

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 March 31, 2022

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**  
(State or other jurisdiction  
of incorporation or organization)

12278 Scripps Summit Drive, San Diego, CA  
(Address of principal executive offices)

65-1311552  
(IRS Employer  
Identification No.)

92131  
(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 April 28, 2022, 96,629,085 shares of the registrant's common stock, par value \$0.001 per share, were issued and outstanding.

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## SUMMARY OF RISK FACTORS

*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 before making investment decisions regarding our common stock.*

- Our product candidates represent a novel therapeutic approach to treating cancer and may cause undesirable side effects or have other properties that could halt their 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, our business would be significantly harmed.
- We use induced pluripotent stem cell technology and gene-editing technology in the creation of our product candidates. Both technologies are relatively new technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval. 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 due to difficulties enrolling patients in our clinical trials, and we may not be able to initiate, conduct or complete them at all.
- Initial, interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. Furthermore, results from our ongoing or future clinical trials involving our product candidates may differ materially from initial, interim and preliminary data.
- The manufacture and distribution of our cell product candidates are complex and subject to a multitude of risks. These risks could substantially limit the clinical and commercial supply of our product candidates and increase our costs, and the development and commercialization of our product candidates could be significantly delayed or restricted if the United States Food and Drug Administration (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.
- We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. Any failure by us or any third parties on whom we depend to manufacture our product candidates consistently and under the proper conditions may result in delays to our clinical development plans and impair our ability to obtain approval for, or commercialize, our product candidates.
- Our inability to manufacture sufficient quantities of our product candidates, or the loss of our third-party contract manufacturers, or our or their failure to supply sufficient quantities of our product candidates at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- We depend 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, the loss of which could adversely impact our ability to conduct our clinical trials or commercialize our product candidates, if approved.
- The ongoing global COVID-19 pandemic, caused by the coronavirus, SARS-CoV-2, and the ongoing conflict in Ukraine, could adversely impact various aspects of our business, results of operations and financial condition, and could cause a disruption to our supply chain and the development and manufacture of our product candidates.
- 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, 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, 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.
- 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, our product candidates.

- 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, including in connection with the potential global development of our product candidates.
- 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.
- If we fail to comply with our obligations under our 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 generation of evidence development around areas like the anticipated budget impact, comparative costs and benefits relative to standard of care and other value demonstrations.
- We face increasing 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.
- The success of our existing product candidates is substantially dependent on developments within the field of cellular immunotherapy, some of which are beyond our control.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business.
- Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over our company.

## 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)

	March 31, 2022	December 31, 2021
(unaudited)		
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 64,741	\$ 133,583
Accounts receivable	13,850	8,676
Short-term investments and related maturity receivables	509,031	482,327
Prepaid expenses and other current assets	11,453	8,826
Total current assets	599,075	633,412
Long-term investments	67,942	100,664
Property and equipment, net	97,857	91,529
Operating lease right-of-use assets	69,475	70,720
Restricted cash	15,227	15,227
Collaboration contract assets	8,777	9,870
Other assets	33	33
Total assets	<u>\$ 858,386</u>	<u>\$ 921,455</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 11,444	\$ 8,612
Accrued expenses	35,110	42,412
CIRM award liability, current portion	3,200	3,200
Deferred revenue, current portion	22,575	21,483
Operating lease liabilities, current portion	5,582	5,577
Total current liabilities	77,911	81,284
Deferred revenue, net of current portion	22,534	27,124
CIRM award liability, net of current portion	800	800
Operating lease liabilities, net of current portion	107,939	109,241
Stock price appreciation milestones	15,809	24,168
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; authorized shares—5,000,000 at March 31, 2022 and December 31, 2021; Class A Convertible Preferred shares issued and outstanding—2,794,549 at March 31, 2022 and December 31, 2021	3	3
Common stock, \$0.001 par value; authorized shares—250,000,000 at March 31, 2022 and December 31, 2021; issued and outstanding—96,538,084 at March 31, 2022 and 95,726,962 at December 31, 2021	97	96
Additional paid-in capital	1,470,916	1,448,584
Accumulated other comprehensive loss	(2,850)	(762)
Accumulated deficit	(834,773)	(769,083)
Total stockholders' equity	633,393	678,838
Total liabilities and stockholders' equity	<u>\$ 858,386</u>	<u>\$ 921,455</u>

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 March 31,	
	2022	2021
	(unaudited)	
Collaboration revenue	\$ 18,414	\$ 11,142
Operating expenses:		
Research and development	72,139	44,852
General and administrative	20,742	12,500
Total operating expenses	92,881	57,352
Loss from operations	(74,467)	(46,210)
Other income:		
Interest income	418	377
Change in fair value of stock price appreciation milestones	8,359	744
Total other income	8,777	1,121
Net loss	\$ (65,690)	\$ (45,089)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net	(2,088)	(330)
Comprehensive loss	\$ (67,778)	\$ (45,419)
Net loss per common share, basic and diluted	\$ (0.68)	\$ (0.48)
Weighted-average common shares used to compute basic and diluted net loss per share	96,343,529	93,431,877

See accompanying notes.

**Condensed Consolidated Statements of Cash Flows**  
(in thousands)

	Three Months Ended March 31,	
	2022	2021
	(unaudited)	
<b>Operating activities</b>		
Net loss	\$ (65,690)	\$ (45,089)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,761	959
Stock-based compensation	19,331	12,976
Accretion and amortization of premiums and discounts on investments, net	873	1,140
Amortization of collaboration contract assets	1,094	623
Deferred revenue	(3,497)	(3,107)
Change in fair value of stock price appreciation milestones	(8,359)	(744)
Changes in operating assets and liabilities:		
Accounts receivable	(5,174)	(1,430)
Prepaid expenses and other assets	(2,407)	(1,301)
Accounts payable and accrued expenses	(3,493)	6,944
Right-of-use assets and lease liabilities, net	(52)	1,933
Net cash used in operating activities	(64,613)	(27,096)
<b>Investing activities</b>		
Purchases of property and equipment	(10,084)	(3,981)
Purchases of investments	(132,166)	(529,907)
Maturities of investments	135,224	62,000
Net cash used in investing activities	(7,026)	(471,888)
<b>Financing activities</b>		
Issuance of common stock from equity incentive plans, net of issuance costs	2,797	5,605
Proceeds from public offering of common stock and issuance of pre-funded warrants, net of issuance costs	—	432,445
Net cash provided by financing activities	2,797	438,050
Net change in cash, cash equivalents and restricted cash	(68,842)	(60,934)
Cash, cash equivalents and restricted cash at beginning of the period	148,810	182,574
Cash, cash equivalents and restricted cash at end of the period	\$ 79,968	\$ 121,640
<b>Supplemental schedule of noncash investing and financing activities</b>		
Purchases of property and equipment in accounts payable	\$ 3,377	\$ 2,624
Right-of use assets obtained in exchange for lease obligations	\$ —	\$ 1,444

*See accompanying notes.*

**Notes to Condensed Consolidated Financial Statements  
(Unaudited)****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 the development of programmed cellular immunotherapies for patients with cancer, including off-the-shelf natural killer (NK) and T-cell product candidates derived from clonal master engineered induced pluripotent stem cell (iPSC) lines.

As of March 31, 2022, 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 products. To date, the Company's revenues have been derived from collaboration agreements and government grants.

**Public Equity Offerings**

In January 2021, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 5.1 million shares of the Company's common stock at a price of \$85.50 per share under a shelf registration statement. In addition, 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 (Pre-Funded Warrants). The purchase price of the 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. See Note 8 for additional detail. Gross proceeds from the public offering and the issuance of the Pre-Funded Warrants were \$460.0 million, and after giving effect to \$27.6 million of costs related to the public offering and the issuance of Pre-Funded Warrants, net proceeds were \$432.4 million.

**Use of Estimates**

The Company's unaudited condensed consolidated financial statements are prepared in accordance with United States generally accepted accounting principles (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, accrued expenses, stock-based compensation, and the estimated total costs expected to be incurred under the Company's collaboration agreements. 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.

**Risks and Uncertainties**

Due to the global outbreak of SARS-CoV-2, the strain of coronavirus that causes Coronavirus disease 2019 (COVID-19), the Company continued to experience impacts on certain aspects of its business, including its clinical trial, manufacturing, and research and development activities, during the three months ended March 31, 2022. For example, with the lifting of governmental stay-at-home orders, we have reopened each of our business locations for work onsite, but have also implemented flexible work arrangements in the interests of maintaining the health and safety of our employees. In addition, the COVID-19 pandemic has impacted the timing of our ongoing clinical studies, with slower site activation, patient enrollment and treatment in our clinical studies as a result of precautionary measures taken by some clinical trial sites to protect both site staff and patients from possible COVID-19 exposure. We have also experienced delays in obtaining equipment, materials, and supplies needed to maintain our operations and manufacture our product candidates as a result of production shortages experienced by our suppliers as a result of the COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of the ongoing COVID-19 pandemic on the Company's operations, are currently unknown, and depend on continuously changing circumstances, including the emergence of new variants of the virus, such as the Delta and Omicron BA.1 and BA.2 variants. While certain measures have been relaxed in certain parts of the world as increasing numbers of people have received COVID-19 vaccines, others have remained in place with some areas continuing to experience renewed outbreaks and surges in infection rates. The extent to which such measures are removed or new measures are put in place will depend upon how the pandemic evolves, as well as the distribution of available vaccines, the rates at which they are administered and the emergence of new variants of the virus. The Company is continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that it determines are in



the best interests of public health and safety and that of the Company's patient community, employees, partners, and stockholders. The Company cannot predict the effects that such actions, or the impact of the ongoing COVID-19 pandemic on global business operations and economic conditions, may have on its business, strategy, collaborations, or financial and operating results.

### Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries, Fate Therapeutics Ltd., incorporated in the United Kingdom, Fate Therapeutics, B.V., incorporated in the Netherlands and Tfinity Therapeutics, Inc., incorporated in the United States. To date, the aggregate operations of these subsidiaries have not been significant and 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 checking and savings 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 amount shown in the unaudited condensed consolidated statements of cash flows as of March 31, 2022 and 2021 (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Cash and cash equivalents	\$ 64,741	\$ 106,413
Restricted cash	15,227	15,227
Total cash, cash equivalents, and restricted cash shown in the unaudited condensed consolidated statement of cash flows	<u>\$ 79,968</u>	<u>\$ 121,640</u>

For each of the three months ended March 31, 2022 and 2021, the restricted cash balance includes cash-collateralized irrevocable standby letters of credit of \$15.2 million associated with the Company's facilities leases.

### Investments

Investments are accounted for as available-for-sale securities and are carried at fair value on the unaudited condensed consolidated balance sheets. Upon initial recognition of the investment and at each reporting period, the Company evaluates whether any unrealized losses on investments are attributable to a credit loss or other factors. Any unrealized losses attributable to credit loss are recorded through an allowance for credit losses, limited to the amount by which the fair value is below amortized cost, with the offsetting amount recorded in other income or expense in the unaudited condensed consolidated statement of operations and comprehensive loss. Unrealized losses not attributable to an expected credit loss and unrealized gains on investments are recorded in other comprehensive income (loss) on the unaudited condensed consolidated statements of operations and comprehensive loss. Realized gains and losses, if any, on investments classified as available-for-sale securities are included in other income or expense.

