arrangement.

Item 6. Exhibits

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-190608	3.2	August 29, 2013
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect	8-K	001-36076	3.1	June 7, 2021
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect	8-K	001-36076	3.1	June 10, 2024
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect	8-K	001-36076	3.1	May 30, 2025
3.5	Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock	8-K	001-36076	3.1	November 29, 2016
3.6	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Class A Convertible Preferred Stock of Fate Therapeutics, Inc.	8-K	001-36076	3.1	April 19, 2023
3.7	Amended and Restated Bylaws of the Registrant, as currently in effect	10-K	001-36076	3.3	February 24, 2021
4.1	Specimen Common Stock Certificate	S-1/A	333-190608	4.1	August 29, 2013
4.2	Form of Pre-Funded Warrant	8-K	001-36076	4.1	January 8, 2021
4.3	Form of Pre-Funded Warrant	8-K	001-36076	4.1	March 21, 2024
4.4	Description of Securities	10-Q	001-36076	4.3	November 8, 2023
10.1#	Severance and Change in Control Policy, as currently in effect	—	—	—	Filed herewith
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith

31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
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.	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	—	—	—	Filed herewith

# Indicates a management contract or any compensatory plan, contract or arrangement.
* This exhibit is furnished herewith and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

Fate Therapeutics, Inc.

Date: November 13, 2025

By: /s/ Bahram Valamehr

Bahram Valamehr, Ph.D., M.B.A.

President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 13, 2025

By: /s/ Kamal Adawi

Kamal Adawi, M.S., M.B.A.

Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

FATE THERAPEUTICS, INC.
SEVERANCE AND CHANGE IN CONTROL POLICY

ADOPTED EFFECTIVE JANUARY 14, 2018

AMENDED ON MAY 27, 2025

The purpose of this Severance and Change in Control Policy (the "Policy") of Fate Therapeutics, Inc. (the "Company") is to provide certain senior management employees of the Company with certain compensation and benefits in the event of a termination of employment without Cause (as defined below) or for Good Reason (as defined below), under the terms and conditions described in this Policy.

1. Termination Not in Connection with a Sale Event

At any time following the first anniversary of the designation of a senior management employee of the Company as an Eligible Employee (as defined below), if the employment of such Eligible Employee is terminated by the Company without Cause (as defined below), or the Eligible Employee resigns for Good Reason (as defined below), then subject to such Eligible Employee's execution and non-revocation of a severance agreement within 60 days following the date of such termination, including a general release of claims acceptable to the Company, such Eligible Employee shall be entitled to receive the following benefits:

- Acceleration of the time-based vesting provisions of outstanding stock options and other equity awards in which the employee would have vested if he or she had remained employed for an additional nine (9) months following the date of termination; provided, however, that for avoidance of doubt, for any equity award that includes both a performance-based vesting condition (which would include the achievement of a certain stock price or market capitalization) and a time-based vesting provision or any equity award that vests solely upon the achievement of a performance-based vesting condition, no acceleration shall be provided unless such performance-based vesting condition has been satisfied as of the date of termination; and

- Payment of (a) severance in a lump sum in the amount set forth below and (b) if the employee was participating in the Company's group health plan immediately prior to the date of termination of his or her employment and elects COBRA health continuation, payment of a monthly cash payment for the period set forth below or the employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the employee if the employee had remained employed by the Company:

Severance (Amount of Base Salary)	**Benefits Continuation**
9 months	9 months

2. Termination in Connection with a Sale Event

If the employment of an Eligible Employee is terminated by the Company (or its successor) without Cause or such Eligible Employee resigns for Good Reason, in either case within three months prior to or one year after the closing of a Sale Event (as defined in the Company's 2013 Stock Option and Incentive Plan, as may be amended from time to time), then subject to such Eligible Employee's execution and non-revocation of a severance agreement within 60 days following the date of such termination, including a general release of claims acceptable to the Company or its successor or acquirer, such Eligible Employee shall be entitled to receive the following benefits:

- Full acceleration of the time-based vesting provisions of outstanding stock options and other equity awards; provided, however, that for avoidance of doubt, for any equity award that includes both a performance-based vesting condition (which would include the achievement of a certain stock price or market capitalization) and a time-based vesting provision or any equity award that vests solely upon the achievement of a performance-based vesting condition, no acceleration shall be provided unless such performance-based vesting condition has been satisfied as of the date of termination; and

