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, 2020

OR

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

From the transition period from to .

Commission File Number 001-36076

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**65-1311552**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
3535 General Atomics Court, Suite 200, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 875-1800
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock	FATE	Nasdaq Global Market

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

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

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

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

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

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

As of May 7, 2020, 77,691,848 shares of the registrant's common stock, par value $0.001 per share, were issued and outstanding.

FATE THERAPEUTICS, INC.

FORM 10-Q

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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, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 83,366	$ 99,814
Short-term investments and related maturity receivables	119,918	121,613
Prepaid expenses and other current assets	4,965	5,662
Total current assets	208,249	227,089
Long-term investments	16,139	39,440
Property and equipment, net	11,896	11,419
Operating lease right-of-use assets	69,200	22,752
Restricted cash	15,227	227
Collaboration contract asset	1,170	1,338
Other assets	9	9
Total assets	$ 321,890	$ 302,274
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,173	$ 5,822
Accrued expenses	11,770	14,697
CIRM award liability, current portion	3,160	2,808
Deferred revenue, current portion	2,923	2,787
Operating lease liabilities, current portion	1,898	1,692
Total current liabilities	24,924	27,806
Deferred revenue, net of current portion	3,124	3,775
CIRM award liability, net of current portion	790	702
Operating lease liabilities, net of current portion	73,834	25,235
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized shares—5,000,000 at March 31, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at March 31, 2020 and December 31, 2019	3	3
Common stock, $0.001 par value; authorized shares—150,000,000 at March 31, 2020 and December 31, 2019; issued and outstanding—75,996,075 at March 31, 2020 and 75,730,260 at December 31, 2019	76	76
Additional paid-in capital	636,062	628,200
Accumulated other comprehensive gain	142	22
Accumulated deficit	(417,065)	(383,545)
Total stockholders' equity	219,218	244,756
Total liabilities and stockholders' equity	$ 321,890	$ 302,274

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,	
	2020	2019
	(unaudited)	
Collaboration revenue	$ 2,515	$ 2,632
Operating expenses:		
Research and development	29,278	17,728
General and administrative	7,729	5,350
Total operating expenses	37,007	23,078
Loss from operations	(34,492)	(20,446)
Other income (expense):		
Interest income	972	1,091
Interest expense	—	(405)
Total other income, net	972	686
Net loss	$ (33,520)	$ (19,760)
Other comprehensive income (loss):		
Unrealized gain on available-for-sale securities, net	120	2
Comprehensive loss	$ (33,400)	$ (19,758)
Net loss per common share, basic and diluted	$ (0.44)	$ (0.30)
Weighted-average common shares used to compute basic and diluted net loss per share	75,886,964	64,920,621

See accompanying notes.

Fate Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2020	2019
	(unaudited)	
Operating activities		
Net loss	$ (33,520)	$ (19,760)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	705	440
Stock-based compensation	6,913	3,868
Amortization of debt discounts and debt issuance costs	—	15
Accretion and amortization of premiums and discounts on investments, net	271	(5)
Amortization of collaboration contract asset	168	107
Noncash interest expense	—	79
Deferred revenue	(515)	(2,132)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	636	792
Accounts payable and accrued expenses	(3,316)	(1,258)
Right-of-use assets and lease liabilities, net	1,985	361
Net cash used in operating activities	(26,673)	(17,493)
Investing activities		
Purchases of property and equipment	(1,070)	(1,746)
Maturities of investments	24,844	10,500
Net cash provided by investing activities	23,774	8,754
Financing activities		
Issuance of common stock from equity incentive plans, net of issuance costs	1,011	1,258
Proceeds from CIRM award	440	—
Net cash provided by financing activities	1,451	1,258
Net change in cash, cash equivalents and restricted cash	(1,448)	(7,481)
Cash, cash equivalents and restricted cash at beginning of the period	100,041	190,741
Cash, cash equivalents and restricted cash at end of the period	$ 98,593	$ 183,260
Supplemental disclosure of cash flow information		
Interest paid	$ —	$ 309
Supplemental schedule of noncash investing and financing activities		
Purchases of property and equipment in accounts payable	$ 343	$ 1,482
Right-of use assets obtained in exchange for lease obligations	$ 47,808	$ 7,705

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization

Fate Therapeutics, Inc. (the Company) was incorporated in the state of Delaware on April 27, 2007 and has its principal operations in San Diego, California. The Company is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's therapeutic pipeline is comprised of immuno-oncology programs, including off-the-shelf engineered natural killer (NK) and T-cell product candidates derived from clonal master induced pluripotent stem cell (iPSC) lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation. The Company's product candidates are based on its proprietary cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells.

As of March 31, 2020, 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 Offering

In September 2019, the Company completed a public offering of common stock in which investors, certain of which are affiliated with the directors of the Company, purchased 9,890,000 shares of its common stock at a price of $17.50 per share under a shelf registration statement. Gross proceeds from the offering were $173.1 million, and, after giving effect to $10.7 million of costs related to the offering, net proceeds were $162.4 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 contracts containing leases, accrued expenses 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 novel strain of coronavirus that causes Coronavirus disease 19 (COVID-19), the Company experienced impacts on certain aspects of its business, including its clinical trial and research and development activities, during the three months ended March 31, 2020. For example, certain of the Company's research and development activities have been delayed or disrupted as a result of measures the Company implemented in response to governmental "stay at home" orders and in the interests of public health and safety, and the Company has experienced delays or disruptions in the initiation and conduct of its clinical trials as a result of 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 COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on the Company's operations, are currently unknown. 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 COVID-19 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, 2020 (in thousands):

	Three Months Ended March 31,	
	2020	2019
Cash and cash equivalents	$ 83,366	$ 183,033
Restricted cash	15,227	227
Total cash, cash equivalents, and restricted cash shown in the unaudited condensed consolidated statement of cash flows	$ 98,593	$ 183,260

During the three months ended March 31, 2020, the Company entered into a lease for a facility in San Diego that it intends to use as its new corporate headquarters. In lieu of a security deposit, Silicon Valley Bank issued a $15.0 million letter of credit on the Company's behalf, which letter of credit is secured by a deposit of equal amount. For the three months ended March 31, 2020 and 2019, the restricted cash balance includes cash-collateralized irrevocable standby letters of credit in the amounts of $15.2 million and $0.2 million, respectively, 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 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, 2019, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed by the Company with the SEC on March 2, 2020. 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, 2020 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.

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 a ROU asset and lease obligation 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. For stock option grants for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants 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 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. 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 plan. 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, 2020, the Company realized a net loss of $33.5 million. Shares of potentially dilutive securities totaled 25.9 million for the three months ended March 31, 2020, 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 11.9 million shares of common stock issuable upon the exercise of outstanding stock options and the settlement of outstanding restricted stock units.

For the three months ended March 31, 2019, the Company realized a net loss of $19.8 million. Shares of potentially dilutive securities totaled 23.9 million for the three months ended March 31, 2019, including 14.1 million shares associated with a hypothetical conversion of all outstanding shares of the Company's Class A convertible preferred stock, and an aggregate of 9.7 million shares of common stock issuable upon the exercise of outstanding stock options and the settlement 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.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2019-12, *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Accounting Standards Codification (ASC) Topic 740 and amends existing guidance to improve consistent application. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020 and early adoption is permitted. The only exception addressed in ASU 2019-12 applicable to the Company is the elimination of the intra-period exception to allocating income taxes when there are losses from continuing operations. The guidance is to be applied prospectively at the beginning in the year of adoption. The Company elected to early adopt the standard as of January 1, 2020 using the prospective method, and such adoption did not have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, which clarifies the interaction between ASC Topic 808, *Collaborative Arrangements*, and ASC Topic 606, *Revenue from Contracts with Customers*. The guidance, among other items, clarifies that certain transactions between collaborative participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020, and such adoption did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which amends the disclosure requirements in ASC 820 by adding, changing, or removing certain disclosures. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020, and such adoption did not have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The standard is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted the standard effective January 1, 2020 using the modified retrospective approach. Due to the nature of the Company's investment portfolio, the adoption of the guidance did not have a material effect on the Company's unaudited condensed consolidated financial statements and no allowance was recorded for expected credit losses.