The amortized cost of investments classified as available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

### 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 United States 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, 2021, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed by the Company with the SEC on February 28, 2022. 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 months ended March 31, 2022 are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

## Revenue Recognition

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. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. The Company applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

### **Stock Price Appreciation Milestones**

The Company estimates the fair value of the stock price appreciation milestones associated with the Amended and Restated Exclusive License Agreement with Memorial Sloan Kettering Cancer Center (see Note 2), using a Monte Carlo simulation model, which relies on the Company's current stock price as well as significant estimates and assumptions to determine the estimated liability associated with the contingent milestone payments. The Company accounts for the fair value of the stock price appreciation milestones in accordance with Accounting Standards Codification (ASC) 815, *Derivatives and Hedging*, with fair value marked-to-market at each reporting date. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the probability of achieving a specified clinical milestone, the expected volatility of the Company's common stock, the risk-free interest rate, and the estimated term, which is based in part on the last valid patent claim date. The Company remeasures the fair value of the stock price appreciation milestones at each balance sheet date, with changes in fair value recorded in earnings as non-operating income or expense on the unaudited condensed consolidated statements of operations and comprehensive loss.

### **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 unaudited condensed 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 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.

## **Convertible Preferred Stock**

The Company applies the relevant accounting standards to distinguish liabilities from equity when assessing the classification and measurement of preferred stock. Preferred shares subject to mandatory redemptions are considered liabilities and measured at fair value. Conditionally redeemable preferred shares are considered temporary equity. All other preferred shares are considered as stockholders' equity.

The Company applies the relevant accounting standards for derivatives and hedging (in addition to distinguishing liabilities from equity) when accounting for hybrid contracts that contain conversion options. Conversion options must be bifurcated from the host instruments and accounted for as free-standing financial instruments according to certain criteria. These criteria include circumstances when (i) the economic characteristics and risks of the embedded derivative instruments are not clearly and closely related to the economic characteristics and risks of the host contract, (ii) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable accounting principles with changes in fair value reported in earnings as they occurred, and (iii) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. The derivative is subsequently measured at fair value at each reporting date, with the changes in fair value reported in earnings.

## **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, other than losses attributable to a credit loss which are included in other income and expense, on investments classified as available-for-sale securities, which was the only difference between net loss and comprehensive loss for the applicable periods.

## **Net Loss per Common Share**

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. The Pre-Funded Warrants associated with the January 2021 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 for the periods presented include 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 and incentive plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

For the three months ended March 31, 2022, the Company realized a net loss of \$65.7 million. Shares of potentially dilutive securities totaled 27.7 million for the three months ended March 31, 2022, including 14.0 million shares associated with a hypothetical conversion of all outstanding shares of the Company's Class A convertible preferred stock, and an aggregate of 13.7 million shares of common stock issuable upon the exercise of outstanding stock options and the vesting of outstanding restricted stock units.

For the three months ended March 31, 2021, the Company realized a net loss of \$45.1 million. Shares of potentially dilutive securities totaled 25.5 million for the three months ended March 31, 2021, including 14.0 million shares associated with a hypothetical conversion of all outstanding shares of the Company's Class A convertible preferred stock, and an aggregate of 11.6 million shares of common stock issuable upon the exercise of outstanding stock options and the vesting of outstanding restricted stock units.

## **Going Concern Assessment**

Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statement issuance date. The Company determined that there are no conditions or events that raise substantial doubt about its ability to continue as a going concern for a period of at least twelve months from the date of issuance of these financial statements.

## **2. Collaboration and License Agreements**

### **Janssen Collaboration and Option Agreement**

On April 2, 2020 (the Janssen Agreement Effective Date), the Company entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Janssen Agreement Effective Date, the Company entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation – JJDC, Inc. (JJDC).

Upon entering the Janssen Agreement, the Company received an upfront, non-refundable and non-creditable payment of \$50.0 million. Under the Janssen Agreement, Janssen and the Company will collaborate to develop iPSC-derived CAR NK- and CAR T-cell

product candidates for the treatment of cancer. Janssen will contribute proprietary antigen binding domains directed to up to four tumor-associated antigen targets (the Janssen Cancer Targets). The Company will research and construct iPSC-derived CAR NK- and CAR T-cell product candidates directed to each of the Janssen Cancer Targets (the Collaboration Candidates) and perform preclinical development of Collaboration Candidates. Upon the Company's completion of activities sufficient to allow the filing of an Investigational New Drug (IND) application for a Collaboration Candidate, Janssen will have the right to exercise an exclusive option and obtain an exclusive license to the Company's intellectual property rights for the development and commercialization of such Collaboration Candidate. Upon the exercise of such exclusive option, Janssen will be solely responsible for the worldwide clinical development and commercialization of such Collaboration Candidate, and the Company will be primarily responsible for the manufacture, at Janssen's cost, of such Collaboration Candidate. For each Collaboration Candidate, upon attaining clinical proof-of-concept, the Company shall have the right to elect to co-commercialize and share equally in the profits and losses in the United States, subject to the Company sharing in certain development costs.

Under the Stock Purchase Agreement, the Company sold 1.6 million shares of common stock to JJDC at \$31.00 per share, for an aggregate purchase price of approximately \$50.0 million, on April 7, 2020. The Company determined that this common stock purchase represented a premium of \$9.93 per share, or \$16.0 million in aggregate (the Equity Premium), and the remaining \$34.0 million was recorded as an issuance of common stock in shareholders' equity.

In addition, under the Stock Purchase Agreement, the Company had the right to require that JJDC purchase an aggregate of \$50.0 million in shares of the Company's common stock in a private placement at the same price per share as that paid by investors in a public offering. In June 2020, in connection with the Company's June 2020 public offering, the Company exercised this right and JJDC purchased in a private placement 1.8 million shares of the Company's common stock at a price of \$28.31 per share, for aggregate proceeds of \$50.0 million.

Under the terms of the Janssen Agreement, the Company is entitled to receive full funding for all research, preclinical development and IND-enabling activities performed by the Company for Collaboration Candidates, and is eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to \$898.0 million upon the achievement of specified development, regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to \$460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, up to \$706.0 million in Janssen Milestone Payments for each of the first Collaboration Candidates, and up to \$340.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments under (i) and (ii) are subject to reduction in the event the Company elects to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. The Company is further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates that are commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances.

Janssen may terminate the Janssen Agreement with respect to one or more Janssen Cancer Targets, or in its entirety, at any time on or after the second anniversary of the Janssen Agreement Effective Date, and the Company may terminate the Janssen Agreement with respect to a particular Janssen Cancer Target if a Collaboration Candidate has not been selected for IND-enabling studies for such Janssen Cancer Target within specified time periods under certain conditions. The Janssen Agreement contains customary provisions for termination by either party in the event of a material breach of the Janssen Agreement, subject to cure, by the other party and in the event of any bankruptcy, insolvency or similar events with respect to the other party.

The Company applied ASC Topic 808, *Collaborative Arrangements* (ASC 808) and determined the Janssen Agreement is applicable to such guidance. The Company concluded that Janssen represented a customer and applied relevant guidance from ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606) to evaluate the appropriate accounting for the Janssen Agreement. In accordance with this guidance, the Company identified its potential performance obligations, including its grant of a license to Janssen to certain of its intellectual property subject to certain conditions, its conduct of research and development services, and its participation in various joint oversight committees. The Company determined that its grant of a license to Janssen to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research and development services. Accordingly, the Company determined that its grant of a license to Janssen and its conduct of research and development services 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 development services, which is estimated to be four years. Additionally, the Company determined that participation in the various joint oversight committees did not constitute a performance obligation as the Company's participation in the various joint oversight committees does not transfer a service.

The Company also assessed the effects of any variable elements under the Janssen Agreement. Such assessment evaluated, among other things, the funding to be received by the Company for its conduct of research and development services. Based on its assessment, the Company concluded that the total amount to be received by the Company for its conduct of research and development services is variable and cannot be readily estimated and, therefore, no amounts associated with such services were included in the initial transaction price. In addition, the Company also assessed its likelihood of receiving (i) preclinical milestones, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of the Collaboration Candidates. Based on the

likelihood of receiving such milestone payments and royalties, no amounts associated with milestones or royalties were included in the initial transaction price.

In accordance with ASC 606, the Company determined that the initial transaction price under the Janssen Agreement equals \$66.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$50.0 million and the Equity Premium of \$16.0 million. The Company concluded that there was not a significant financing component under the Janssen Agreement. The upfront payment of \$66.0 million was recorded as deferred revenue and is being recognized as revenue consistent with the Company's efforts related to the conduct of research and development services, as the research and development services are the primary component of the combined performance obligation. Since the total amount to be received by the Company for its research and development services under the Janssen Agreement could not be readily estimated, revenue associated with the upfront payment will be recognized based on actual headcount utilized as a percentage of total headcount expected to be utilized over the expected term of the conduct of the research and development services. Revenue associated with the research and development services will be recognized in an amount equal to the actual costs incurred during the period in which the research and development services are performed by the Company.

During the three months ended March 31, 2022, the Company achieved a second research milestone under the Janssen Agreement and recorded a \$3.0 million receivable. In accordance with ASC 606, the Company determined that the \$3.0 million milestone receivable represented an increase in the initial transaction price under the Janssen Agreement in the form of the receipt of variable consideration that was previously constrained. The Company recognized revenue associated with the \$3.0 million milestone receivable in an amount equal to the proportional percentage of actual headcount incurred under the Janssen Agreement since its inception as a percentage of the total headcount expected to be utilized over the expected term of conduct of research and development services under the Janssen Agreement. The remaining unrecognized revenue associated with the \$3.0 million milestone was recorded to deferred revenue, and is being recognized as revenue over the expected term of conduct of research and development services.

In connection with the Janssen Agreement, the Company has incurred \$14.0 million in sublicense fees to certain of its existing licensors as of March 31, 2022. The \$14.0 million in sublicense consideration represents an asset under ASC Topic 340, *Other Assets and Deferred Costs* (ASC 340) and is amortized to research and development expense ratably with the Company's revenue recognition under the Janssen Agreement. During the three months ended March 31, 2022 and 2021, the Company recognized \$1.1 million and \$0.4 million of such expense, respectively. As of March 31, 2022, the Janssen Agreement contract asset balance was \$8.8 million.

The Company recognized revenue of \$15.9 million under the Janssen Agreement for the three months ended March 31, 2022. Such revenue comprised \$9.8 million associated with research and development services and \$6.1 million associated with the upfront fee and Equity Premium for the three months ended March 31, 2022. The Company recognized revenue of \$8.6 million for the three months ended March 31, 2021. Such revenue comprised \$6.8 million associated with research and development services and \$1.8 million associated with the upfront fee and Equity Premium for the three months ended March 31, 2021. As of March 31, 2022, aggregate deferred revenue related to the Janssen Agreement was \$45.1 million, of which \$22.6 million is classified as current.

As of March 31, 2022, the Company has received \$39.9 million in aggregate research and development fees from Janssen.

### **Ono Collaboration and Option Agreement**

On September 14, 2018 (the Ono Agreement Effective Date), 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 chimeric antigen receptor (CAR) T-cell product candidates. The first off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 1) targets an antigen expressed on certain lymphoblastic leukemias, and the second off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 2) targets a novel antigen identified by Ono expressed on certain solid tumors (each a Candidate and collectively the Candidates).

On December 4, 2020, the Company and Ono entered into a letter agreement (the Ono Letter Agreement) in connection with the Ono Agreement. Pursuant to the Ono Letter Agreement, Ono delivered to the Company proprietary antigen binding domains targeting an antigen expressed on certain solid tumors and nominated such antigen binding domains as the Ono Antigen Binding Domain for incorporation into Candidate 2. In connection with such nomination and pursuant to the original agreement, in December 2020, Ono paid the Company a milestone fee of \$10.0 million for further research and development of Candidate 2 and Ono maintains its option to this candidate. In addition, in connection with the Ono Letter Agreement, the Company and Ono agreed to the termination of the Ono Agreement with respect to Candidate 1. The Company retains all rights, in its sole discretion, to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

Pursuant to the Ono Agreement, the Company and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing Candidate 2 to a pre-defined preclinical milestone. The Company has granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize Candidate 2 in all territories of the world, with the Company retaining the right to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement whereby it is eligible to share at least 50% of the profits and losses (the Option).

