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

FORM 10-Q

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from_____ to _____

Commission file number 001-36548

ATARA BIOTHERAPEUTICS, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**46-0920988**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
611 Gateway Blvd., Suite 900 South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 278-8930

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	**ATRA**	**The Nasdaq Stock Market LLC**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 ☒

The number of outstanding shares of the Registrant's Common Stock as of July 31, 2020 was74,307,894 shares.

ATARA BIOTHERAPEUTICS, INC.

INDEX

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except per share amounts)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 74,511	$ 74,317
Short-term investments	273,201	184,792
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	11,081	13,689
Total current assets	358,987	272,992
Property and equipment, net	53,587	54,176
Operating lease assets	13,321	14,007
Restricted cash - long-term	1,200	1,200
Other assets	1,016	567
Total assets	$ 428,111	$ 342,942
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,106	$ 7,963
Accrued compensation	12,657	14,706
Accrued research and development expenses	8,244	8,341
Other current liabilities	5,677	5,733
Total current liabilities	31,684	36,743
Operating lease liabilities - long-term	13,420	14,136
Other long-term liabilities	1,882	1,282
Total liabilities	46,986	52,161
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock—$0.0001 par value, 500,000 shares authorized as of June 30, 2020 and December 31, 2019; 74,308 and 56,806 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	7	6
Additional paid-in capital	1,349,234	1,108,516
Accumulated other comprehensive income	810	220
Accumulated deficit	(968,926)	(817,961)
Total stockholders' equity	381,125	290,781
Total liabilities and stockholders' equity	$ 428,111	$ 342,942

See accompanying notes.

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 61,560	$ 52,251	$ 119,219	$ 100,919
General and administrative	16,392	23,284	33,430	42,507
Total operating expenses	77,952	75,535	152,649	143,426
Loss from operations	(77,952)	(75,535)	(152,649)	(143,426)
Interest and other income, net	497	1,207	1,685	2,841
Loss before provision for income taxes	(77,455)	(74,328)	(150,964)	(140,585)
Provision for income taxes	1	—	1	—
Net loss	$ (77,456)	$ (74,328)	$ (150,965)	$ (140,585)
Other comprehensive gain:				
Unrealized gain on available-for-sale securities	606	135	590	513
Comprehensive loss	$ (76,850)	$ (74,193)	$ (150,375)	$ (140,072)
Net loss per common share:				
Basic and diluted net loss per common share	$ (1.14)	$ (1.60)	$ (2.34)	$ (3.04)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	67,975	46,426	64,592	46,276

See accompanying notes.

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)
(In thousands)

For the Six Months Ended June 30, 2020	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2019	56,806	$ 6	$ 1,108,516	$ 220	$ (817,961)	$ 290,781
Issuance of common stock through ATM facilities, net of commissions and offering costs of $704	1,528	—	22,987	—	—	22,987
Exercise of pre-funded warrants	57	—	—	—	—	—
RSU settlements, net of shares withheld	455	—	(1,395)	—	—	(1,395)
Issuance of common stock pursuant to employee stock awards	94	—	1,330	—	—	1,330
Stock-based compensation expense	—	—	12,644	—	—	12,644
Net loss	—	—	—	—	(73,509)	(73,509)
Unrealized loss on available-for-sale securities	—	—	—	(16)	—	(16)
Balance as of March 31, 2020	58,940	6	1,144,082	204	(891,470)	252,822
Issuance of common stock and pre-funded warrants through underwritten offering, net of offering costs of $370	14,958	1	189,300	—	—	189,301
RSU settlements, net of shares withheld	219	—	—	—	—	—
Issuance of common stock pursuant to employee stock awards	191	—	1,904	—	—	1,904
Stock-based compensation expense	—	—	13,948	—	—	13,948
Net loss	—	—	—	—	(77,456)	(77,456)
Unrealized gain on available-for-sale securities	—	—	—	606	—	606
Balance as of June 30, 2020	74,308	$ 7	$ 1,349,234	$ 810	$ (968,926)	$ 381,125