2. Collaboration and License Agreements

Ono Collaboration and Option Agreement

On September 14, 2018, the Company entered into a Collaboration and Option Agreement (the Ono Agreement) with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of two off-the-shelf iPSC-derived 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).

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 each Candidate 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 (a) Candidate 1 in Asia, with the Company retaining rights for development and commercialization in all other territories of the world and (b) 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 (each, an Option).

For each Candidate, 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 the Candidate and (c) the date that is the later of (i) four years after the 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 both Candidates.

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. As of March 31, 2020, the Company received $8.5 million in aggregate research and development fees from Ono.

Further, under the terms of the Ono Agreement, Ono has agreed to pay the Company up to an additional $40.0 million, subject to the achievement of a preclinical milestone (Option Milestone) and the exercise by Ono of the Options (Option Exercise Fees) during the Option Period. Such fees are in addition to the upfront payment and research and development fees.

Subject to Ono's exercise of the Options and to the achievement of certain clinical, regulatory and commercial milestones (Milestones) with respect to each Candidate in specified territories, the Company is entitled to receive an aggregate of up to $285.0 million in milestone payments for Candidate 1 and an aggregate of up to $895.0 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 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 of each Candidate in specified territories, with such royalties subject to certain reductions.

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, *Collaborative Arrangements* and determined that the Ono Agreement is applicable to such guidance. The Company concluded that Ono represented a customer and applied relevant guidance from ASC 606, *Revenue from Contracts with Customers* (ASC 606) to evaluate the appropriate accounting for the Ono 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. As a result, the license is classified as symbolic intellectual property under ASC 606. 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 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, whether a significant financing component exists under the Ono Agreement. Such assessment evaluated whether: (i) a substantial amount of the consideration is variable, (ii) the amount, or timing of payment, of the consideration would have varied based on the occurrence or non-occurrence of future events that are not substantially within the control of the Company or Ono, and (iii) the timing of the transfer of the performance obligations is at the discretion of Ono. Based on its assessment, the Company concluded that there was not a significant financing component.

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.

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 over the estimated four-year period based on actual costs incurred compared to the estimated total costs expected to be incurred under the Ono Agreement, as the research and development activities are the primary component of the combined performance obligation. 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.

The Company has not assigned a transaction price to any Option Milestone, Milestones or Option Exercise Fees given the substantial uncertainty related to their achievement and has not assigned a transaction price to any Royalties.

As a direct result of the Company's entry into the Ono Agreement, the Company incurred an aggregate of $2.0 million in sublicense consideration to existing licensors of the Company. The $2.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* and is amortized to research and development expense in conjunction with the Company's revenue recognition under the Ono Agreement. During the three months ended March 31, 2020 and 2019, the Company recognized $0.2 million and $0.1 million of such expense, respectively. As of March 31, 2020, the Ono Agreement contract asset balance was $1.2 million.

The Company recognized revenue of $2.5 million under the Ono Agreement for the three months ended March 31, 2020. Such revenue comprised $1.7 million associated with research services and $0.8 million associated with the upfront payment for the three months ended March 31, 2020. During the three months ended March 31, 2019, the Company recognized revenue of $1.6 million under the Ono Agreement. Such revenue comprised $1.1 million associated with research services and $0.5 million associated with the upfront payment. As of March 31, 2020, aggregate deferred revenue related to the Ono Agreement was $6.0 million, of which $2.9 million is classified as current.

Juno Collaboration and License Agreement

On May 4, 2015, the Company entered into a strategic research collaboration and license agreement (the Juno Agreement) with Juno Therapeutics, Inc. (Juno) to screen for and identify small molecules that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. The four-year initial research term under the Juno Agreement concluded as scheduled on May 4, 2019, and the overall agreement was terminated upon the receipt of the last quarterly research payment of $0.2 million, which occurred in May 2019. No additional funding is expected from Juno.

The Company applied ASC 606 to evaluate the appropriate accounting for the Juno Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of an exclusive worldwide license to certain of its intellectual property subject to certain conditions, its conduct of research services and its participation in a joint research committee.

No revenue was recognized under the Juno Agreement during the three months ended March 31, 2020. Total revenue recognized under the Juno Agreement during the three months ended March 31, 2019 was $1.0 million. Such revenue comprised $0.5 million associated with the upfront fee and equity premium, and $0.5 million associated with research services. No additional revenue is expected to be recognized under the Juno Agreement in future periods.

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. In December 2018, the Company discussed with CIRM its intent to pursue the clinical development of FT516 in relapsed / refractory hematologic malignancies in addition to advanced solid tumors, and the Company's preference to first submit an Investigational New Drug (IND) application for FT516 in relapsed / refractory hematologic malignancies rather than in advanced solid tumors. In January 2019, the Company submitted its IND application for FT516 in relapsed / refractory hematologic malignancies, which IND submission was allowed by the FDA in February 2019. The Company and CIRM agreed to suspend the Award until such time as the Company elected to proceed with its submission of an IND application for FT516 in advanced solid tumors. In November 2019, the Company filed an IND application for FT516 in advanced solid tumors and the Award was removed from suspension by CIRM in January 2020. In February 2020, the Company received a $0.4 million disbursement based on a milestone achievement.

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, 2020, 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 and corporate debt securities with maturities ranging from three to eighteen 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, 2020 and December 31, 2019 (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
March 31, 2020					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	$ 41,769	$ —	$ 330	$ 42,099
Corporate debt securities	1 or less	77,981	(162)	—	77,819
Total short-term investments		$ 119,750	$ (162)	$ 330	$ 119,918
Classified as non-current assets:					
Corporate debt securities	Greater than 1	16,165	(26)	—	16,139
Total long-term investments		$ 16,165	$ (26)	$ 0	$ 16,139
December 31, 2019					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	$ 50,445	$ (4)	$ 16	$ 50,457
Corporate debt securities	1 or less	71,171	(24)	9	71,156
Total short-term investments		$ 121,616	$ (28)	$ 25	$ 121,613
Classified as non-current assets:					
U.S. Treasury debt securities	Greater than 1	$ 9,841	$ —	$ 5	$ 9,846
Corporate debt securities	Greater than 1	29,572	(1)	23	29,594
Total long-term investments		$ 39,413	$ (1)	$ 28	$ 39,440

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, 2020 and 2019, 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 carrying amounts of accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates available to the Company for loans with similar terms, which is considered a Level 2 input as described below, the Company believes that the fair value of long-term debt approximated its carrying value during the periods the debt was outstanding.

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.

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and investments. Cash equivalents consisted of money market funds and investments consisted of United States treasuries and corporate debt securities. The following table presents the Company's assets which were measured at fair value on a recurring basis as of March 31, 2020 and December 31, 2019 (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of March 31, 2020:				
Cash equivalents				
Money market funds	$ 83,366	$ 83,366	$ —	$ —
Investments				
U.S. Treasury debt securities	42,099	42,099	—	—
Corporate debt securities	93,958	—	93,958	
Total assets measured at fair value on a recurring basis	$ 219,423	$ 125,465	$ 93,958	$ —
As of December 31, 2019				
Cash equivalents				
Money market funds	$ 84,814	$ 84,814	$ —	$ —
Investments				
U.S. Treasury debt securities	60,303	60,303	—	—
Corporate debt securities	100,750	—	100,750	—
Total assets measured at fair value on a recurring basis	$ 245,867	$ 145,117	$ 100,750	$ —

The Company obtains pricing information from quoted market prices from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers.