The Option will expire upon the earliest of: (a) the achievement of the pre-defined preclinical milestone, (b) termination by Ono of research and development activities for Candidate 2 and (c) the date that is the later of (i) four years after the Ono Agreement Effective Date and (ii) completion of all applicable activities contemplated under the joint development plan (the Option Period). The Company has maintained worldwide rights of manufacture for Candidate 2.

Under the terms of the Ono Agreement, Ono paid the Company an upfront, non-refundable and non-creditable payment of \$10.0 million in connection with entering into the Ono Agreement. Additionally, as consideration for the Company's conduct of research and preclinical development under a joint development plan, Ono pays the Company annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be \$20.0 million in aggregate over the course of the joint development plan.

Further, under the terms of the Ono Agreement, Ono has agreed to pay the Company up to an additional \$20.0 million, subject to the exercise by Ono of the Option (Option Exercise Fees) during the Option Period for Candidate 2. Such fees are in addition to the upfront payment, research and development fees, and the previously paid \$10.0 million milestone associated with the Ono Letter Agreement.

Subject to Ono's exercise of the Option and to the achievement of certain clinical, regulatory and commercial milestones (the Ono Milestones) with respect to the Candidate in specified territories, the Company is entitled to receive an aggregate of up to \$885.0 million in additional milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if the Company elects to co-develop and co-commercialize Candidate 2 as described above. The Company is also 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 Candidate 2 in specified territories, with such royalties subject to certain reductions.

No milestone payments specific to Candidate 1 are payable under the Ono Agreement, given the termination of the agreement with respect to such candidate.

The Ono Agreement will terminate with respect to a Candidate if Ono does not exercise its Option for a Candidate within the Option Period, or in its entirety if Ono does not exercise any of its 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 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 Ono Agreement.

The Company applied ASC 808 to the Ono Agreement and Ono Letter Agreement and determined that the agreements are applicable to such guidance. The Company concluded that Ono represented a customer and applied relevant guidance from ASC 606 to evaluate the appropriate accounting for the Ono Agreement and the Ono Letter Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of a license to Ono to certain of its intellectual property subject to certain conditions, its conduct of research services, and its participation in a joint steering committee. The Company determined that its grant of a license to Ono to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research services. Additionally, the Company determined that its conduct of research services was not distinct from other performance obligations since such conduct is dependent on the guidance of the joint steering committee. Accordingly, the Company determined that all performance obligations 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 services, which is estimated to be four years. The termination of the Ono Agreement with respect to Candidate 1 did not impact this assessment.

The Company also assessed, in connection with the upfront, non-refundable and non-creditable payment of \$10.0 million received in September 2018 and the \$5.0 million prepayment of the first-year research and development fees in October 2018, and concluded that there was not a significant financing component to the Ono Agreement.

The Company also assessed the effects of any variable elements under the Ono Agreement. Such assessment evaluated, among other things, the likelihood of receiving (i) preclinical milestone and option fees, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of either product Candidate. Based on its assessment, the Company concluded that, based on the likelihood of these variable components occurring, there was not a significant variable element included in the transaction price. Accordingly, the Company has not assigned a transaction price to any Ono Option Milestone, Ono Milestones or Ono Option Exercise Fees, other than the \$10.0 million milestone triggered as part of the Ono Letter Agreement in December 2020, given the substantial uncertainty related to their achievement and has not assigned a transaction price to any Ono Royalties.

In accordance with ASC 606, the Company determined that the initial transaction price under the Ono Agreement equals \$30.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$10.0 million and the aggregate estimated research and development fees of \$20.0 million. The upfront payment of \$10.0 million was recorded as deferred revenue and is being recognized as revenue over time in conjunction with the Company's conduct of research services as the research services are the

primary component of the combined performance obligations. Revenue associated with the upfront payment will be recognized 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 services. The Company recorded the \$5.0 million prepayment of the first-year research and development fees as deferred revenue, and such fees were recognized as revenue as the research services were delivered.

In accordance with ASC 606, the Company concluded that the \$10.0 million milestone payment associated with the Ono Letter Agreement represented an increase in the initial transaction price under the Ono Agreement in the form of the receipt of variable consideration that was previously constrained. The Company recognized revenue associated with the \$10.0 million milestone payment in an amount equal to the proportional percentage of actual costs incurred under the Ono Agreement as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services. The remaining unrecognized revenue associated with the \$10.0 million milestone was recorded to deferred revenue and is being recognized as revenue over the expected term of conduct of research services.

In connection with the Ono Agreement and the Ono Letter Agreement, the Company has incurred \$4.0 million in sublicense fees to certain of its existing licensors as of March 31, 2022. The \$4.0 million in sublicense consideration represents an asset under ASC 340 and is being amortized to research and development expense ratably with the Company's revenue recognition under the Ono Agreement. During the three months ended March 31, 2022 and 2021, the Company recognized \$0.3 million and \$0.2 million of such expense, respectively.

The Company recognized revenue of \$2.5 million under the Ono Agreement for the three months ended March 31, 2022. Such revenue comprised \$1.2 million associated with research services and \$1.3 million associated with the upfront payment for the three months ended March 31, 2022. During the three months ended March 31, 2021, the Company recognized revenue of \$2.5 million under the Ono Agreement. Such revenue comprised \$1.3 million associated with research services and \$1.2 million associated with the upfront payment for the three months ended March 31, 2021.

As of March 31, 2022, the Company has received \$18.0 million in aggregate research and development fees from Ono.

### Memorial Sloan Kettering Cancer Center License Agreement

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

Pursuant to the Amended MSK License, MSK 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 MSK License, in which case it is obligated to pay MSK a percentage of certain sublicense income received by the Company.

In the event a licensed product achieves a specified clinical milestone, MSK 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 MSK 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 MSK License, adjusted for any stock splits, cash dividends, stock dividends, other distributions, combinations, recapitalizations, or similar events. Under the terms of the Amended MSK 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 MSK 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 agreement:

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 MSK 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 MSK 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 following variables were incorporated in the calculation of the estimated fair value of the stock price appreciation milestones as of March 31, 2022:

	<u>As of March 31,</u> <u>2022</u>	<u>As of December 31,</u> <u>2021</u>
Risk-free interest rate	2.5 %	1.7 %
Expected volatility	77.7 %	77.6 %
Estimated term (in years)	16.8	17.0
Closing stock price as of remeasurement date	\$ 38.77	\$ 58.51

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 measurement 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 months ended March 31, 2022, the Company recorded \$8.4 million of income associated with the change in fair value of the stock price appreciation milestones. As of March 31, 2022, the Company recorded a liability of \$15.8 million associated with the stock price appreciation milestones for the Amended MSK License.

### 3. California Institute for Regenerative Medicine Award

On April 5, 2018, the Company executed an award agreement with the California Institute for Regenerative Medicine (CIRM) pursuant to which CIRM awarded the Company \$4.0 million to advance the Company's FT516 product candidate into a first-in-human clinical trial for the treatment of subjects with advanced solid tumors, including in combination with monoclonal antibody therapy (the Award). Pursuant to the terms of the Award, the Company is eligible to receive five disbursements in varying amounts totaling \$4.0 million, with one disbursement receivable upon the execution of the Award, and four disbursements receivable upon the completion of certain milestones throughout the project period. The Award is subject to certain co-funding requirements by the Company, and the Company is required to provide CIRM progress and financial update reports under the Award.

Pursuant to the terms of the Award, the Company, in its sole discretion, has the option to treat the Award either as a loan or as a grant. In the event the Company elects to treat the Award as a loan, the Company will be obligated to repay (i) 60%, (ii) 80%, (iii) 100% or (iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of the Company's election. If the Company does not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant and the Company will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to the Company under the Award.

Since the Company may, at its election, repay some or all of the Award, the Company accounts for the Award as a liability until the time of election. As of March 31, 2022, the Company has received aggregate disbursements under the Award in the amount of \$4.0 million. The aggregate amount received is recorded as a CIRM Liability on the accompanying unaudited condensed consolidated balance sheets and classified as current or non-current based on the potential amount payable within twelve months of the current balance sheet.

### 4. Investments

The Company invests portions of excess cash in United States treasuries, non-U.S. government securities, municipal securities, corporate debt securities and commercial paper with maturities ranging from three to thirty-six months from the purchase date. These securities are classified as short-term and long-term investments in the accompanying unaudited condensed consolidated balance sheets based on each security's contractual maturity date and are accounted for as available-for-sale securities.

The following table summarizes the Company's investments accounted for as available-for-sale securities as of March 31, 2022 and December 31, 2021 (in thousands, except for maturity in years):

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
<b>March 31, 2022</b>					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	\$ 140,478	\$ (773)	\$ 3	\$ 139,708
Municipal securities	1 or less	16,847	(157)	—	16,690
Corporate debt securities	1 or less	168,484	(491)	—	167,993
Commercial paper	1 or less	184,976	(336)	—	184,640
Total short-term investments		<u>\$ 510,785</u>	<u>\$ (1,757)</u>	<u>\$ 3</u>	<u>\$ 509,031</u>
Classified as non-current assets:					
Municipal securities	Greater than 1	\$ 4,979	\$ (39)	\$ —	\$ 4,940
Corporate debt securities	Greater than 1	64,070	(1,068)	—	63,002
Total long-term investments		<u>\$ 69,049</u>	<u>\$ (1,107)</u>	<u>\$ —</u>	<u>\$ 67,942</u>
<b>December 31, 2021</b>					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	\$ 70,653	\$ (163)	\$ —	\$ 70,490
Municipal securities	1 or less	18,017	(6)	1	18,012
Corporate debt securities	1 or less	169,736	(187)	—	169,549
Commercial paper	1 or less	224,333	(59)	2	224,276
Total short-term investments		<u>\$ 482,739</u>	<u>\$ (415)</u>	<u>\$ 3</u>	<u>\$ 482,327</u>
Classified as non-current assets:					
U.S. Treasury debt securities	Greater than 1	\$ 9,989	\$ (35)	\$ —	\$ 9,954
Municipal securities	Greater than 1	9,034	(42)	—	8,992
Corporate debt securities	Greater than 1	81,989	(271)	—	81,718
Total long-term investments		<u>\$ 101,012</u>	<u>\$ (348)</u>	<u>\$ —</u>	<u>\$ 100,664</u>

As of March 31, 2022 and December 31, 2021, the Company had \$1.4 million and \$1.1 million, respectively, of accrued interest on investments recorded in prepaid expenses and other assets on the unaudited condensed consolidated balance sheets.

The following tables present gross unrealized losses and fair values for those investments that were in an unrealized loss position as of March 31, 2022 and December 31, 2021, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
<b>March 31, 2022</b>						
U.S. Treasury debt securities	\$ 129,711	\$ (773)	\$ —	\$ —	\$ 129,711	\$ (773)
Municipal securities	21,630	(196)	—	—	21,630	(196)
Corporate debt securities	202,366	(1,536)	23,192	(23)	225,558	(1,559)
Commercial paper	66,900	(336)	—	—	66,900	(336)
Total	<u>\$ 420,607</u>	<u>\$ (2,841)</u>	<u>\$ 23,192</u>	<u>\$ (23)</u>	<u>\$ 443,799</u>	<u>\$ (2,864)</u>
<b>December 31, 2021</b>						
U.S. Treasury debt securities	\$ 80,444	\$ (198)	\$ —	\$ —	\$ 80,444	\$ (198)
Municipal securities	23,352	(48)	—	—	23,352	(48)
Corporate debt securities	250,467	(458)	—	—	250,467	(458)
Commercial paper	59,863	(59)	—	—	59,863	(59)
Total	<u>\$ 414,126</u>	<u>\$ (763)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 414,126</u>	<u>\$ (763)</u>

The Company reviews its investment holdings at the end of each reporting period and evaluates any unrealized losses using the expected credit loss model to determine if the unrealized loss is a result of a credit loss or other factors. The Company also evaluates its investment holdings for impairment using a variety of factors including the Company's intent to sell the underlying securities prior to maturity and whether it is more likely than not that the Company would be required to sell the securities before the recovery of their amortized basis. During each of the three months ended March 31, 2022 and 2021, the Company did not recognize any impairment or realized gains or losses on sales of investments, and the Company did not record an allowance for, or recognize, any expected credit losses.