For the Six Months Ended June 30, 2019	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2018	45,951	$ 5	$ 866,541	$ (340)	$ (527,349)	$ 338,857
Effect of the adoption of ASC topic 842 (Leases)	—	—	—	—	364	364
Balance as of January 1, 2019	45,951	$ 5	$ 866,541	$ (340)	$ (526,985)	$ 339,221
RSU settlements, net of shares withheld	197	—	(4,575)	—	—	(4,575)
Issuance of common stock pursuant to employee stock awards	159	—	2,898	—	—	2,898
Stock-based compensation expense	—	—	12,269	—	—	12,269
Net loss	—	—	—	—	(66,257)	(66,257)
Unrealized gain on available-for-sale securities	—	—	—	378	—	378
Balance as of March 31, 2019	46,307	5	877,133	38	(593,242)	283,934
Issuance of common stock through ATM facilities, net of commissions and offering costs of $338	359	—	7,630	—	—	7,630
RSU settlements, net of shares withheld	120	—	(2,095)	—	—	(2,095)
Issuance of common stock pursuant to employee stock awards	97	—	1,802	—	—	1,802
Stock-based compensation expense	—	—	15,201	—	—	15,201
Net loss	—	—	—	—	(74,328)	(74,328)
Unrealized gain on available-for-sale securities	—	—	—	135	—	135
Balance as of June 30, 2019	46,883	$ 5	$ 899,671	$ 173	$ (667,570)	$ 232,279

See accompanying notes.

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2020	**2019**
Operating activities		
Net loss	$ (150,965)	$ (140,585)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	26,592	27,470
Depreciation and amortization expense	4,002	3,385
Amortization (accretion) of investment premiums (discounts)	170	(817)
Non-cash operating lease expense	734	576
Loss on disposals of property and equipment	93	127
Asset retirement obligation accretion expense	38	35
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,423	720
Operating lease assets	-	238
Other assets	(288)	255
Accounts payable	(2,933)	2,649
Accrued compensation	(2,049)	(2,814)
Accrued research and development expenses	(97)	(14,071)
Other current liabilities	(406)	(1,658)
Operating lease liabilities	(535)	(299)
Other long-term liabilities	541	—
Net cash used in operating activities	(123,680)	(124,789)
Investing activities		
Purchases of short-term investments	(228,224)	(17,589)
Proceeds from maturities and sales of short-term investments	140,235	136,876
Purchases of property and equipment	(3,409)	(1,534)
Proceeds from sale of property and equipment	—	96
Net cash (used in) provided by investing activities	(91,398)	117,849
Financing activities		
Proceeds from sale of common stock in underwritten offerings, net	189,623	—
Proceeds from issuance of common stock through ATM facilities, net	24,172	7,630
Proceeds from employee stock awards	3,234	4,676
Taxes paid related to net share settlement of restricted stock units	(1,395)	(6,670)
Principal payments on finance lease obligations	(197)	(235)
Other financing activities, net	(165)	—
Net cash provided by financing activities	215,272	5,401
Increase (decrease) in cash, cash equivalents and restricted cash	194	(1,539)
Cash, cash equivalents and restricted cash at beginning of period	75,711	62,092
Cash, cash equivalents and restricted cash at end of period	$ 75,905	$ 60,553
Non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and other accrued liabilities	$ 253	$ 473
Finance lease assets obtained in exchange for lease obligations	$ 281	$ —
Accrued costs related to underwritten public offering	$ 322	$ —
Receivable for options exercised	$ —	$ 24
Supplemental cash flow disclosure		
Cash paid for interest	$ 37	$ 31
Cash paid for income taxes	$ 1	$ —

See accompanying notes.

1. Description of Business

Atara Biotherapeutics, Inc. ("Atara", "we", "our" or "the Company") was incorporated in August 2012 in Delaware. Atara is a pioneer in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with severe diseases, including solid tumors, hematologiccancers and autoimmune disease.

We have several T-cell immunotherapies in clinical development and are progressing multiple next-generation allogeneic chimeric antigen receptor T-cell ("CAR T") programs.