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.

As of March 31, 2020, and December 31, 2019, the Company had no material financial liabilities measured at fair value on a recurring basis.

6. Accrued Expenses and Long-Term Debt

Accrued Expenses

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

	March 31, 2020	December 31, 2019
Accrued payroll and other employee benefits	$ 3,059	$ 5,329
Accrued clinical trial related costs	5,473	5,976
Accrued other	3,238	3,392
Total current accrued expenses	$ 11,770	$ 14,697

Long-Term Debt

Silicon Valley Bank Debt Facilities

On July 30, 2014, the Company entered into the Amended and Restated Loan and Security Agreement (the Restated LSA) with Silicon Valley Bank (the Bank), collateralized by substantially all of the Company's assets, excluding certain intellectual property. The Restated LSA amends and restates the Loan and Security Agreement, dated as of January 5, 2009, as amended, by and between the Company and the Bank (Loan Agreement). On July 14, 2017 (the First Amendment Effective Date), the Company and the Bank entered into the First Amendment (the SVB Loan Amendment) to the Restated LSA between the Company and the Bank dated July 30, 2014. Pursuant to the SVB Loan Amendment, the Bank extended an additional term loan to the Company on July 14, 2017 in the principal amount of $15.0 million (the 2017 Term Loan), a portion of which was applied to repay in full the Company's existing outstanding debt with the Bank under the Restated LSA, which included outstanding principal, accrued interest, and final payment fees. On November 13, 2019, the Company repaid in full all outstanding obligations under the 2017 Term Loan. The Company used cash on hand in the amount of $14.2 million for the repayment of such obligations associated with the 2017 Term Loan, including the repayment of $13.0 million in principal and $1.2 million associated with the final fee and outstanding interest. The Company expensed the remaining debt issuance cost capitalized of $0.1 million to interest expense upon the repayment of the 2017 Term Loan.

For the three months ended March 31, 2019, the Company recorded $0.4 million in aggregate interest expense related to the 2017 Term Loan.

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

In January 2020, the Company entered into a lease agreement (the Premises), and such lease is accounted for as an operating lease. The Premises is located in San Diego, California and the Company intends to move its corporate headquarters to the Premises in the middle of 2021. Lease payments shall commence, subject to certain conditions, in May 2021 (the Rent Commencement Date) and the lease has a lease term of 15 years starting from the Rent Commencement Date. The Company has the option to extend the lease for two successive five-year periods. The Company also has a one-time option to terminate the lease after 10 years from the Rent Commencement Date, subject to payment of a $30.0 million early termination fee. The landlord of the Premises is obligated to contribute an aggregate of up to $29.8 million toward tenant improvements of the Premises. As of March 31, 2020, the Company had utilized $0.5 million associated with the tenant improvements allowance and expects the remainder of the tenant improvements to be utilized within the next twelve months. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in an amount equal to $15.0 million, which amount is subject to reduction over time.

As of March 31, 2020, future undiscounted minimum contractual payments under the Company's operating leases were $195.7 million, which will be paid over a remaining weighted-average lease term of 13.5 years. The weighted-average discount rate for the operating lease liabilities was 8.4%, which was the Company's incremental borrowing rate at lease commencement, as the discount rates implicit in the leases could not be readily determined.

For the three months ended March 31, 2020, total operating lease expense was $3.5 million, which consisted of $2.9 million associated with the straight-line recognition of fixed payments, and $0.6 million associated with variable costs associated with the leases. For the three months ended March 31, 2019, total operating lease expense was $1.5 million, which consisted of $0.9 million associated with the straight-line recognition of fixed payments, and $0.6 million associated with variable costs associated with the leases.

Total short-term lease expense associated with short-term leases for the three months ended March 31, 2020 was $0.6 million. The Company did not recognize any short-term lease expense during the three months ended March 31, 2019.

Future minimum lease payments under the Company's operating leases as of March 31, 2020 are as follows (in thousands):

	Operating Lease Payments
Remaining in 2020	$ 2,938
2021	9,541
2022	12,610
2023	12,988
2024	13,378
2025	13,779
Thereafter	130,447
Total undiscounted lease payments	$ 195,681
Less: imputed interest	(90,678)
Less: amounts associated with tenant improvement allowance not yet utilized	(29,271)
Total lease liability	$ 75,732

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.

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, 2019	9,327,742	$ 9.67
Granted	1,460,708	22.44
Exercised	(188,315)	5.11
Cancelled	(110,986)	14.16
Balance at March 31, 2020	10,489,149	$ 11.48

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, 2019	520,000	$ 16.41
Granted	979,323	21.95
Vested	(77,500)	16.34
Cancelled	(18,573)	21.94
Balance at March 31, 2020	1,403,250	$ 20.21

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

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 4,253	$ 2,183
General and administrative	2,660	1,685
Total	$ 6,913	$ 3,868

As of March 31, 2020, the unrecognized compensation cost related to outstanding options was $54.5 million and is expected to be recognized as expense over a weighted-average period of approximately 3.1 years.

As of March 31, 2020, the unrecognized compensation cost related to restricted stock units was $25.5 million which is expected to be recognized as expense over a weighted-average period of approximately 3.5 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,	
	2020	2019
Risk-free interest rate	1.6%	2.6%
Expected volatility	77.0%	79.3%
Expected term (in years)	5.6	6.1
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, 2020 (in thousands, except share data):

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Gain	Deficit	Equity
Balance at December 31, 2019	2,794,549	$ 3	75,730,260	$ 76	$ 628,200	$ 22	$ (383,545)	$ 244,756
Exercise of stock options, net of issuance costs	—	—	188,315	—	949	—	—	949
Issuance of common stock upon vesting of restricted stock units	—	—	77,500	—	—	—	—	—
Stock-based compensation	—	—	—	—	6,913	—	—	6,913
Unrealized gain on investments	—	—	—	—	—	120	—	120
Net loss	—	—	—	—	—	—	(33,520)	(33,520)
Balance at March 31, 2020	2,794,549	$ 3	75,996,075	$ 76	$ 636,062	$ 142	$ (417,065)	$ 219,218

The following table summarizes the Company's changes in stockholders' equity accounts for the three months ended March 31, 2019 (in thousands, except share data):

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
Balance at December 31, 2018	2,819,549	$ 3	64,693,681	$ 65	$ 445,799	$ (2)	$ (285,396)	$ 160,469
Exercise of stock options, net of issuance costs	—	—	420,920	—	1,258	—	—	1,258
Issuance of common stock upon cashless warrant exercise	—	—	1,245	—	—	—	—	—
Stock-based compensation	—	—	—	—	3,868	—	—	3,868
Unrealized gain on investments	—	—	—	—	—	2	—	2
Net loss	—	—	—	—	—	—	(19,760)	(19,760)
Balance at March 31, 2019	2,819,549	$ 3	65,115,846	$ 65	$ 450,925	$ —	$ (305,156)	$ 145,837

9. Subsequent Events

On April 2, 2020 (the 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 Effective Date, the Company entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation – JJDC, Inc. (JJDC).

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 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 agreed to sell 1,612,904 shares of common stock (the Shares) to JJDC at $31.00 per share, for an aggregate purchase price of approximately $50.0 million, on April 7, 2020 (the SPA Closing). The Company has agreed to register the shares issued to JJDC under the Stock Purchase Agreement pursuant to a registration statement on Form S-3 within eighteen months of the Effective Date and to grant JJDC certain piggyback registration rights in the event there is not an effective registration statement covering the resale of such shares thereafter.

Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, the Company received: (i) $100.0 million, of which $50.0 million is an upfront cash payment and $50.0 million is in the form of the equity investment by JJDC at the SPA Closing; (ii) full funding for all research, preclinical development and IND-enabling activities performed by the Company for Collaboration Candidates; (iii) 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 Milestone Payments) for the first Collaboration Candidate, and up to $460.0 million in Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (iv) with respect to each of the second, third and fourth Janssen Cancer Targets, up to $706.0 million in Milestone Payments for each of the first Collaboration Candidates, and up to $340.0 million in Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Milestone Payments under (iii) and (iv) 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 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.

As a direct result of the Company’s entry into the Janssen Agreement, it incurred $12.9 million in sublicense fees to certain of its existing licensors.

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, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2020.

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 cancer and immune disorders. 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. For certain of our product candidates, we use pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of healthy donor-sourced cells ex vivo before our product candidates are administered to a patient. In other cases, we use human induced pluripotent stem cells (iPSCs) to generate a clonal master iPSC line having preferred biological properties and 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, including natural killer (NK) cells, T cells and $CD34^+$ cells, and are advancing a pipeline of programmed cellular immunotherapies.

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 (Memorial Sloan Kettering) to develop off-the-shelf, engineered T-cell cancer immunotherapies derived from clonal master iPSC lines.

We have entered into a collaboration and option 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 (Ono Agreement).

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). Under the Janssen Agreement, Janssen and us will collaborate to develop 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;
- conduct GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;

- 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, Ono, University of Minnesota and Memorial Sloan Kettering;
- 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 design and build of laboratory space and 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; and
- hire general and administrative personnel to continue operating as a public company and support our operations.

We do not expect to generate any revenues from sales of any therapeutic products 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 novel strain of coronavirus that causes Coronavirus disease 19 (COVID-19), we experienced impacts on certain aspects of our business, including our clinical trial and research and development activities, during the three months ended March 31, 2020. For example, certain of our research and development activities have been delayed or disrupted as a result of measures we have implemented in response to governmental “stay at home” orders and in the interests of public health and safety, and we have experienced delays or disruptions in the initiation and conduct of our clinical trials as a result of 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 COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on our operations, are currently unknown. 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 COVID-19 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 in San Diego, California. Fate Therapeutics, Inc. owns 100% of the voting shares of Tfinity Therapeutics, Inc. (Tfinity), 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 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. 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, of which $8.5 million has been received as of March 31, 2020. Further, under the terms of the Ono Agreement, Ono has 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 certain options to obtain an exclusive license under certain intellectual property rights to develop and commercialize each product candidate under the agreement. Such fees are in addition to the upfront payment and research and development fees.

We concluded that Ono represented a customer and in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, and 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.

During the three months ended March 31, 2020 and 2019, we recognized $2.5 million and $1.6 million, respectively, of collaboration revenue under the Ono Agreement. As of March 31, 2020, aggregate deferred revenue related to the Ono Agreement was $6.0 million.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement (the Juno Agreement) with Juno Therapeutics, Inc. (Juno) to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies.

In connection with the Juno Agreement, during the three months ended March 31, 2019, we recognized $1.0 million as collaboration revenue in the unaudited condensed consolidated statements of operations and comprehensive loss. No revenue was recognized in the three months ended March 31, 2020.

On May 4, 2019, the four-year initial research term under the Juno Agreement concluded as scheduled. The final quarterly research payment of $0.2 million was received during May 2019 and no additional payments are expected.

Agreement with Janssen Biotech, Inc.

On April 2, 2020 (the 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 Effective Date, the Company 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. As a direct result of our entry into the Janssen Agreement, we incurred $12.9 million in sublicense fees to certain of our existing licensors.

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 of our product candidates, research and develop our cell programming technology including our iPSC product platform, and perform our obligations under collaboration agreements including under our agreements with Janssen, Ono, University of Minnesota and Memorial Sloan Kettering. Our current planned research and development activities over the next twelve months consist primarily of the following:

- initiating and conducting clinical trials of our product candidates;
- conducting GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;
- source 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, Ono, University of Minnesota and Memorial Sloan Kettering.

Due to the inherently unpredictable nature of preclinical and clinical development, 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 of our product candidates. Clinical and preclinical development timelines and costs, and the potential of development 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 plans and capital requirements. We cannot predict the effects of the impact of COVID-19 on our business and operations, and our expenditures may be increased by potential delays or disruptions due to the COVID-19 pandemic, 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 primarily of interest income earned on cash and cash equivalents, interest income from investments (including the amortization of discounts and premiums), and interest expense for the periods where debt was outstanding.

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 accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, 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.

With the exception of our adoption of new credit impairment loss guidance, 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, 2019 continue to be our critical accounting policies and there have been no material changes to our critical accounting policies during the three months ended March 31, 2020.

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, 2020 and 2019

The following table summarizes the results of our operations for the three months ended March 31, 2020 and 2019 (in thousands):

	Three Months Ended March 31,		Increase/
	2020	2019	(Decrease)
Collaboration revenue	$ 2,515	$ 2,632	$ (117)
Research and development expense	29,278	17,728	11,550
General and administrative expense	7,729	5,350	2,379
Total other income, net	972	686	286

Revenue. During the three months ended March 31, 2020, we recognized revenue of $2.5 million under our collaboration agreement with Ono. During the three months ended March 31, 2019, we recognized $2.6 million under our collaboration agreements with Ono and Juno.

Research and development expenses. Research and development expenses were $29.3 million for the three months ended March 31, 2020, compared to $17.7 million for the three months ended March 31, 2019. The increase in research and development expenses was attributable primarily to the following:

- $4.7 million increase in employee compensation and benefits expense, including $2.1 million in employee stock-based compensation expense;
- $3.2 million increase in expenditures for laboratory equipment, materials and supplies relating to the manufacture of our product candidates and the conduct of our research activities, including under our research collaboration agreements;
- $1.8 million increase in facility lease expense primarily relating to our future headquarters lease, which commenced in January 2020; and
- $1.5 million increase in third-party service provider expenses relating to the clinical development and manufacture of our product candidates and the conduct of our research activities, including under our collaboration agreements.

General and administrative expenses. General and administrative expenses were $7.7 million for the three months ended March 31, 2020, compared to $5.4 million for the three months ended March 31, 2019. The increase in general and administrative expenses was attributable primarily to a $1.4 million increase in employee compensation and benefits expense, including $1.0 million in employee stock-based compensation expense, and an increase of $0.6 million in legal, accounting and tax expenses.

Other income, net. Other income, net was $1.0 million for the three months ended March 31, 2020 and $0.7 million for the three months ended March 31, 2019. Other income, net for each period consisted primarily of interest income earned on cash and cash equivalents, and interest income from investments (including the amortization of discounts and premiums). Other income, net for the three months ended March 31, 2019 also included interest expense relating to the term loan with Silicon Valley Bank.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of March 31, 2020, we had an accumulated deficit of $417.1 million and we anticipate that we will continue to incur net losses for the foreseeable future.

Operating Activities

Cash used in operating activities increased from $17.5 million for the three months ended March 31, 2019 to $26.7 million for the three months ended March 31, 2020. The primary driver of this change in cash used in operating activities was our increase in net loss and a decrease in working capital, partially offset by an increase in stock-based compensation expense and depreciation and amortization expense.

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 has agreed to pay us 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 each Candidate 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 (a) Candidate 1 in Asia, with us retaining rights for development and commercialization in all other territories of the world and (b) 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.