## 5. Fair Value Measurements

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts receivable, stock price appreciation milestones, accounts payable, and accrued liabilities. The carrying amounts of accounts receivable, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the relatively short-term nature of those instruments.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

The following table presents the Company's financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2022 and December 31, 2021 (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)
<b>As of March 31, 2022</b>				
Financial assets:				
Money market funds	\$ 64,741	\$ 64,741	\$ —	\$ —
U.S. Treasury debt securities	139,708	139,708	—	—
Municipal securities	21,630	—	21,630	—
Corporate debt securities	230,995	—	230,995	—
Commercial paper	184,640	—	184,640	—
Total financial assets measured at fair value on a recurring basis	<u>\$ 641,714</u>	<u>\$ 204,449</u>	<u>\$ 437,265</u>	<u>\$ —</u>
Financial liabilities:				
Stock price appreciation milestones	\$ 15,809	\$ —	\$ —	\$ 15,809
Total financial liabilities measured at fair value on a recurring basis	<u>\$ 15,809</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 15,809</u>
<b>As of December 31, 2021</b>				
Financial assets:				
Money market funds	\$ 133,583	\$ 133,583	\$ —	\$ —
U.S. Treasury debt securities	80,444	80,444	—	—
Municipal securities	27,004	—	27,004	—
Corporate debt securities	251,267	—	251,267	—
Commercial paper	224,276	—	224,276	—
Total assets measured at fair value on a recurring basis	<u>\$ 716,574</u>	<u>\$ 214,027</u>	<u>\$ 502,547</u>	<u>\$ —</u>
Financial liabilities:				
Stock price appreciation milestones	\$ 24,168	\$ —	\$ —	\$ 24,168
Total financial liabilities measured at fair value on a recurring basis	<u>\$ 24,168</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 24,168</u>

Level 1 assets consisted of money market funds and U.S. Treasury debt 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 non-U.S. government securities, municipal securities, corporate debt securities, and commercial paper 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 March 31, 2022.

Level 3 liabilities consisted of stock price appreciation milestones associated with the Amended MSK License as described in detail in Note 2. To determine the estimated fair value of the stock price appreciation milestones, the Company uses a Monte Carlo simulation methodology which models future Company common stock prices based on several key variables. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the expected volatility of the Company's common stock and estimated term, which is based in part on the last valid patent claim date. 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. This assessment is based on several factors including the successful achievement of technological, manufacturing, and regulatory requirements.

A small change in the assumptions and other inputs, such as the price of the Company's common stock, may have a relatively large change in the estimated fair value of the stock price appreciation milestones and associated liability and expense. For example,

keeping all other variables constant, a hypothetical 10% increase in the stock price at March 31, 2022 from \$38.77 to \$42.65 per share would have decreased the income recorded during the three months ended March 31, 2022 by \$1.7 million related to the stock price appreciation milestones. Keeping all other variables constant, a hypothetical 10% decrease in the stock price at March 31, 2022 from \$38.77 to \$34.89 per share would have increased the income recorded during the three months ended March 31, 2022 by \$1.6 million related to the stock price appreciation milestones.

The following table presents the changes in fair value of the Company's Level 3 stock price appreciation milestones liability (in thousands):

Balance at December 31, 2021	\$	24,168
Changes in fair value of stock price appreciation milestones liability		(8,359)
Balance at March 31, 2022	\$	<u>15,809</u>

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

## 6. Accrued Expenses

### Accrued Expenses

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

	March 31, 2022	December 31, 2021
Accrued payroll and other employee benefits	\$ 11,568	\$ 18,358
Accrued clinical trial related costs	10,511	12,344
Accrued other	13,031	11,710
Total current accrued expenses	<u>\$ 35,110</u>	<u>\$ 42,412</u>

## 7. Leases

The Company has lease agreements for office, laboratory and manufacturing spaces that are classified as operating leases on the unaudited condensed 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.

As of March 31, 2022, future undiscounted minimum contractual payments under the Company's operating leases were \$188.9 million, which will be paid over a remaining weighted-average lease term of 12.1 years. The weighted-average discount rate for the operating lease liabilities was 6.9%, which was the Company's incremental borrowing rate at lease commencement, as the discount rates implicit in the leases could not be readily determined.

The components of lease expense were as follows:

	Three Months Ended March 31,	
	2022	2021
Straight-line lease expense	\$ 3,815	\$ 3,534
Variable lease expense	618	235
Total operating lease expense	<u>\$ 4,433</u>	<u>\$ 3,769</u>

No short-term lease expense was recognized during the three months ended March 31, 2022 and 2021.

Future minimum lease payments under the Company's operating leases as of March 31, 2022 are as follows (in thousands):

	<b>Operating Lease Payments</b>
Remaining in 2022	\$ 11,285
2023	14,498
2024	14,836
2025	15,087
2026	15,540
2027	16,006
Thereafter	101,636
Total undiscounted lease payments	\$ 188,888
Less: imputed interest	(75,367)
Total lease liability	\$ 113,521

## 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 non-voting Class A Convertible Preferred Stock (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.

The Class A Preferred are non-voting shares and have a stated par value of \$0.001 per share 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).

During the year ended December 31, 2019, 25,000 shares of the Class A Preferred were converted into 125,000 shares of the Company's 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 purchase price for the 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 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 March 31, 2022, there were 257,310 Pre-Funded Warrants outstanding.

## Stock Options and Restricted Stock Units

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

	Number of Options	Weighted- Average Price
Balance at December 31, 2021	7,708,263	\$ 20.43
Granted	671,420	39.87
Exercised	(398,415)	7.56
Cancelled	(51,924)	33.61
Balance at March 31, 2022	<u>7,929,344</u>	<u>\$ 22.63</u>

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, 2021	4,008,832	\$ 58.60
Granted	2,293,106	40.49
Vested	(412,707)	45.87
Cancelled	(98,518)	56.29
Balance at March 31, 2022	<u>5,790,713</u>	<u>\$ 52.54</u>

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

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 12,694	\$ 8,522
General and administrative	\$ 6,637	4,454
Total	<u>\$ 19,331</u>	<u>\$ 12,976</u>

As of March 31, 2022, the unrecognized compensation cost related to outstanding options was \$58.1 million and is expected to be recognized as expense over a weighted-average period of approximately 2.6 years.

As of March 31, 2022, the unrecognized compensation cost related to restricted stock units was \$175.1 million which is expected to be recognized as expense over a weighted-average period of approximately 3.4 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:

	Three Months Ended March 31,	
	2022	2021
Risk-free interest rate	1.6 %	0.4 %
Expected volatility	75.8 %	76.5 %
Expected term (in years)	5.6	5.1
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 months ended March 31, 2022 (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, 2021	2,794,549	\$ 3	95,726,962	\$ 96	\$ 1,448,584	\$ (762)	\$ (769,083)	\$ 678,838
Exercise of stock options, net of issuance costs	—	—	398,415	—	3,001	—	—	3,001
Issuance of common stock upon vesting of restricted stock units	—	—	412,707	—	—	—	—	1
Stock-based compensation	—	—	—	—	19,331	—	—	19,331
Unrealized loss on investments	—	—	—	—	—	(2,088)	—	(2,088)
Net loss	—	—	—	—	—	—	(65,690)	(65,690)
Balance at March 31, 2022	2,794,549	\$ 3	96,538,084	\$ 97	\$ 1,470,916	\$ (2,850)	\$ (834,773)	\$ 633,393

The following table summarizes the Company's changes in stockholders' equity accounts for the three months ended March 31, 2021 (in thousands, except share data):

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	2,794,549	\$ 3	87,722,237	\$ 88	\$ 941,216	\$ 70	\$ (556,932)	\$ 384,445
Exercise of stock options, net of issuance costs	—	—	613,015	1	5,647	—	—	5,648
Issuance of common stock upon vesting of restricted stock units	—	—	430,620	—	—	—	—	—
Stock-based compensation	—	—	—	—	12,976	—	—	12,976
Public offering of common stock and issuance of pre-funded warrants, net of issuance costs	—	—	5,122,807	5	432,440	—	—	432,445
Unrealized loss on investments	—	—	—	—	—	(330)	—	(330)
Net loss	—	—	—	—	—	—	(45,089)	(45,089)
Balance at March 31, 2021	2,794,549	\$ 3	93,888,679	\$ 94	\$ 1,392,279	\$ (260)	\$ (602,021)	\$ 790,095

## 9. Subsequent Events

In April 2022, the Company achieved a research milestone associated with a product candidate directed to a third tumor-associated antigen under the Janssen Agreement; the amount due under the milestone is \$3.0 million.



## 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, 2021 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 February 28, 2022.

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 the development of programmed cellular immunotherapies for patients with cancer. We are developing first-in-class cell therapy product candidates based on a simple notion: we believe that better cell therapies start with better cells.

To create better cell therapies, we use a therapeutic approach that we generally refer to as cell programming. We use human induced pluripotent stem cells (iPSCs) to generate a clonal master iPSC line having preferred biological properties, and we direct the fate of the clonal master iPSC line to create our cell therapy product candidate. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used as a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be repeatedly mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients. Utilizing these therapeutic approaches, we program cells of the blood and immune system and are advancing a pipeline of programmed cellular immunotherapies, including off-the-shelf natural killer (NK) and T-cell product candidates derived from clonal master iPSC lines for the treatment of cancer.

We have entered into a research collaboration and license agreement with the Regents of the University of Minnesota to develop off-the-shelf, engineered NK-cell cancer immunotherapies derived from clonal master iPSC lines. Additionally, we have entered into a research collaboration and license agreement with Memorial Sloan Kettering Cancer Center (MSK) to develop off-the-shelf, engineered T-cell cancer immunotherapies derived from clonal master iPSC lines.

In September 2018, we entered into a collaboration and option agreement with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of off-the-shelf, iPSC-derived chimeric antigen receptor (CAR) T-cell product candidates (Ono Agreement) for the treatment of cancer.

In April 2020, we entered into a collaboration and option agreement with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen Agreement), for the development and commercialization of off-the-shelf, iPSC-derived CAR NK- and CAR T-cell product candidates for the treatment of cancer.

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. 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, 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 increase substantially in connection with our ongoing and planned activities as we:

- conduct our ongoing and planned 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;
- conduct 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 IND-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 agreements with Janssen and 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;
- establish business operations at our new corporate headquarters, including internal GMP production capabilities;
- hire additional clinical, manufacturing, regulatory, quality control and technical personnel to advance our product candidates;
- hire additional scientific personnel to advance our research and development efforts;
- hire additional personnel to build out our commercialization, marketing and medical teams; and
- hire general and administrative personnel to continue operating as a public company and support our operations and develop commercial infrastructure for potential commercialization of our product candidates.

We do not expect to generate any meaningful product sales or royalty revenue 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 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.