We have licensed rights to T-cell product candidates from Memorial Sloan Kettering Cancer Center ("MSK"), rights related to our next-generation CAR T programs from MSK and from Moffitt Cancer Center, and rights to know-how and technology from the Council of the Queensland Institute of Medical Research ("QIMR Berghofer"). See Note 6 for further information.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Atara and its wholly-owned subsidiaries and have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, except for the adoption of accounting pronouncements relating to credit losses on financial instruments, implementation of cloud computing arrangements, and simplification of income tax accounting, effective January 1, 2020, as discussed below. In the opinion of management, the condensed consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company's consolidated financial statements. The results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or any other future period. The condensed consolidated balance sheet as of December 31, 2019 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete consolidated financial statements.

Liquidity

We have incurred significant operating losses since inception and have relied on public and private equity financings to fund our operations. As of June 30, 2020, we had an accumulated deficit of $968.9 million. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of product candidates and on the achievement of sufficient revenues to support our cost structure. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital. We expect that our cash, cash equivalents and short-term investments as of June 30, 2020 will be sufficient to fund our planned operations into 2022.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgments that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relied upon in preparing these financial statements include estimates related to clinical trial and other accruals, stock-based compensation expense and income taxes. Actual results could differ materially from those estimates.

Recent Accounting Pronouncements

The Company considers the applicability and impact of any Accounting Standards Update ("ASU") issued by the Financial Accounting Standards Board ("FASB"). Other than the ASUs we adopted effective January 1, 2020 and listed below, all other ASUs were assessed and determined to be either not applicable or are expected to have minimal impact on our consolidated financial statements.

Adoption of New Accounting Pronouncements

We adopted ASU No. 2016-13 (as amended by ASUs 2018-19, 2019-04, 2019-05 and 2019-11), *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, prospectively on January 1, 2020. Under this new guidance, a company is required to estimate credit losses on certain types of financial instruments using an expected-loss model, replacing the current incurred-loss model, and record the estimate through an allowance for credit losses. We do not hold material amounts of the types of financial instruments impacted by this guidance on our balance sheet. The guidance also establishes a new impairment model for available-for-sale debt securities. The adoption did not have a material impact on our condensed consolidated balance sheet or our condensed consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the three and six months ended June 30, 2020 and 2019.

We adopted ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, effective January 1, 2020, electing a prospective adoption method. The new standard requires that certain implementation costs for cloud computing arrangements are capitalized and amortized over the term of associated hosted cloud computing arrangement service. Capitalized implementation costs are classified in prepaid expenses and other assets. The amortization of the capitalized asset is presented in the same line on the statement of operations and comprehensive loss as the fees for the associated hosted cloud computing arrangement service and not included with depreciation or amortization expense related to property and equipment or intangible assets. Cash flows related to capitalized implementation costs are presented in cash flows used in operating activities. The adoption did not have a material impact on our condensed consolidated balance sheet or our condensed consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the three and six months ended June 30, 2020 and 2019.

We adopted ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as of January 1, 2020, which eliminates certain exceptions related to the general principles in ASC 740 and makes amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The provisions of the ASU that are applicable to Atara are applied on a prospective basis. The adoption did not have a material impact on our condensed consolidated balance sheet or our condensed consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the three and six months ended June 30, 2020 and 2019.

3. Net Loss per Common Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of shares of common stock and pre-funded warrants outstanding during the period, without consideration of common share equivalents. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock, pre-funded warrants and common share equivalents outstanding for the period. The pre-funded warrants are included in the computation of basic and diluted net loss per common share as the exercise price is negligible and the pre-funded warrants are fully vested and exercisable. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Potential dilutive securities, which include unvested restricted stock units ("RSUs"), unvested performance-based RSUs for which established performance criteria have been achieved as of the end of the respective periods, vested and unvested options to purchase common stock and shares to be issued under our employee stock purchase plan ("ESPP"), have been excluded from the computation of diluted net loss per share as the effect is antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following table represents the potential common shares issuable pursuant to outstanding securities as of the related period end dates that were excluded from the computation of diluted net loss per common share, as their inclusion would have an antidilutive effect:

	As of June 30,	
	2020	2019
Unvested RSUs	3,414,239	1,531,211
Vested and unvested options	8,476,516	7,291,729
ESPP share purchase rights	26,690	15,296
Total	11,917,445	8,838,236

4. Financial Instruments

Our financial assets are measured at fair valueon a recurring basis using the following hierarchy to prioritize valuation inputs, in accordance with applicable U.S. GAAP:

Level 1:Quoted prices in active markets for identical assets or liabilities that we have the ability to access

Level 2:Observable market-based inputs or unobservable inputs that are corroborated by market data such as quoted prices, interest rates and yield curves

Level 3:Inputs that are unobservable data points that are not corroborated by market data

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs. There have been no transfers between Level 1, Level 2 and Level 3 in any periods presented.

Financial assets and liabilities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities are valued primarily using market prices of comparable securities, bid/ask quotes, interest rate yields and prepayment spreads and are included in Level 2.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. We have no Level 3 financial assets or liabilities.

The following tables summarize the estimated fair value and related valuation input hierarchy of our available-for-sale securities as of each period end:

As of June 30, 2020:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	$ 54,181	$ —	$ —	$ 54,181
U.S. Treasury obligations	Level 2	186,555	202	(1)	186,756
Government agency obligations	Level 2	6,080	9	-	6,089
Corporate debt obligations	Level 2	81,631	599	(8)	82,222
Commercial paper	Level 2	9,988	—	—	9,988
Asset-backed securities	Level 2	7,256	9	—	7,265
Total available-for-sale securities		345,691	819	(9)	346,501
Less: amounts classified as cash equivalents		(73,300)	—	—	(73,300)
Amounts classified as short-term investments		$ 272,391	$ 819	$ (9)	$ 273,201

As of December 31, 2019:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	$ 63,554	$ —	$ —	$ 63,554
U.S. Treasury obligations	Level 2	52,805	46	(1)	52,850
Government agency obligations	Level 2	6,151	1	(1)	6,151
Corporate debt obligations	Level 2	100,512	180	(10)	100,682
Commercial paper	Level 2	26,290	—	—	26,290
Asset-backed securities	Level 2	7,266	6		7,272
Certificates of deposit	Level 2	500	—	—	500
Total available-for-sale securities		257,078	233	(12)	257,299
Less: amounts classified as cash equivalents		(72,507)	—	—	(72,507)
Amounts classified as short-term investments		$ 184,571	$ 233	$ (12)	$ 184,792

The amortized cost and fair value of our available-for-sale securities by contractual maturity were as follows:

	As of June 30, 2020		As of December 31, 2019	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(in thousands)		(in thousands)	
Maturing within one year	$ 308,021	$ 308,492	$ 214,085	$ 214,199
Maturing in one to five years	37,670	38,009	42,993	43,100
Total available-for-sale securities	$ 345,691	$ 346,501	$ 257,078	$ 257,299

As of June 30, 2020, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the available-for-sale securities we hold, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. We considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and determined that our investments were not significantly impacted. For all securities with a fair value less than its amortized cost basis, we determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for losses has been recorded. During the three and six months ended June 30, 2020 and 2019, we did not recognize any impairment losses on our investments.

We have elected the practical expedient to exclude the applicable accrued interest from both the fair value and the amortized cost basis of our available-for-sale securities for purposes of identifying and measuring an impairment. We present accrued interest receivable related to our available-for-sale securities in prepaid expenses and other current assets, separate from short-term investments on our condensed consolidated balance sheet. As of June 30, 2020 and December 31, 2019, accrued interest receivable was $0.8 million and $0.9 million, respectively. Our accounting policy is to not measure an allowance for credit losses for accrued interest receivables and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which we consider to be in the period in which we determine the accrued interest will not be collected by us. We have not written off any accrued interest receivables for the three and six months ended June 30, 2020 and 2019.