Subject to Ono's exercise of its options to obtain exclusive licenses to develop and commercialize the Candidates and to the achievement of certain clinical, regulatory and commercial milestones with respect to each Candidate in specified territories, we are entitled to receive an aggregate of up to $285.0 million in milestone payments for Candidate 1 and an aggregate of up to $895.0 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, 2020, we have not received any such payments. 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 of each Candidate in specified territories, with such royalties subject to certain reductions. As of March 31, 2020, no royalties have been paid to us.

As a direct result of our entry into the Ono Agreement, we incurred an aggregate of $2.0 million in sublicense consideration to certain of our existing licensors. The $2.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs*. As of March 31, 2020, all such consideration has been paid, with $1.0 million paid during the three months ended March 31, 2019.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement with Juno Therapeutics, Inc. (the Juno Agreement) to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. During the three months ended March 31, 2019, we received $0.5 million in research payments related to the Juno Agreement.

On May 4, 2019, the four-year initial research term under the Juno Agreement concluded as scheduled and the overall agreement terminated upon receipt of the final quarterly research payment of $0.2 million.

Investing Activities

During the three months ended March 31, 2020 and 2019, investing activities provided cash of $23.8 million and $8.8 million, respectively. During the three months ended March 31, 2020, maturities of the investments provided cash of $24.8 million. During the three months ended March 31, 2019, maturities of investments were $10.5 million. 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, 2020, financing activities provided cash of $1.5 million, which primarily consisted of $1.0 million received from the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options and $0.4 million in proceeds from the CIRM award (as described in detail below).

For the three months ended March 31, 2019, financing activities provided cash of $1.3 million, which primarily consisted of the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

From our inception through March 31, 2020, we have funded our consolidated 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. As of March 31, 2020, we had aggregate cash and cash equivalents and investments of $219.4 million.

Public Offering of Common Stock

In September 2019, we completed a public offering of common stock in which investors, certain of which are affiliated with our directors, purchased 9,890,000 shares of our common stock at a price of $17.50 per share under our shelf registration statement. Gross proceeds from the offering were $173.1 million. After giving effect to $10.7 million in underwriting discounts, commissions and expenses related to the offering, net proceeds were $162.4 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 December 2018, we discussed with CIRM our intent to pursue the clinical development of FT516 in relapsed / refractory hematologic malignancies in addition to advanced solid tumors, and our preference to first submit an IND application for FT516 in relapsed / refractory hematologic malignancies rather than in advanced solid tumors. In January 2019, we submitted our IND application for FT516 in relapsed / refractory hematologic malignancies, which IND submission was allowed by the FDA in February 2019. We agreed with CIRM to suspend the Award until such time as we elected to proceed with our submission of an IND application for FT516 in advanced solid tumors. In November 2019, we submitted an IND application for FT516 in advanced solid tumors and the Award was removed from suspension by CIRM in January 2020. In February 2020, we received a $0.4 million disbursement based on a milestone achievement.

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.

Silicon Valley Bank Debt Facility

On July 30, 2014, we entered into an Amended and Restated Loan and Security Agreement (Restated LSA) with Silicon Valley Bank (Bank), collateralized by substantially all of our assets, excluding certain intellectual property. On July 14, 2017, we entered into an amendment (SVB Loan Amendment) of the Restated LSA with the Bank where the Bank extended an additional term loan to us in the principal amount of $15.0 million (2017 Term Loan), a portion of which was applied to repay in full all amounts previously outstanding under the Restated LSA. On November 13, 2019 we used cash on hand in the amount of $14.2 million to repay in full all outstanding obligations related to the Restated LSA and SVB Loan Amendment. Accordingly, all of our obligations under the Restated LSA and SVB Loan Amendment have been paid and discharged in full, and all security interests and other liens granted by us to the Bank to secure our obligations have been terminated and released.

Registration Statements on Form S-3

In November 2018, we filed an automatic shelf registration statement (File No. 333-228513), 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, as we did in our September 2019 public offering of common stock. 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 Leerink Partners LLC (Leerink) 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 $50.0 million through Leerink as the sales agent.

In May 2018, the SEC declared effective a shelf registration statement filed by us in May 2018 (File No. 333-224680). 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, if any, under the shelf registration statement would be established at the time of such offering. As of March 31, 2020, after giving effect to a September 2018 public offering, we are eligible to issue an aggregate of $6.2 million in securities under this shelf registration statement.

In August 2017, the SEC declared effective a shelf registration statement filed by us in August 2017 (File No. 333-219987). 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, if any, under the shelf registration statement would be established at the time of such offering. As of March 31, 2020, after giving effect to a December 2017 public offering, we are eligible to issue an aggregate of $54.0 million in securities under this shelf registration statement. In addition, this registration statement registered for resale one million shares of common stock held by Juno, which were issued in May 2015 as described above.

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, 2020 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. 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 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 business operations at our new corporate headquarters, including internal GMP production capabilities to support the clinical and potential commercial manufacture of our product candidates;

- 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;
- 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 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

The following table summarizes our contractual obligations at March 31, 2020 that are expected to affect our liquidity and cash flow in future periods:

(in thousands)	Total	Less than 1 Year	Years 1 - 3	Years 3 - 5	More than 5 Years
Operating lease obligations	195,681	2,938	22,151	26,366	144,226
Total	$ 195,681	$ 2,938	$ 22,151	$ 26,366	$ 144,226

We lease certain office and laboratory space under non-cancelable operating leases. In addition to rent, our leases are subject to certain fixed fees, which have been included in the table above. 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 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.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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, 2020, our cash and cash equivalents consisted of cash and money market mutual funds, and our investments consisted of United States treasuries and corporate debt securities 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.

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, who serves as both our principal executive officer and our principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, the individual serving as our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2020.

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. Enhancements were made to our existing internal controls over financial reporting, effective beginning on January 1, 2020, due to the adoption and implementation of the new credit loss reporting requirements under ASU 2016-13.

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

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

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 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 COVID-19 pandemic;
- difficulties determining suitable doses 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 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 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, cell processing facilities at our clinical trial sites, 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 possible supply chain issues related to the COVID-19 pandemic;
- 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;
- data monitoring committees recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety;
- 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 travel relating to the COVID-19 pandemic, or other reasons; and
- approval of competitive agents that may materially alter the standard of care or otherwise 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.

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 research and development activities and our current or planned clinical development 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 preclinical studies or clinical trials;

- 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;
- 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;
- 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
- our prioritization of other product candidates for advancement, including a decision to cease research and development of any existing product candidate due to 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 favorable marketing exclusivity, including greater market acceptance or commercial potential, or more advantageous intellectual property position.

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. 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. 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.

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. 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 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. The requirements to manufacture ProTmune in close proximity to transplant centers within a short period of time before transplantation present unprecedented complexities associated with ensuring consistent manufacture in compliance with regulatory requirements as necessary for marketing approval. 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 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. 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.

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.

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 meet demand.

While certain components required for the production of our product candidates are currently manufactured internally at our facilities, we rely, and expect to continue to rely, on third parties for the manufacture of other components and also to manufacture our product candidates for use in conducting clinical trials. As such, we are required to transfer certain manufacturing process know-how and certain intermediates to third parties, including clinical cell processing facilities operated by our clinical trial sites, and larger-scale facilities operated by either 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. For example, in response to governmental shelter-in-place orders resulting from the COVID-19 pandemic, we have limited our on-site staff's availability to conduct manufacturing activities at our facility, and we may encounter problems with shortages of qualified personnel, key contractors, laboratory equipment, and materials and supplies for the manufacture of our product candidates. These problems may include employee absenteeism and supply chain failures or delays relating to the COVID-19 pandemic. 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, and thereby limit our opportunities for growth. In addition, we and our third-party manufacturers may have limited manufacturing capacity for certain product candidates or components, and we may not be able to locate additional or replacement manufacturing capacity on a reasonable basis or at all.