Due to the global outbreak of SARS-CoV-2, the strain of coronavirus that causes Coronavirus disease 2019 (COVID-19), we continued to experience impacts on certain aspects of our business, including our clinical trial, manufacturing, and research and development activities, during the three months ended March 31, 2022. For example, with the lifting of governmental stay-at-home orders, we have reopened each of our business locations for work onsite, but have also implemented flexible work arrangements in the interests of maintaining the health and safety of our employees. In addition, the COVID-19 pandemic has impacted the timing of our ongoing clinical studies, with slower site activation, patient enrollment and treatment in our clinical studies as a result of precautionary measures taken by some clinical trial sites to protect both site staff and patients from possible COVID-19 exposure. We have also experienced delays in obtaining equipment, materials, and supplies needed to maintain our operations and manufacture our product candidates as a result of production shortages experienced by our suppliers as a result of the COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of the COVID-19 pandemic on our operations, are currently unknown, and depend on continuously changing circumstances, including the emergence of new variants of the virus, such as the Delta and Omicron BA.1 and BA.2 variants. We are continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that we determine are in the best interests of public health and safety and that of our patient community, employees, partners, and stockholders. We cannot predict the effects that such actions, or the impact of the ongoing COVID-19 pandemic, including the emergence of new variants of the virus, on global business operations and economic conditions, may have on our business, strategy, collaborations, or financial and operating results.

## **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. Fate Therapeutics, Inc. owns 100% of the voting shares of Tfinity Therapeutics, Inc. (Tfinity), incorporated in the United States, 100% of the voting shares of Fate Therapeutics Ltd. (Fate Ltd.), incorporated in the United Kingdom, and 100% of the voting shares of Fate Therapeutics B.V. (Fate B.V.), incorporated in the Netherlands. The following information is presented on a consolidated basis to include the accounts of Fate Therapeutics, Inc., Tfinity, Fate B.V., and Fate Ltd. 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. Our revenues have been derived from collaboration agreements and government grants.

### ***Agreement with Janssen Biotech, Inc.***

On April 2, 2020 (the Janssen Agreement Effective Date), we entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Janssen Agreement Effective Date, we entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation - JJDC, Inc. (JJDC). Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received \$100.0 million, of which \$50.0 million is an upfront cash payment and \$50.0 million is in the form of an equity investment by JJDC. Additionally, we are entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement.

We determined the common stock purchase by JJDC represented a premium of \$9.93 per share, or \$16.0 million in aggregate (the Equity Premium), and the remaining \$34.0 million was recorded as issuance of common stock in shareholders' equity.

We concluded that Janssen represented a customer, and in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), we determined that the initial transaction price under the Janssen Agreement equals \$66.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$50.0 million and the Equity Premium of \$16.0 million. In addition, we identified our potential performance obligations under the Janssen Agreement, including our grant to Janssen of a license to certain of our intellectual property subject to certain conditions, our conduct of research and development services, and our participation in various joint oversight committees. We determined that our grant of a license to Janssen and our conduct of research and development services 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 development services, which is estimated to be four years. Additionally, we determined that participation in the various joint oversight committees did not constitute a performance obligation as our participation in the various joint oversight committees does not transfer a service.

During the three months ended March 31, 2022, we achieved a second pre-defined research milestone under the Janssen Agreement and recorded a \$3.0 million receivable.

During the three months ended March 31, 2022, we recognized \$15.9 million of collaboration revenue under the Janssen Agreement. During the three months ended March 31, 2021, we recognized \$8.6 million of collaboration revenue under the Janssen Agreement, respectively. As of March 31, 2022, aggregate deferred revenue related to the Janssen Agreement was \$45.1 million.

### ***Agreement with Ono Pharmaceutical Co., Ltd.***

On September 14, 2018, we entered into a Collaboration and Option Agreement (the Ono Agreement) with 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, 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 are estimated to be \$20.0 million in aggregate.

We concluded that Ono represented a customer and in accordance with ASC 606, we determined that the initial transaction price under the Ono Agreement equals \$30.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$10.0 million and the aggregate estimated research and development fees of \$20.0 million. In addition, we identified our performance obligations under the Ono Agreement, including 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 all performance obligations should be accounted for as one combined performance obligation since no individual performance obligation is distinct, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years.

On December 4, 2020, we entered into a letter agreement (the Ono Letter Agreement) with Ono in connection with the Ono Agreement. Pursuant to the Ono Letter Agreement, Ono delivered to us proprietary antigen binding domains targeting an antigen expressed on certain solid tumors and nominated such antigen binding domains as the Ono Antigen Binding Domain for incorporation into Candidate 2. In connection with such nomination, Ono paid us a milestone fee of \$10.0 million for further research and development of Candidate 2 under the Ono Agreement, and Ono continues to maintain its option to Candidate 2 under the Ono Agreement.

In addition, together with Ono, we agreed to the termination of the Ono Agreement with respect to Candidate 1. We retain all rights, in our sole discretion, to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

During the three months ended March 31, 2022, we recognized \$2.5 million of collaboration revenue under the Ono Agreement. During the three months ended March 31, 2021, we recognized \$2.5 million of collaboration revenue under the Ono Agreement.

### ***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 increase our current level of research and development expenses for the foreseeable future as we continue the clinical and preclinical development and the manufacture of our product candidates, research and develop our iPSC product platform, and perform our obligations under collaboration agreements including under our agreements with Janssen, Ono, University of Minnesota and MSK. 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, 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 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 agreements with Janssen and 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 the ongoing COVID-19 pandemic and the ongoing conflict in Ukraine on our business and operations, and our expenditures may be increased by delays or disruptions due to the COVID-19 pandemic or the ongoing conflict in Ukraine, 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 and maintaining 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 increase in the future as we increase our research and development activities, maintain compliance with exchange listing and SEC requirements 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 and Restated Exclusive License Agreement dated May 15, 2018 (the Amended MSK License) with Memorial Sloan Kettering Cancer Center (MSK), interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

### 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 United States generally accepted accounting principles. 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 MSK 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, 2021 continue to be our critical accounting policies and there have been no other material changes to our critical accounting policies during the three months ended March 31, 2022.

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 March 31, 2022 and 2021

The following table summarizes the results of our operations for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,		Increase/ (Decrease)
	2022	2021	
Collaboration revenue	\$ 18,414	\$ 11,142	\$ 7,272
Research and development expense	72,139	44,852	27,287
General and administrative expense	20,742	12,500	8,242
Total other income	8,777	1,121	7,656

*Collaboration Revenue.* During the three months ended March 31, 2022 and 2021, we recognized revenue of \$18.4 million and \$11.1 million, respectively, under our collaboration agreements with Janssen and Ono.

*Research and development expenses.* Research and development expenses were \$72.1 million for the three months ended March 31, 2022, compared to \$44.9 million for the three months ended March 31, 2021. The increase in research and development expenses was attributable primarily to the following:

- \$11.8 million increase in employee compensation and benefits expense, including \$4.1 million increase in employee stock-based compensation expense;
- \$7.6 million increase in expenditures for laboratory materials and supplies relating to the manufacture of our product candidates and the conduct of our research activities, including under our collaboration agreements; and
- \$3.9 million increase in third-party professional consultant and clinical trial related expense.

*General and administrative expenses.* General and administrative expenses were \$20.7 million for the three months ended March 31, 2022, compared to \$12.5 million for the three months ended March 31, 2021. The increase in general and administrative expenses was attributable primarily to a \$5.0 million increase in employee compensation and benefits expense, including \$2.2 million increase in employee stock-based compensation expense, and a \$1.1 million increase in facility lease and related expenses.

*Other income (expense), net.* Other income (expense), net was \$8.8 million and \$1.1 million for the three months ended March 31, 2022 and 2021, respectively. During the three months ended March 31, 2022, we recorded \$8.4 million in income attributable to the change in fair value of the stock price appreciation milestones under the Amended MSK License. Other income (expense), net for the three months ended March 31, 2022 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 March 31, 2021, we recorded \$0.7 million in other expense attributable to the change in fair value of the stock price appreciation milestones under the Amended MSK License. Other income (expense), net for the three months ended March 31, 2021 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 March 31, 2022, we had an accumulated deficit of \$834.8 million and we anticipate that we will continue to incur net losses for the foreseeable future.

### ***Operating Activities***

During the three months ended March 31, 2022, cash used in operating activities was \$64.6 million compared to cash used in operating activities of \$21.7 million during the three months ended March 31, 2021. The primary driver of this change in cash used in operating activities was our increase in net loss. The change in cash from the period is also attributed to the increase in prepaid expenses and decrease in accrued liabilities.

#### *Agreement with Janssen Biotech, Inc.*

On April 2, 2020 (the Janssen Agreement Effective Date), we entered into the Janssen Agreement with Janssen to develop iPSC-derived CAR NK- and CAR T-cell product candidates for the treatment of cancer. Additionally, on the Janssen Agreement Effective Date, we entered into the Stock Purchase Agreement with JJDC. Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received \$100.0 million as of the Janssen Agreement Effective Date, of which \$50.0 million is an upfront cash payment and \$50.0 million is in the form of an equity investment by JJDC. Of the \$50.0 million equity investment, \$16.0 million represented a premium over the fair value of our common stock and was classified under operating activities.

We are entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement. Additionally, we are eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to \$898.0 million upon the achievement of specified development, regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to \$460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, payments of up to \$706.0 million in Janssen Milestone Payments for each of the first Collaboration Candidates, and up to \$340.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments are subject to reduction in the event we elect to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. We are further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates that are commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances.

During the three months ended March 31, 2022, we achieved a second pre-defined research milestone under the Janssen Agreement and recorded a \$3.0 million receivable. As of March 31, 2022, no royalties have been paid to us.

In connection with the Janssen Agreement, we have incurred \$14.0 million in sublicense fees to certain of our existing licensors, all of which has been paid as of March 31, 2022. The \$14.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs*.

#### *Agreement with Ono Pharmaceutical Co., Ltd.*

On September 14, 2018, we entered into the Ono Agreement with Ono for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates (each a Candidate and collectively the Candidates). Under the terms of the Ono Agreement, Ono paid to us an upfront, non-refundable and non-creditable payment of \$10.0 million. Additionally, as consideration for our conduct of research and preclinical development under a joint development plan, Ono pays us annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be \$20.0 million in aggregate over the course of the joint development plan. Further, under the terms of the Ono Agreement, Ono had agreed to pay us up to an additional \$40.0 million, subject to the achievement of a preclinical milestone and the exercise by Ono of its options to obtain exclusive licenses to develop and commercialize the Candidates. Such fees are in addition to the upfront payment and research and development fees.

Pursuant to the Ono Agreement, we and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing Candidate 2 to a pre-defined preclinical milestone. We have granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize Candidate 2 in all territories of the world, with us retaining the right to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement whereby it is eligible to share at least 50% of the profits and losses.

On December 4, 2020, we entered into the Ono Letter Agreement with Ono in connection with the Ono Agreement. Pursuant to the Ono Letter Agreement, Ono delivered to us proprietary antigen binding domains targeting an antigen expressed on certain solid tumors and nominated such antigen binding domains as the Ono Antigen Binding Domain for incorporation into Candidate 2. In connection with such nomination, Ono paid us a milestone fee of \$10.0 million in December 2020 for further research and development of Candidate 2 under the Ono Agreement, and Ono continues to maintain its option to Candidate 2 under the Ono Agreement. In addition, the Ono Letter Agreement terminated further development with respect to Candidate 1.

Subject to Ono's exercise of its options to obtain exclusive licenses to develop and commercialize Candidate 2 and to the achievement of certain clinical, regulatory and commercial milestones in specified territories, we are eligible to receive an aggregate of up to \$885.0 million in milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if we elect to co-develop and co-commercialize Candidate 2 as described above. As of March 31, 2022, we have not received any milestone payments other than the \$10.0 million associated with the Ono Letter Agreement in December 2020. We are also eligible to receive tiered royalties ranging from the mid-single digits to the low-double digits based on annual net sales by Ono for Candidate 2 in specified territories, with such royalties subject to certain reductions. As of March 31, 2022, no royalties have been paid to us.