- Payment of (a) severance in a lump sum in the amount set forth below, (b) target bonus in the amount set forth below and (c) if the employee was participating in the Company's group health plan immediately prior to the date of termination of his or her employment and elects COBRA health continuation, payment of a monthly cash payment for the period set forth below or the employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the employee if the employee had remained employed by the Company:

Severance (Base Salary)	Bonus	Benefits Continuation
12 months	1x bonus target	12 months

For the avoidance of doubt, an Eligible Employee shall be eligible to receive benefits pursuant to only one of either Section 1 or Section 2 of this Policy (depending on whether such Eligible Employee's termination without Cause or resignation for Good Reason occurs within three months prior to or one year after the closing of a Sale Event), but not both.

3. Additional Limitation

Anything in the Policy to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of any Eligible Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Policy or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced to the extent necessary so that no portion of the Aggregate Payments would be subject to the excise tax. In such event, the Aggregate

Payments shall be reduced in the following order: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits. To the extent any payment is to be made over time (e.g., in installments, etc.), then the payments shall be reduced in reverse chronological order.

4. Definitions.

(a) "Cause" shall mean (i) the employee's dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business; (ii) the employee's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) any conduct by the employee that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries and affiliates if the employee were retained in the employee's position; (iv) the employee's failure to perform his or her assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, after written notice given to the employee by the Company; (v) the employee's gross negligence, willful misconduct or insubordination with respect to the Company or any affiliate of the Company; or (vi) the employee's material violation of any provision of any agreement(s) between the employee and the Company relating to noncompetition, nonsolicitation, nondisclosure and/or assignment of inventions.

(b) "Committee" shall mean the Compensation Committee of the Board of Directors of the Company.

(c) "Eligible Employees" shall mean the senior management employees of the Company designated by the Committee as eligible to receive benefits under this Policy, whose names are set forth on Exhibit A attached hereto, as amended from time to time.

(d) "Good Reason" shall mean (i) a material diminution in the employee's responsibilities, authority or duties; (ii) a material diminution in the employee's base compensation except for across-the-board compensation reductions similarly affecting all or substantially all similarly situated service providers of the Company; or (iii) a change of more than twenty-five (25) miles in the geographic location at which the employee provides services to the Company, in each case so long as the employee provides at least 60 days' notice to the Company following the initial occurrence of any such event, the Company fails to cure such event within 30 days thereafter and the employee terminates his or her employment within 30 days after the end of such cure period.

5. General Terms and Conditions.

(a) The amounts payable pursuant to this Policy shall be paid or commence to be paid within 60 days following the date of termination of employment; provided that if the 60-day period begins in one calendar year and ends in a second calendar year, such

payments shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) This Policy shall be administered by the Committee, and the Committee shall have the power and authority to interpret the terms and provisions of this Policy, to make all determinations it deems advisable for the administration of this Policy, to decide all disputes arising in connection with this Policy and to otherwise supervise administration of this Policy. The Committee retains the right to amend, revise, change or end this Policy at any point in the future; provided that the Committee may not amend or end the Policy during the period commencing on the date that it enters into a definitive agreement that if consummated, would result in a Sale Event and ending on the earlier of (i) 12 months after a Sale Event and (ii) the termination of the definitive agreement without the consummation of a Sale Event. This Policy does not change the "at-will" employment status of any employee.

(c) In the event an Eligible Employee of the Company is party to an agreement or other arrangement with the Company that provides greater benefits in the aggregate than set forth in this Policy, such Eligible Employee shall be entitled to receive the payments or benefits under such other agreement or arrangement and shall not be eligible to receive any payments or benefits under this Policy.

[*Remainder of page intentionally left blank*]

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Bahram Valamehr, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Fate Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

/s/ BAHRAM VALAMEHR
Bahram Valamehr, Ph.D., M.B.A.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kamal Adawi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Fate Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

/s/ KAMAL ADAWI
Kamal Adawi, M.S., M.B.A.
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the quarterly report of Fate Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Bahram Valamehr, Chief Executive Officer of the Company, and Kamal Adawi, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2025

/s/ BAHRAM VALAMEHR
Bahram Valamehr, Ph.D., M.B.A.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2025

/s/ KAMAL ADAWI
Kamal Adawi, M.S., M.B.A.
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.