Even if we are successful in developing manufacturing capabilities sufficient for clinical and commercial supply, problems with manufacturing operations, including difficulties with production costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, 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. 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 the manufacturing facilities, 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, financial condition and results of operations.

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

All of our product candidates are currently in research, preclinical or clinical development. Only a small number of research and development programs ultimately result in commercially successful drugs. The development of cell therapies is a relatively new and emerging field, and the scientific research that forms the basis of our efforts to discover and develop programmed cellular immunotherapies is ongoing. We may determine to incorporate information learned from this research into the design of our ongoing Phase 2 clinical trial of ProTmune and 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. In addition, our product candidates may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. It may take many years before we develop a full understanding of the pharmacological properties of our product candidates, and we may never know precisely how they function in vivo. As with any new biologic or product developed using novel technologies, our product candidates have an unknown immunogenicity profile. As a result, our 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 such as FT500, FT516, and FT596, 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, including ProTmune;
- 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 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.

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, 2020, our cash and cash equivalents and investments were $219.4 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, including for our other iPSC-derived cell 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;
- 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 Memorial Sloan Kettering, 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 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.

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 cancer and immune disorders, including NK- and T-cell immuno-oncology programs that encompass off-the-shelf engineered product candidates derived from clonal master iPSC lines, and immuno-regulatory programs. 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 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 stem cell therapies 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. 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 product candidates based on other, better known or more extensively studied technologies and therapeutic approaches. For example, there are currently no FDA approved products with a label designation that supports the use of a product to prevent acute graft-versus-host disease in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT), which makes it difficult to determine the clinical endpoints and data required to support an application or regulatory approval, and the time and cost required to obtain regulatory approval in the United States for ProTmune.

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, and results from earlier studies, may not be predictive of the final results, or of later studies or future clinical trials.

All of our product candidates are still in an early stage of development, and we cannot be assured that the development of any of our product candidates will ultimately be successful. Although 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. While we have demonstrated in preclinical models that a single administration of ProTmune resulted in a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, we may not observe similar results in future preclinical or clinical studies of ProTmune, including our Phase 1/2 PROTECT study. Additionally, the data reported from the Phase 1 stage of PROTECT as of the November 26, 2018 data cut-off date may not continue for these subjects or be repeated or observed in ongoing or future studies involving ProTmune, including in the Phase 2 stage of the PROTECT study. It is possible that subjects for whom events of acute GvHD have been reduced or eliminated may experience acute GvHD in the future, as there is limited data concerning long-term safety and efficacy following treatment with ProTmune. Accordingly, ProTmune may not demonstrate in the Phase 2 stage of PROTECT, or in subsequent trials, an adequate safety or efficacy profile to support further development or commercialization.

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 that enroll in our current or future clinical trials.

From time to time, we also publish interim, “top-line,” or preliminary data from our clinical studies. 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. 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.

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, 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 expect to rely on orphan drug status to develop and commercialize certain of our product candidates, but our existing 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 expect to rely on orphan drug exclusivity for ProTmune and may rely on orphan drug exclusivity for other 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. We have been granted orphan drug designation in the United States for *ex vivo* programmed mobilized peripheral blood for the prevention of GvHD in patients undergoing allogeneic hematopoietic cell transplantation, and in the European Union for ProTmune for treatment in hematopoietic stem cell transplantation. While we have been granted these orphan designations, even if we 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. In addition, we may be unable to obtain orphan drug designations for any other product candidates that we are currently developing or may pursue.

For any product candidate for which we are 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 and health information privacy and security laws. Any 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. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. It is possible that some of our business activities could be subject to challenge under one or more of these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Reliance on Third Parties

We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. 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, including cell processing facilities associated with clinical trial sites, 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. In addition, we have not yet caused 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.

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, or in the event of problems with any of the manufacturing facilities that we rely on to manufacture our product candidates or materials, we may not be able to locate additional or replacement facilities for 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.

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 addition, the operations of our third-party manufacturers may be disrupted or delayed by the outbreak of the COVID-19 pandemic, which may impact such third-party manufacturers' ability to obtain materials for manufacture or to continue ongoing operations under shelter-in-place orders. We and our third-party manufacturers do not know yet the full extent of potential impacts on our ability to conduct our operations, including manufacture of our product candidates, and so we and our manufacturers are continuing to monitor the situation closely. However, any failure by third parties that are manufacturing our product candidates, or components for such product candidates, to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of such components or product candidates in a timely manner, including as a result of any disruption, delay, or closure resulting from the COVID-19 pandemic, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, 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.

Our continued development of ProTmune may depend on third-party cell processing facilities for the manufacture of ProTmune under specific conditions. Any failure by these facilities 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, these product candidates.

Clinical cell processing facilities operated by or affiliated with our clinical sites have manufactured ProTmune for use in our clinical trials of ProTmune to date. We will be required by the FDA to standardize the manufacture of ProTmune, and any other product candidates we may develop, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. The manufacture of ProTmune for use in registrational clinical trials and commercialization will be subject to the requirements of applicable regulatory authorities, including the FDA, and the anticipated manufacture of these product candidates for commercialization may require each of the clinical cell processing facilities at which ProTmune is manufactured to comply with cGMP and other regulatory requirements, and be subject to inspections by the FDA or other applicable regulatory authorities that would be conducted after the submission of a BLA or other marketing application. Although we are responsible for ensuring compliance with applicable regulatory requirements and for overseeing all aspects of product manufacture and release prior to applying for marketing approval, we do not control the activities of these third-party cell processing facilities and are completely dependent on their ability to comply with regulatory requirements and to properly execute the protocol for the manufacture of any of our product candidates. In particular, if the FDA requires each of the clinical cell processing facilities to comply with cGMP, there can be no guarantee that they will be able to do so. Because of these manufacturing requirements, if the applicable clinical cell processing facilities are unable to manufacture any of our product candidates, including ProTmune, in a manner that conforms to our specifications and the FDA's strict regulatory requirements, we may be required to identify alternative processes or facilities for the manufacture of such product candidate, which may require us to spend significant additional time and resources, and would impair our ability to manufacture, complete the clinical development of, and to commercialize, such product candidate. To comply with applicable regulatory and manufacturing requirements, the clinical cell processing facility may be required to possess or obtain certain equipment, including but not limited to biosafety cabinets, warming devices, cell washing devices, freezers or other materials, or to modify aspects of its operations, including its physical facility or layout, environmental systems, monitoring systems, quality systems or training procedures. If a clinical cell processing facility is unwilling or unable to comply with these regulatory or manufacturing requirements, it will be restricted or prohibited from manufacturing such product candidate and making it available for administration to patients. Any failure by these clinical cell processing facilities to properly manufacture ProTmune may adversely affect the safety and efficacy profile of such product candidate or cause the FDA or other regulatory authorities to impose restrictions or prohibitions on the manufacture and use of ProTmune in both the clinical and the commercial setting, which would have an adverse effect on our business.

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, operations, financial condition, prospects, or results of operations.

We currently depend on third-party cell processing facilities for the manufacture of ProTmune under specific conditions. Any failure by these facilities 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, these product candidates.