In connection with the Ono Agreement and the Ono Letter Agreement, we have incurred \$4.0 million in sublicense fees to certain of our existing licensors. The \$4.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs*. As of March 31, 2022, all such consideration has been paid.

#### *Memorial Sloan Kettering Cancer Center License Agreement*

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

Pursuant to the Amended MSK License, MSK granted us 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. We have the right to grant sublicenses to certain licensed rights in accordance with the terms of the Amended MSK License, in which case we are obligated to pay MSK a percentage of certain sublicense income received.

In the event a licensed product achieves a specified clinical milestone, MSK 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 MSK is contingent upon certain increases in the price of our 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 our common stock and the denominator being the ten-trading day trailing average closing price our common stock as of the effective date of the Amended MSK License, adjusted for any stock splits, cash dividends, stock dividends, other distributions, combinations, recapitalizations, or similar events. Under the terms of the Amended MSK License, upon a change of control of the Company, in certain circumstances, we may be required to pay a portion of these payments to MSK based on the price of our common stock in connection with such change of control.

As of March 31, 2022, we recorded a liability of \$15.8 million associated with the stock price appreciation milestones for the Amended MSK License. In July 2021, we achieved a specified clinical milestone for a licensed product under the Amended MSK License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, we remitted payment to MSK of \$20.0 million during the year ended December 31, 2021.

#### *Investing Activities*

During the three months ended March 31, 2022, investing activities used cash of \$7.0 million compared to cash used by investing activities of \$471.9 million during the three months ended March 31, 2021. The change was primarily attributable to a decrease in the purchases of investments of \$132.2 million during the three months ended March 31, 2022 compared to the purchase of investments of \$529.9 million during the three months ended March 31, 2021. All other investing activities for the periods presented were attributable to the purchase of property and equipment.

## *Financing Activities*

For the three months ended March 31, 2022, financing activities provided cash of \$2.8 million, which primarily consisted of the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

For the three months ended March 31, 2021, financing activities provided cash of \$438.1 million, which consisted of \$432.4 million of net proceeds from our January 2021 public offering of common stock and issuance of pre-funded warrants and \$5.6 million received from the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

From our inception through March 31, 2022, 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 March 31, 2022, we had aggregate cash and cash equivalents and investments of \$641.7 million.

### *Public Offering of Common Stock*

In January 2021, we completed a public offering of common stock in which investors, certain of which are affiliated with a director of ours, purchased 5.1 million shares of our common stock at a price of \$85.50 per share under a shelf registration statement. In addition, we issued pre-funded warrants, in lieu of common stock to certain investors, to purchase 257,310 shares of our common stock (Pre-Funded Warrants). The purchase price of for the 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. See Note 8 for additional detail. Gross proceeds from the public offering and the issuance of the Pre-Funded Warrants were \$460.0 million. After giving effect to \$27.6 million in underwriting discounts, commissions and expenses related to the public offering and the issuance of Pre-Funded Warrants, net proceeds were \$432.4 million.

### *California Institute for Regenerative Medicine Award*

On April 5, 2018, we executed an award agreement with the CIRM pursuant to which CIRM awarded us \$4.0 million to advance our FT516 product candidate into a first-in-human clinical trial (the Award). Pursuant to the terms of the Award, we are eligible to receive five disbursements in varying amounts totaling \$4.0 million throughout the project period of the Award. In November 2019, we submitted an IND application for FT516 in advanced solid tumors. As of March 31, 2022, we have received aggregate disbursements under the Award in the amount of \$4.0 million.

The Award is subject to certain co-funding requirements by us. We, in our sole discretion, have the option to treat the Award either as a loan or as a grant. In the event we elect to treat the Award as a loan, we will be obligated to repay i) 60%, ii) 80%, iii) 100% or iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of our election. If we do not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant and we will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to us under the Award.

### *Registration Statement on Form S-3*

In November 2021, we filed an automatic shelf registration statement (File No. 333-260772), which became effective upon filing. 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 automatic shelf registration statement are established at the time of such offering. 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 \$350.0 million through Jefferies as the sales agent, pursuant to this automatic shelf registration statement.

### *Operating Capital Requirements*

We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase 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 agreements with Janssen and Ono. Our product candidates have not yet achieved regulatory approval and we may not be successful in achieving commercialization of our product candidates.



We believe our existing cash and cash equivalents and investments as of March 31, 2022 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are subject to all the risks and uncertainties incident in the research, manufacture and development of therapeutic products. 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 the COVID-19 pandemic and the ongoing conflict in Ukraine. We expect to finance our capital requirements in the foreseeable future through the sale of public or private equity or debt securities. 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, while the full impact of the COVID-19 pandemic and the ongoing conflict in Ukraine on our business, operations, financial condition and prospects, and on the global economy, are currently unknown and difficult to predict, the pandemic has caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of the pandemic 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 and 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;
- the number and the nature of product candidates that we pursue;
- the time to and cost of establishing internal GMP production capabilities to support the clinical and potential commercial manufacture of our product candidates at our new 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 MSK in connection with the stock price appreciation milestones;
- the extent to which milestones are achieved under our collaboration agreements with Ono and Janssen, 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;
- 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 ongoing developments in connection with the COVID-19 pandemic and the ongoing conflict in Ukraine 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 fees. The leases are also subject to additional variable charges for common area maintenance, property taxes, property insurance and other variable costs. See Note 7 of the unaudited condensed consolidated financial statements for additional detail surrounding our lease obligations.

We entered into a license agreement with MSK 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, MSK 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 MSK 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 MSK License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, we remitted payment to MSK for the first milestone payment of \$20.0 million. See Note 2 of 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.

### **Inflation**

Inflation has increased during the periods covered by this Quarterly Report, and is expected to continue to increase for the near future. Inflationary factors, such as increases in the prices of material, interest rates and cost of labor may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future, especially if inflation rates continue to rise.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

#### ***Interest Rate Risk***

We are exposed to market risk related to changes in interest rates. As of March 31, 2022, our cash and cash equivalents consisted of cash and money market mutual funds, and our investments consisted of United States treasuries, non-U.S. government securities, municipal securities, corporate debt securities and commercial paper with maturities ranging from three to eighteen months from the date of acquisition. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the low risk profile of the instruments in our portfolio, a 10% change in market interest rates would not have a material impact on our financial condition and/or results of operations.

#### ***Stock Price Sensitivity***

We entered into an amended and restated license agreement with MSK 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. MSK is eligible to receive certain milestone payments totaling up to \$75.0 million in the event a licensed product achieves a specified clinical milestone, where the amount of such payments owed to MSK is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. As of March 31, 2022, the estimated fair value of the stock price appreciation milestones for the remaining milestones was \$15.8 million.

Changes in the price of our common stock as of each balance sheet date may cause a relatively large change in the estimated fair value of the stock price appreciation milestones and the associated liability and resulting expense or gain. See Note 5 to our unaudited condensed consolidated financial statements for a related sensitivity analysis.

#### **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 chief executive officer and our chief financial officer, who serve as our principal executive officer and our principal financial officer, respectively, 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 each concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2022.

##### ***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

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse effect on us because of defense and settlement costs, diversion of management resources and other factors.

### 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.

We may delay 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:

- determining 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 to support 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 FDA for the conduct of clinical trials or for marketing approval;
- our prioritization of other 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 more a favorable commercial profile, including greater market acceptance or commercial potential, or more advantageous intellectual property position;
- challenges and delays in trial execution associated with 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 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, or may fail to achieve market acceptance or 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); or
- 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 final 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 identifying eligible patients for participation in clinical trials of our product candidates, due in part to our focus on the development of certain of our product candidates for the treatment of rare diseases;
- 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 shelter-in-place orders, mandated travel restrictions, prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the ongoing COVID-19 pandemic;
- 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;
- difficulties in obtaining agreement from 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 identify;
- 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;

- 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 the ongoing COVID-19 pandemic, failure to obtain regulatory approval, or uncertainty or changes in U.S. or foreign regulatory requirements, policy or guidelines;
- limitations on clinical trial conduct at our clinical trial sites resulting from prioritization of hospital and other medical resources toward COVID-19 pandemic efforts, 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 the COVID-19 pandemic;
- 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, by us or third parties that we contract with, to manufacture certain of our product candidates consistently, and in sufficient quantities, in accordance with our protocol-specified manufacturing requirements and applicable regulatory requirements;
- 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;
- failure or delays in obtaining sufficient quantities of suitable raw materials, components, and equipment necessary for the manufacture of any product candidate, including any inability to obtain materials as a result of supply chain issues related to the COVID-19 pandemic and the ongoing conflict in Ukraine;
- 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 or the timelines for these activities being longer than we anticipate;
- regulatory authorities or data monitoring committees requiring or recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety or the safety of novel therapeutics derived from pluripotent or genome edited therapies;
- the serious, life-threatening diseases of the patients enrolled in our 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 clinical trials or adhere to study protocols due to safety issues, side effects, disruptions in study conduct, including study monitoring, data collection and analysis, restrictions on hospital visits or travel relating to the COVID-19 pandemic, or other reasons; and
- approval of competitive agents that may materially alter the standard of care 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.

If there are delays in initiating or conducting any clinical trials of our product candidates or any of these clinical trials are 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 the COVID-19 pandemic, 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.

***The manufacture and distribution of our cell product candidates, particularly our 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 involve 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, in some cases 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 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 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 several challenges as we scale our manufacturing for large-scale clinical trials or commercial-scale production, 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 still optimizing 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 to make changes to our manufacturing processes, including materials 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 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 will need to meet, and our CMOs or other third party manufacturers 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 or by third-party cell processing facilities or CMOs, including facilities operated by or affiliated with our clinical sites, 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 our CMOs or other third-party manufacturers 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 our CMOs or other third-party manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities 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 our third-party manufacturers 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 variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.***

We plan to globally develop our product candidates. Accordingly, we expect that it 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 U.S. and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the FCPA 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 U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and 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.

***A disruption to our manufacturing operations, or our or our third-party suppliers' or manufacturers' inability 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 and also 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 facility to produce our product candidates and on third parties for the manufacture of certain components and the product candidates themselves, 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 for manufacturing 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 our CMOs could delay the continued development of our product candidates.

In addition to relying on third parties for the manufacture of our product candidates, we also manufacture certain of our product candidates ourselves, and intend to manufacture some or all of the clinical supply of our iPSC-derived NK-cell and T-cell product candidates for our ongoing and planned clinical trials. To do so, 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 the conduct of each of our clinical trials or commercialization of each of our product candidates, if approved. Accordingly, we will be required to make significant investments to expand our existing 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, facility shutdowns due to the ongoing COVID-19 pandemic, the ongoing conflict in Ukraine, natural disasters 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. For example, in response to governmental shelter-in-place orders resulting from the COVID-19 pandemic, we or our third-party manufacturers have been, and may from time to time be required to limit our or their on-site staff's availability to conduct manufacturing activities at our or their respective facilities, and we and our third-party manufacturers may encounter problems with shortages of qualified personnel and key contractors, and delays or pauses in the production and delivery of laboratory equipment, materials and supplies necessary for the manufacture of our product candidates. These problems may include workforce reductions, employee absenteeism and attrition, and supply chain failures or delays relating to the COVID-19 pandemic or other events affecting raw material supply or manufacturing capabilities. Since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA, and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the product candidates needed for our clinical trials, which could lead to delays in these trials. Further, delays in regulatory inspections, commissioning and receiving regulatory approvals for our manufacturing capabilities or facilities, including new facilities, as a result of limited governmental resources due to the COVID-19 pandemic or otherwise, 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, and we may fail to locate suitable additional or replacement manufacturing capacity, including for the manufacture of our product candidates in compliance with cGMP or cGTP, on a reasonable basis or at all. Any such failure could be the basis for the FDA 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 applicable standards or specifications 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 need to 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.

***We are subject to risks associated with the ongoing spread of the coronavirus, SARS-CoV-2, and the global COVID-19 pandemic could seriously impact the research and development of our product candidates.***

The ongoing COVID-19 pandemic has broadly affected the global economy, resulted in significant travel and work restrictions in many regions and put a significant strain on healthcare resources. The pandemic has had, and we expect it will continue to have, an impact on our operations and on the operations of our collaborators, third-party contractors and other entities, including governmental agencies with which we interact. In particular, state and local regulations requiring during certain periods that a significant portion of our employees work remotely has had an impact on our operations and research and development of our product candidates. We have also experienced delays in obtaining materials and supplies needed to maintain our operations and manufacture our product candidates as a result of production shortages experienced by our suppliers. Additionally, at times we have been subject to temporary pauses in enrollment and dosing implemented by some clinical trial sites due to COVID-19, and some clinical trial sites have also restricted initiation of new trials at times as well as visits by sponsors and clinical research organizations (CROs) for ongoing trials to protect both site staff and patients from possible COVID-19 exposure.

The COVID-19 pandemic, including the emergence of new variants, has impacted, and may in the future impact, the clinical development of our product candidates if we are subject to restrictions or limitations on, or delays in, the performance of study procedures (particularly any procedures that may be deemed non-essential), participant dosing, distribution of our product candidates or clinical trial materials, study monitoring, or site inspections and data analysis, including as a result of changes in hospital or research institution policies, federal, state or local regulations, prioritization of hospital and other medical resources toward pandemic efforts, reduced availability of site staff supporting the conduct of clinical trials, heightened risks of exposure of study participants, principal investigators or site staff to COVID-19 if an outbreak occurs in their geographic region, or other reasons related to the pandemic. Quarantine or other travel limitations (whether voluntary or required) also may impede participant movement, affect access to study sites, or interrupt healthcare services.

Furthermore, the pandemic could cause delays in review and response times by the FDA and other regulatory agencies, or such health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we implement in response to the COVID-19 pandemic and current regulatory guidance. In addition, our ability to manufacture and ship our product candidates for our clinical trials may be impacted if we, or any third parties which manufacture and supply materials used in either the manufacture of our product candidates or the conduct of our research and development activities, or which perform certain testing relating to our product candidates, are adversely impacted by restrictions resulting from the coronavirus outbreak. There is also the potential that manufacturing facilities, equipment, and materials required for manufacture or administration of our product candidates could be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials, equipment, or manufacturing slots necessary for the clinical supply of our product candidates.

The extent to which the pandemic affects our operations and the research and development of our product candidates will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, including the emergence of new variants of the virus, such as the Delta and Omicron BA.1 and BA.2 variants, which may impact rates of infection and vaccination efforts, developments or perceptions regarding the safety of vaccines, future waves of infection, and the effectiveness of actions taken to contain the pandemic or mitigate its impact, including vaccination campaigns. While the ultimate impact of the COVID-19 pandemic on our business is highly uncertain, any negative impacts that materialize could materially adversely affect our clinical development and operations, financial performance and stock price.

***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. 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*. Moreover, our genome editing approach may cause unintended changes to the DNA such as a non-target site gene editing, a large deletion or a DNA translocation, any of which could lead to oncogenesis or other adverse effects. 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.

***If we encounter difficulties enrolling patients in our clinical trials, 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.

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:

- the ability to identify, solicit and recruit a sufficient number of patients;
- severity of the disease under investigation;
- design of the trial protocol;
- the relatively small size and nature of the patient populations for certain of our clinical trials;
- eligibility criteria for the trials in question;
- perceived risks and benefits of the product candidate under study, including any perceived risks associated with 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;
- 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 the COVID-19 pandemic;
- the availability of cells suitable for the manufacture of our clinical product candidates from eligible and qualified donors for certain of our product candidates;
- the ability to monitor patients adequately during and after treatment, including through remote monitoring if required as a result of precautionary changes implemented at certain clinical trial sites as a result of the COVID-19 pandemic; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition, certain of our clinical trial sites at times have delayed or paused patient enrollment in clinical trials as a result of the COVID-19 pandemic, and quarantines or other travel limitations relating to the COVID-19 pandemic may impede patient movement and affect access to study sites, which may further impact patient enrollment in our clinical trials. The extent and duration of such delays and disruptions, and the overall impact on the timing and conduct of our clinical trials, are uncertain. 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. 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 with cancer, 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. 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.

***We study our product candidates in patient populations with significant comorbidities 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 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. 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.***

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. To date, there are relatively few approved cell therapies, and 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 cell therapy products 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, within the FDA, the Center for Biologics Evaluation and Research, or CBER, restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time 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, such as ours. 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. 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 clinical trials of our product candidates performed to date were generated from open-label studies and 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 reported positive interim clinical data from our FT516 and FT596 programs for patients with relapsed / refractory B-cell lymphoma, 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 current 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. 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 regenerative medicine advanced therapy, or RMAT, designation for the treatment of relapsed/refractory diffuse large B-cell lymphoma, and we may in the future seek RMAT designation for some of our other 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 regenerative medicine advanced therapy, or RMAT, designation from the FDA for FT516 for the treatment of relapsed/refractory diffuse large B-cell lymphoma. 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 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. In addition, even if one or more of our product candidates qualifies for RMAT designation, the FDA may later decide that the product candidate no longer meet 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 timeframes. 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 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.

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. 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.

### **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.***

We currently rely, and expect to continue to rely, on third parties to manufacture our product candidates, or certain components required for the manufacture of our product candidates, for use in conducting 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, such as our collaboration arrangements with Janssen and Ono, for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements 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 corporate collaboration agreements with Janssen and Ono. These corporate collaboration agreements provide for, among other things, research funding and significant future payments should certain development, regulatory and commercial milestones be achieved. Under these arrangements, our corporate collaborators are typically responsible for:

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

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

This lack of control over the research funding for, and the development and commercialization of, certain of our product candidates 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 corporate collaborators 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 be unable to meet demand requirements;
- exercises its rights under the agreement to terminate the collaboration, or otherwise withdraws support for, or otherwise impairs development under the collaboration;
- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments 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 Janssen Agreement or 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 manufacture of our product candidates and do not have supply arrangements for certain of these components.***

Manufacturing 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. As a result of the ongoing COVID-19 pandemic, the business and operations of our suppliers 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 from any of these suppliers, which could be due to the impacts of the COVID-19 pandemic, the ongoing conflict in Ukraine, 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 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.

### **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.

***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 and Restated Exclusive License Agreement dated May 15, 2018 (the Amended MSK License) with Memorial Sloan Kettering Cancer Center (MSK), in the event a licensed product achieves a specified clinical milestone, MSK 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 MSK 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 may be 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.***

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company 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 be required 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 would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in any such proceeding. Such litigation or 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. There is also the risk that, even if the validity of such patents is upheld, the court will 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 were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our 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 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 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 are 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 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 may need to 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, 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 is 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.

***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. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. 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 emergence, and timing of market introduction, of competitive products;
- the effectiveness of our marketing strategy;
- 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.

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, 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.

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.

Additionally, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

***If the market opportunities for our product candidates are 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 are small, 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, including cancer. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect, and 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 may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Additionally, because our target patient populations are small, we will be required to capture a significant market share to achieve and maintain profitability.

***We may be subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.***

Although we do not currently have any products on the market, if we obtain FDA approval for any of our product candidates and begins commercializing our products, we may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians, third-party payors, and others play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our product candidates, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute (“AKS”) prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal AKS or specific intent to violate it to have committed a violation. The AKS has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other;
- the federal False Claims Act imposes criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. When an entity is determined to have violated the False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, healthcare clearing houses, and certain healthcare providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal transparency requirements, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act (the “ACA”) require manufacturers of drugs, devices, biologics, and medical supplies that are

reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians ( as defined by the law), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and teaching hospitals, as well as physician ownership and investment interests, and requires applicable manufacturers and group purchasing organizations to report annually the ownership and investment interests held by such physicians and their immediate family members and payments or other “transfers of value” to such physician owners; Such information is subsequently made publicly available in a searchable format on a CMS website, effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician assistants and nurse practitioners; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. 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, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

***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. In particular, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government’s comparative effectiveness research.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining

access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical and biologics pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in various congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

On July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede generic drug and biosimilar competition.

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 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 each state that does not choose to expand its Medicaid program, there likely will be fewer insured patients overall, which could impact the sales, business and financial condition of manufacturers of branded prescription drugs. Where patients receive insurance coverage under any of the new options made available through the ACA, the possibility exists that manufacturers may be required to pay Medicaid rebates on that resulting drug utilization, a decision that could impact manufacturer revenues. The U.S. federal government also has announced delays in the implementation of key provisions of the ACA. The implications of these delays for our and our partners' business and financial condition, if any, are not yet clear.

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.

### **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, some 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 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 and genome edited therapeutics. 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. There can be no assurance that any product candidates developed from or related to our iPSC 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 will negatively affect our ability to develop and commercialize our product candidates.

***We face intense competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.***

The biotechnology and pharmaceutical industries, and the immune-oncology industry specifically, are intensely competitive and characterized by rapid and significant innovation. We face competition from biotechnology and pharmaceutical companies, universities, and other research institutions, and many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations and facilities. In particular, there are several companies and institutions developing products that may be competitive to our iPSC-derived product candidates or candidates in our research and development pipeline, or may render our product candidates obsolete or noncompetitive. Should one or more of these products be successful, the market for our products may be reduced or eliminated, and we may not achieve commercial success. For additional information regarding our competition, see “Item 1. Business—Competition” in our Annual Report.

***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 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. The loss of any members of our senior management team could adversely impact our operations if we experience difficulties in recruiting and hiring qualified successors. 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. 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.

***We expect to continue to expand our development and manufacturing operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We are experiencing rapid growth and as of March 31, 2022, we had 511 employees. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our clinical and research operations, and to expand our regulatory, quality, and manufacturing operations. This expected growth may place a strain on our administrative and operational infrastructure, and managing this growth may impose significant added responsibilities on members of management and divert a substantial amount of attention from day-to-day activities.

To manage our anticipated future growth, we will continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any inability to manage our expected growth and the expansion of our operations may result in loss of business opportunities, loss of employees and reduced productivity among remaining employees, weaknesses in our infrastructure, and operational mistakes, including in the operation and qualification of our GMP manufacturing operations and facility, and could delay the execution of our business plans or disrupt our operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***The global COVID-19 pandemic could adversely impact various aspects of our business, results of operations and financial condition.***

The COVID-19 pandemic has dramatically impacted the global health and economic environment, including millions of confirmed cases and deaths, business slowdowns or shutdowns, labor shortages, supply chain challenges, changes in government requirements, regulatory challenges, inflationary pressures and market volatility. Although we have, to date, managed to continue most of our operations, we cannot predict the future course of events nor can we assure that this global pandemic, including its economic impact, will not have a material adverse impact on our business, results of operations and financial condition.

As a result of the ongoing COVID-19 pandemic, various aspects of our business operations have been, and could continue to be, disrupted. The pandemic likely will continue to impact our workforce, including impacts on staffing levels (as a result of illnesses, quarantine, isolation and absenteeism), adjusted work locations and schedules and access to our facilities. The pandemic may require us to continue to take extraordinary measures to protect the health and well-being of our employees. For example, since the start of the pandemic we have implemented a range of health and safety measures, which have included, at various times, imposing onsite occupancy limits, restricting on-site staff to only those required to execute certain laboratory, manufacturing and related support activities, and requiring self-health testing prior to coming onsite.