Clinical cell processing facilities operated by or affiliated with our clinical sites currently manufacture ProTmune for use in our clinical trials of these product candidates. We will be required by the FDA to standardize the manufacture of ProTmune, and any other product candidates we may develop, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. The manufacture of ProTmune for use in registrational clinical trials and commercialization will be subject to the requirements of applicable regulatory authorities, including the FDA, and the anticipated manufacture of these product candidates for commercialization may require each of the clinical cell processing facilities at which ProTmune are manufactured to comply with cGMP and other regulatory requirements, and be subject to inspections by the FDA or other applicable regulatory authorities that would be conducted after the submission of a BLA or other marketing application. Although we are responsible for ensuring compliance with applicable regulatory requirements and for overseeing all aspects of product manufacture and release prior to applying for marketing approval, we do not control the activities of these third-party cell processing facilities and are completely dependent on their ability to comply with regulatory requirements and to properly execute the protocol for the manufacture of any of our product candidates. In particular, if the FDA requires each of the clinical cell processing facilities to comply with cGMP, there can be no guarantee that they will be able to do so. Because of these manufacturing requirements, if the applicable clinical cell processing facilities are unable to manufacture any of our product candidates, including ProTmune, in a manner that conforms to our specifications and the FDA's strict regulatory requirements, we may be required to identify alternative processes or facilities for the manufacture of such product candidate, which may require us to spend significant additional time and resources, and would impair our ability to manufacture, complete the clinical development of, and to commercialize, such product candidate. To comply with applicable regulatory and manufacturing requirements, the clinical cell processing facility may be required to possess or obtain certain equipment, including but not limited to biosafety cabinets, warming devices, cell washing devices, freezers or other materials, or to modify aspects of its operations, including its physical facility or layout, environmental systems, monitoring systems, quality systems or training procedures. If a clinical cell processing facility is unwilling or unable to comply with these regulatory or manufacturing requirements, it will be restricted or prohibited from manufacturing such product candidate and making it available for administration to patients. Any failure by these clinical cell processing facilities to properly manufacture ProTmune may adversely affect the safety and efficacy profile of such product candidate or cause the FDA or other regulatory authorities to impose restrictions or prohibitions on the manufacture and use of ProTmune in both the clinical and the commercial setting, which would have an adverse effect on our business.

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 clinical cell processing facilities and CMOs have purchased equipment, materials and disposables, such as automated cell washing devices, automated cell warming units, commercially available media and cell transfer and wash sets, 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 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, including our pharmacologic modulators and components for our cell processing media. As a result of the 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. An inability to continue to source product from any of these suppliers, which could be due to the impacts of the COVID-19 pandemic, regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

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 face a variety of challenges and uncertainties associated with our dependence on human donor material for the manufacture of ProTmune.

ProTmune is manufactured from the blood of third-party donors, and therefore, the manufacture of ProTmune is subject to the availability and quality of the third-party donor material. The selection of the appropriate donor material for manufacture of ProTmune requires close coordination between clinical and manufacturing personnel.

ProTmune is manufactured using mobilized peripheral blood (mPB), which is currently procured directly by the clinical cell processing facilities from the National Marrow Donor Program (NMDP) for our ongoing Phase 1/2 PROTECT clinical study. The availability of mPB for the manufacture of ProTmune depends on a number of regulatory, political, economic and technical factors outside of our control, including:

- government policies relating to the regulation of mPB for clinical use;
- NMDP and individual blood bank policies and practices relating to mPB acquisition and banking;
- the pricing of mPB;
- the methods used in searching for and matching mPB to patients, which involve emerging technology related to current and future mPB parameters that guide the selection of an appropriate unit of mPB for transplantation; and
- methods for the procurement and shipment of mPB and its handling and storage at clinical sites.

Additionally, we do not have control over the supply, availability, price or types of mPB that these clinical cell processing facilities use in the manufacture of ProTmune. We rely heavily, and expect to continue to rely heavily, on these third parties to procure mPB that is collected in compliance with government regulations and within the current standard of care. In addition, we may identify specific characteristics of specific units of mPB, such as the volume and red blood cell content, which may limit the ability to use such units in the manufacture of ProTmune even though this mPB may otherwise be suitable for use in allogeneic transplant. As a result, the requirement for mPB to meet our specifications may limit the potential inventory of mPB eligible for use in the manufacture of ProTmune for our ongoing and any future clinical trials and for commercial supplies of ProTmune, if approved.

In the United States, the banking and use of mPB does not require a BLA, and mPB is not an FDA licensed product. However, the FDA does require that units of mPB adhere to and meet the standards set forth by the Foundation for Accreditation for Cell Therapy (FACT), the NMDP, and the American Association of Blood Banks (AABB), as applicable. In our current Phase 1/2 PROTECT clinical trial of ProTmune, ProTmune is manufactured using unlicensed mPB units. It may be possible that in the future, regulatory policy could change, and the FDA may later require that mPB units be licensed, and that ProTmune be manufactured using only licensed mPB units. Any inability to procure sufficient supplies of mPB will adversely affect our ability to develop and commercialize ProTmune.

Further, manufacture of ProTmune from donor material involves complex processes, with specialized equipment and highly skilled and trained personnel. The processes for manufacturing ProTmune are susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. Such contaminations increase the risk of adverse side effects and result in delays in the development of ProTmune.

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

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

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

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 collaborator’s or partner’s 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. 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 ProTmune and 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. If we fail to comply with our obligations under our license agreements, 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. 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 part*e 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 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. If any third-party patents were held by a court of competent jurisdiction to cover aspects of the manufacture of any of our product candidates, any compositions formed during the manufacture, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property rights, unless that third-party grants us rights to use its intellectual property. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

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. Trade secrets, however, may be difficult to protect, and if our employees, collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors, which would adversely affect our business position.

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. 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 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; 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 product candidates, and the targeted indication of HSCT procedures in general and our cellular immunotherapy product candidates in particular, 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, including in the area of orphan drug products. 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 new products could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments, such as HSCT or cellular immunotherapy. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products by government and third-party payers. In particular, there is no body of established practices and precedents for reimbursement of cellular immunotherapies, and it is difficult to predict what the regulatory authority or private payer will decide with respect to reimbursement levels for novel products such as ours. Our products may not qualify for coverage or direct reimbursement, or may be subject to limited reimbursement. If reimbursement or insurance coverage is not available, 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.

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 payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

If the market opportunities for our product candidates are 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 orphan indications and other rare diseases. 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.

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.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Since its enactment, there have been many judicial, President, and Congressional challenges to numerous aspects of the ACA. As a result, the full impact on our business of the ACA, the potential impacts of any challenges including any laws repealing and/or replacing elements of it, as well as the political uncertainty surrounding any repeal or replacement legislation, remain unclear.

Additionally, at the federal level, statutes and regulations routinely impact a variety of parameters relating to federal programs and Medicare. In July 2018, the Centers for Medicare and Medicaid Services (CMS) published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these federal and state laws and regulations, as well as other new laws and reform measures that may be proposed and adopted in the future, remains uncertain, but may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

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.

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

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration has also taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our existing product candidates or any future product candidates we may develop. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional non-clinical or clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our existing product candidates or other product candidates we may develop, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Risks Related to Our Business and Industry

The success of our existing product candidates is substantially dependent on developments within the field of HSCT and cellular immunotherapy, some of which are beyond our control.

Our product candidates are designed and are being developed as therapeutic entities for use as cellular immunotherapies. Any adverse developments in the field of cellular immunotherapy generally, and in the practice of HSCT in particular, will negatively affect our ability to develop and commercialize our product candidates. If the market for HSCT procedures declines or fails to grow at anticipated levels for any reason, or if the need for patients to undergo HSCT procedures is obviated due to the development and commercialization of therapeutics targeting the underlying cause of diseases addressed by HSCT, our business prospects will be significantly harmed.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. 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 obviate the need for HSCT, may be competitive to product 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.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to retain or attract qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. 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.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and preclinical studies.