The increase in working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, and clinical trial sites. If our on-site staff conducting research and development, preclinical studies, and manufacturing activities are not able to access our laboratories or manufacturing space, whether due to quarantine/isolation orders, travel restrictions or other government restrictions, these core activities may be significantly limited or curtailed, possibly for an extended period of time, which could impair our ability to complete IND-enabling studies or select future development candidates. Our business operations may be further disrupted if our manufacturing facility becomes subject to a viral contamination requiring a suspension of manufacturing activities, or if any of our employees, officers or directors, or their respective personal or business contacts, contract an illness related to COVID-19, including new variants of the virus, that renders them unable to perform their duties as a result.

The macroeconomic impacts of the pandemic, including a tightened labor market and evolving government requirements, including those related to vaccinations, will also likely continue to affect our company. They may further affect our ability to hire, develop and retain our talented and diverse workforce, to maintain performance levels, and to maintain our corporate culture. We expect to continue to incur additional costs as a result of the COVID-19 pandemic, including to protect the health and well-being of our employees and to respond to government requirements, which costs we may not be fully able to recover.

The pandemic has impacted and may continue to impact our supply chains. If our suppliers have increased challenges with their workforce (including as a result of illness, absenteeism, reactions to health and safety or government requirements), facility closures, timely access to necessary components, materials and other supplies at reasonable prices, access to capital, and access to fundamental support services (such as shipping and transportation), they may be unable to provide the agreed-upon goods and services in a timely, compliant and cost-effective manner. We have incurred and may in the future incur additional costs and delays in our business, including as a result of higher prices, schedule delays or the need to identify and develop alternative suppliers.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through equity or debt financings, or such financing transactions may be on unfavorable terms. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruptions and uncertainties in global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19, including new variants of the virus or spikes or surges in infection and hospitalization rates, could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. For example, the emergence of the Delta and Omicron variants in 2021, and the emergence of the BA.2 subvariant in 2022, significantly impacted rates of infection and prompted public health officials to reconsider certain health and safety measures that had been adopted

to date, including vaccination requirements, guidance around quarantine and isolation periods, and mask wearing. We do not yet know the full extent of potential delays or impacts on our business, our clinical and preclinical programs, our research, manufacturing, and regulatory activities, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our operations, and we will continue to monitor the situation closely.

***The global economic conditions created by the conflict between Russia and Ukraine could adversely affect our business, financial condition, stock price and results of operations.***

In February 2022, Russia commenced a military invasion of Ukraine, and sustained conflict and disruption in the region is likely. Although the conflict has had little direct impact on our business to date, the uncertainty and ripple effects created by this conflict may have unknown indirect impacts. As a result of the invasion, the U.S. and certain other countries have imposed sanctions on Russia and could impose further sanctions that could damage or disrupt international commerce and the global economy. It is not possible to predict the broader or longer-term consequences of this conflict, or the sanctions imposed to date, which could include further sanctions, embargoes, regional instability, retaliatory cyber-attacks, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. The potential effects of the conflict include but are not limited to changes in laws and regulations affecting our business, fluctuations in foreign currency markets, potential supply chain disruptions, and increased market volatility and uncertainty that could have an adverse impact on macroeconomic factors that affect our business and operations.

***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, cyber, 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. Further, insurance coverage may not be available or successfully secured for loss profits or business interruption relating to the COVID-19 pandemic and its impacts. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

***Our employees 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 fraud or other misconduct. Misconduct by employees 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 and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and 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 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 (CCPA) and its related regulations, and (once effective) the California Privacy Rights Act (CPRA) amending the CCPA, which establish additional 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 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 been proposed in other states and at the federal level, and if passed, such laws 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.

Certain state laws may be more stringent or broader in scope than the CPRA, 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.

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 where private rights of action are available 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 customers to reduce their use of our products and services 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, services 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 sensitive 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. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. 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. 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.

***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 future CROs and other contractors, vendors, and consultants may be vulnerable to damage from cyber risks, including attempts to gain unauthorized access to

and to harm sensitive information and networks, insider threats, and ransomware. These vulnerabilities may be heightened as a result of remote work policies implemented by us and our third-party contractors in response to the COVID-19 pandemic.

We have from time to time experienced, and may continue to experience in the future, cyber-attacks on our information technology systems despite our best efforts to prevent them. Although such breaches have been immaterial to our business to date, investigations into and remedial efforts in connection with any breaches, even those with immaterial impact, can be costly and time-consuming, and any future breaches could be material, or cause significant disruption, to our business. 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 cyber 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 disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Cyber threats, both on premises and in the cloud, are evolving and include, but are not limited to: malicious software, destructive malware, ransomware, attempts to gain unauthorized access to systems or data, disruption to operations, critical systems or denial of service attacks; unauthorized release of confidential, personal or otherwise protected information; corruption of data, networks or systems; harm to individuals; and loss of assets. In addition, we could be impacted by cyber threats or other disruptions or vulnerabilities found in products or services we use that are provided to us by third-parties. 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 insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. 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.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. 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. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

## Risks Related to Our Financial Condition and the Ownership of Our Common Stock

***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, our product candidates.***

We are currently advancing multiple product candidates through clinical development, and conducting preclinical research and development activities in our other programs. Drug development is expensive, and we expect our research and development expenses to increase substantially 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 March 31, 2022, our cash and cash equivalents and investments were \$641.7 million. We intend to use our cash and cash equivalents and 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 MSK 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 Janssen Biotech, Inc., Ono Pharmaceutical Co., Ltd., the University of Minnesota, and MSK, 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 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 impact of the COVID-19 pandemic and the ongoing conflict in Ukraine on the global economy is currently unknown and difficult to predict, the pandemic has caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of the pandemic 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 March 31, 2022, we had an accumulated deficit of \$834.8 million. 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.

***Our stock price is subject to fluctuation based on a variety of factors.***

The market price of shares of our common stock could be subject to wide fluctuations 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;
- 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;
- 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 conflicts in Ukraine; and
- general economic and market conditions.

These and other market and industry factors, including the effects of the COVID-19 pandemic and the ongoing conflict in Ukraine on the global economy, 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 our license agreement with MSK, MSK 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 MSK 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 our license agreement with MSK and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. Accordingly, MSK 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.

***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 April 28, 2022, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 42.4% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 9 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 9 of the notes to the consolidated financial statements herewith) elects to remove certain limitations on the percentage of the our outstanding common stock that it may own such that the 2,794,549 shares of Class A Convertible Preferred Stock currently held by Redmile become fully convertible at Redmile's option into 13,972,745 shares of common stock, the beneficial ownership of our executive officers, directors and entities affiliated with our five percent stockholders would increase to 49.5%. 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.***

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 2021 we filed a Form S-3 pursuant to which we may issue up to \$350.0 million in common stock in sales deemed to be an "at the market offering" as defined by the Securities Act of 1933, as amended (the Securities Act) and, so long as we qualify as a "well-known seasoned issuer" as defined in Rule 405 of the Securities Act, an unlimited amount of shares of our common stock, preferred stock, debt securities, warrants and/or units. 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 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.

***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 a stock purchase agreement entered into 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 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, employees and affiliates have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, 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.

***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.

***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.

***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, 2021, we had federal and California net operating loss carryforwards of \$289.7 million and \$291.2 million, respectively, some of which begin to expire in various amounts in 2027 and 2028, respectively. As of December 31, 2021, we also had federal and California research and development tax credit carryforwards of \$25.7 million and \$25.8 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 2021. We have not analyzed periods subsequent to December 2021. 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, 2021, 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 could be subject to securities class action litigation.***

The stock market in general, and the Nasdaq Global Market 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. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. 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.

***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, 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 (particularly as a result of the COVID-19 pandemic), underemployment or the repeal of certain provisions of the ACA may decrease the demand for healthcare services and pharmaceuticals. Additionally, the availability of healthcare services and resources is currently constrained due to the COVID-19 pandemic. 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, including as a result of the COVID-19 pandemic or the ongoing conflict in Ukraine, 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 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 the COVID-19 pandemic, the ongoing conflict in Ukraine, current economic climate and financial market conditions could adversely impact our business.

***Geopolitical risks associated with the ongoing military conflict between Russia and Ukraine could have an adverse impact on our business, financial condition and results of operations, including our clinical trials.***

In late February 2022, Russia commenced a military invasion of Ukraine, and sustained conflict and disruption in the region is likely. The uncertain nature, magnitude, and duration of hostilities stemming from the conflict in Ukraine, including the potential effects of sanctions limitations, retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations.

Sanctions imposed by the U.S., EU, and other countries in response to the conflict between Russia and Ukraine and the potential response to such sanctions may have an adverse impact our business, including our clinical trials, the financial markets and the global economy. As the conflict in Ukraine continues, there can be no certainty regarding whether such governments or other governments will impose additional sanctions, or other economic or military measures relating to Russia.

***We or the third parties upon whom we depend may be adversely affected by earthquakes, fires, or other natural disasters, including epidemics and pandemics such as COVID-19, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Earthquakes, fires, or other natural disasters could severely disrupt our operations, 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, as a result of the COVID-19 pandemic, we may experience delays or disruptions in our clinical development activities, our research and development activities, and in the supply of drug product for our clinical trials. Any continued or subsequent measures taken by governmental authorities or businesses to contain the spread of COVID-19, or the perception that such measures may be required in the future should another outbreak occur, 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 have in place currently are limited and may not prove adequate for protecting and continuing our business in the event that our business is disrupted as a result of the COVID-19 pandemic 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, when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

***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, or 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 such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act, or the TCJA, 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. Additionally, the Coronavirus Aid, Relief, and Economic Security Act, which, among other things, suspended the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. 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.

***Our business could be negatively impacted by corporate citizenship and environmental, social and corporate governance matters and/or our reporting of such matters.***

There is an increasing focus from certain investors, consumers, and other stakeholders concerning corporate citizenship and sustainability matters. We could be perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

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

- a) None.
- b) None.
- c) None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosure**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Title</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant</a>	S-1/A	333-190608	3.2	August 29, 2013
3.2	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect</a>	8-K	001-36076	3.1	June 7, 2021
3.3	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock</a>	8-K	001-36076	3.1	November 29, 2016
3.4	<a href="#">Amended and Restated Bylaws of the Registrant, as currently in effect</a>	10-K	001-36076	3.3	February 24, 2021
4.1	<a href="#">Specimen Common Stock Certificate</a>	S-1/A	333-190608	4.1	August 29, 2013
4.2	<a href="#">Form of Pre-Funded Warrant</a>	8-K	001-36076	4.1	January 8, 2021
31.1	<a href="#">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</a>	—	—	—	Filed herewith
31.2	<a href="#">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</a>	—	—	—	Filed herewith
32.1	<a href="#">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</a>	—	—	—	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

**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: May 4, 2022

By: /s/ J. SCOTT WOLCHKO  
J. Scott Wolchko  
President and Chief Executive Officer and Director  
(Principal Executive Officer)

Date: May 4, 2022

By: /s/ EDWARD J. DULAC III  
Edward J. Dulac III  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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, J. Scott Wolchko, 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: May 4, 2022

/s/ J. SCOTT WOLCHKO  
J. Scott Wolchko  
President and Chief Executive Officer  
(Principal Executive Officer)

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## 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, Edward J. Dulac III, 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: May 4, 2022

/s/ EDWARD J. DULAC III

Edward J. Dulac III

Chief Financial Officer

(Principal Financial and Accounting Officer)

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

In connection with the quarterly report of Fate Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, J. Scott Wolchko, President and Chief Executive Officer of the Company, and Edward J. Dulac III, 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: May 4, 2022

/s/ J. SCOTT WOLCHKO

J. Scott Wolchko  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 4, 2022

/s/ EDWARD J. DULAC III

Edward J. Dulac III  
Chief Financial Officer  
(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.

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