The outbreak of the novel coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), has evolved into a global pandemic. The coronavirus has spread to many regions of the world, including the United States and Europe. As a result of the coronavirus pandemic, we may experience disruptions that could materially impact our business. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the pandemic and the actions taken to contain its spread or treat its impact, among others.

As a result of the COVID-19 pandemic, various aspects of our business operations have been, and could continue to be, disrupted. In response to the pandemic, we have implemented a work from home policy, with our administrative employees continuing their work outside of our offices, and restricted on-site staff to only those required to execute certain laboratory, manufacturing and related support activities. 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. In addition, as a result of shelter-in-place orders or other mandated travel restrictions, our on-site staff conducting research and development, preclinical studies, and manufacturing activities may not be able to access our laboratories or manufacturing space, and these core activities may be significantly limited or curtailed, possibly for an extended period of time.

In addition, our ongoing and planned clinical trials have been and will likely continue to be affected by the pandemic. Study procedures (particularly any procedures that may be deemed non-essential), site initiation, participant recruitment and enrollment, participant dosing, shipment of our product candidates, distribution of clinical trial materials, study monitoring, site inspections and data analysis may be paused or delayed due to changes in hospital or research institution policies, federal, state or local regulations, prioritization of hospital and other medical resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Furthermore, the pandemic could result in interruption or delays in the operations of the FDA and other regulatory agencies. The extent and impact of such disruptions are currently unpredictable. Any prolongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

Our research, preclinical development, and manufacturing operations also may be adversely impacted by the COVID-19 pandemic. We currently utilize third parties to, among other things, supply and manufacture raw materials, components, consumables, and our product candidates, to ship our product candidates and manufacturing materials, and to perform certain testing relating to our product candidates. We also manufacture our product candidates and perform various related testing at our manufacturing facility, and conduct research and development activities. If we, or any third parties in our supply chain for materials which are used in either the manufacture of our product candidates or the conduct of our research and development, are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted and our ability to manufacture and ship our product candidates for our clinical trials and to conduct research and development activities may be limited.

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 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. We do not yet know the full extent of potential delays or impacts on our business, our clinical and preclinical programs, our clinical, preclinical, 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.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this ‘‘Risk Factors’’ section, such as those relating to our clinical and preclinical development operations, manufacturing activities, the supply chain for our ongoing and planned clinical trials, and our ability and need to raise additional capital to support our operations.

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 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.

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.

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.

Our business activities may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, physician payment transparency laws, health information privacy and security laws, and anti-bribery and anti-corruption laws. Our actual or perceived failure to comply with such laws or their relevant foreign counterparts could adversely affect our business.

Our business activities may be subject to the Foreign Corrupt Practices Act (FCPA) and various federal and state fraud and abuse laws, including, without limitation, physician sunshine laws and regulations, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits improper payments or offers of payments, either directly or indirectly, to foreign governments and their officials and political parties by U.S. persons in order to influence official action, or otherwise obtain or retain business. Additionally, the U.S. federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the Affordable Care Act, and their implementing regulations, require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, information related to payments or other transfers of value made to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians, other healthcare providers, and their immediate family members. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for knowingly and willfully defrauding any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services.

We and any potential collaborators may be subject to 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. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, 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.

In addition, as of May 25, 2018, the General Data Protection Regulation (GDPR) regulates the collection and use of personal data in the EU. The GDPR covers any business, regardless of its location, that provides goods or services to residents in the EU and, thus, could incorporate our activities in EU member states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information," which includes health and genetic information of individuals residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the EU to regions that have not been deemed to offer "adequate" privacy protections, such as the U.S. currently. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states, which may deviate slightly from the GDPR, may result in warning letters, mandatory audits and financial penalties, including fines of up to 4% of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is unclear whether the authorities will conduct random audits of companies doing business in the EU, or act solely after complaints are filed claiming a violation of the GDPR. The lack of compliance standards and precedent, enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

We or the third parties upon whom we depend may be adversely affected by earthquakes 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 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.

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. 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 PPACA 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, 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, 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, current economic climate and financial market conditions could adversely impact 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 computer viruses and unauthorized access. In addition, 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, and similar events relating to their computer systems could also have a material adverse effect on our business. 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.

Certain data breaches must also be reported to affected individuals and the government, 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.

Risks Related to Our Financial Condition and the Ownership 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, 2020, we had an accumulated deficit of $417.1 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, including pursuant to the terms of our stock purchase agreement with Juno Therapeutics, Inc., 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; and
- general economic and market conditions.

These and other market and industry factors, including the effects of the COVID-19 pandemic 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. In addition, 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, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and this could divert the time and attention of our management.

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 May 7, 2020, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 40.7% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 8 of the notes to the consolidated financial statements herewith) relating to the Class A Convertible Preferred Stock, Redmile (as such term is defined in Note 8 of the notes to the consolidated financial statements herewith) elects to remove certain limitations on the percentage of 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. 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. As a result, all of these shares are currently available for resale to the public, which may result in dilution to our stockholders. During 2019, 25,000 shares of the Class A Convertible Preferred Stock were converted into 125,000 shares of common stock. In addition, pursuant to a shelf registration statement declared effective by the SEC in May 2018, we may sell up to a remaining $6.2 million in shares of our common stock, preferred stock, debt securities, warrants and/or units, and pursuant to a shelf registration statement declared effective by the SEC in August 2017, we may sell up to a remaining $54.0 million in the aggregate of shares of our common stock, preferred stock, debt securities, warrants and/or units. The August 2017 registration statement also provides for the resale by Juno of up to one million shares of common stock held by Juno pursuant to the Stock Purchase Agreement entered into in May 2015. Further, in November 2018 we filed a Form S-3 pursuant to which we may issue up to $50.0 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. Additionally, we have agreed to register 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. 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.

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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act of 2017 (the Tax Act), that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate, limiting interest deductions, limiting the deduction for net operating losses and eliminating net operating loss carrybacks (though any such tax losses may be carried forward indefinitely), in each case, for losses arising in our taxable years beginning after December 31, 2017, allowing for the expensing of capital expenditures and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the Tax Act on our business, whether adverse or favorable, is uncertain, and may not become evident for some period of time. We urge you to consult with your own legal and tax advisors with respect to applicable tax laws, including this legislation, and the potential tax consequences of investing in our common stock.

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, 2019, we had federal and California net operating loss carryforwards of $168.2 million and $168.2 million, respectively, which begin to expire in various amounts in 2027. As of December 31, 2019, we also had federal and California research and development tax credit carryforwards of $13.4 million and $8.5 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 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 2019. We have not analyzed periods subsequent to December 2019. 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. In addition, under the Tax Act the amount of NOLs generated in taxable periods beginning after December 31, 2017, 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. The Tax Act generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely.

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

a) All information with respect to this item has been previously reported in our Current Report on Form 8-K.

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

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect	S-1/A	333-190608	3.2	August 29, 2013
3.2	Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock	8-K	001-36076	3.1	November 29, 2016
3.3	Amended and Restated Bylaws of the Registrant, as currently in effect	S-1/A	333-190608	3.4	August 29, 2013
4.1	Specimen Common Stock Certificate	S-1/A	333-190608	4.1	August 29, 2013
10.1†	Lease Agreement by and between the Registrant and Scripps Summit Investments LLC, dated January 7, 2020	10-K	001-36076	10.34	March 2, 2020
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	—	—	—	Filed herewith

† Certain provisions of this Exhibit have been omitted as confidential information.

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 11, 2020

By: /s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer and Director
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL 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 11, 2020

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

Exhibit 32.1

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

In connection with the quarterly report of Fate Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, J. Scott Wolchko, Principal Executive Officer and Principal 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 11, 2020

/s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer
(Principal Executive and Financial 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.