In addition, restricted cash collateralized by money market funds is a financial asset measured at fair value and is a Level 1 financial instrument under the fair value hierarchy. As of June 30, 2020 and December 31, 2019, restricted cash was $1.4 million.

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the condensed consolidated balance sheets that sum to the total of the same such amounts in the condensed consolidated statement of cash flows:

	June 30, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 74,511	$ 74,317
Restricted cash - short term	194	194
Restricted cash - long term	1,200	1,200
Total cash, cash equivalents and restricted cash	$ 75,905	$ 75,711

5. Property and Equipment

Property and equipment consisted of the following as of each period end:

	June 30, 2020	December 31, 2019
	(in thousands)	
Leasehold improvements	$ 50,038	$ 49,028
Lab equipment	7,581	6,815
Machinery and equipment	4,216	3,832
Computer equipment and software	3,976	3,299
Furniture and fixtures	2,052	1,764
Construction in progress	1,228	1,116
Property and equipment, gross	69,091	65,854
Less: accumulated depreciation and amortization	(15,504)	(11,678)
Property and equipment, net	$ 53,587	$ 54,176

Depreciation and amortization expense was $2.1 million and $1.8 million for the three months ended June 30, 2020 and 2019, respectively, and $4.0 million and $3.4 million for the six months ended June 30, 2020 and 2019, respectively.

6. License and Collaboration Agreements

MSK Agreements – In June 2015, we entered into an exclusive license agreement with MSK for three clinical stage T-cell therapies. We are required to make additional payments of up to $33.0 million to MSK based on achievement of specified regulatory and sales-related milestones, as well as mid-single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any. In addition, under certain circumstances, we are required to make certain minimum annual royalty payments to MSK, which are creditable against earned royalties owed for the same annual period. We are also required to pay a low double-digit percentage of any consideration we receive for sublicensing the licensed rights. The license agreement expires on a product-by-product and country-by-country basis on the later of: (i) expiration of the last licensed patent rights related to each licensed product, (ii) expiration of any market exclusivity period granted by law with respect to each licensed product, and (iii) a specified number of years after the first commercial sale of the licensed product in each country. Upon expiration of the license agreement, Atara will retain non-exclusive rights to the licensed products.

In May 2018 and December 2018, we licensed additional technology from MSK. In connection with the effectiveness of the December 2018 license agreement, we made upfront cash payments of $12.5 million in the first quarter of 2019, which were recorded as research and development expense in our consolidated statement of operations and comprehensive loss in the fourth quarter of 2018. We are obligated to make additional milestone payments based on achievement of specified development, regulatory and sales-related milestones, as well as mid-single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any.

QIMR Berghofer Agreements – In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer. Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell therapy programs utilizing technology and know-how developed by QIMR Berghofer. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional T-cell programs, as well as the option to license additional technology. We exercised this option in June 2018. We further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019 to eliminate our license to certain rights related to cytomegalovirus. Our current license agreement also provides for various milestone and royalty payments to QIMR Berghofer based on future product sales, if any. Under the terms of our current research and development collaboration agreement, we are also required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. These payments are expensed on a straight-line basis over the related development periods. The agreement also provides for various milestone payments to QIMR Berghofer based on achievement of certain developmental and regulatory milestones.

From time to time, we have entered into other license and collaboration agreements with other parties. For example, we licensed additional rights related to our MSK-partnered next-generation CAR T programs from MSK in May 2018 and we licensed rights related to our next-generation CAR T programs from Moffitt Cancer Center in August 2018, and we agreed to collaborate through sponsored research in connection with each of these licenses. We also licensed rights related to our MSK-partnered next-generation CAR T programs from the National Institutes of Health in December 2018.

Milestones and royalties under each of the above agreements are contingent upon future events and will be recorded as expense when it is probable that the milestones will be achieved or royalties are due. As of June 30, 2020 and December 31, 2019, there were no outstanding obligations for milestones and royalties under our license and collaboration agreements.

Cognate Agreement - In December 2019, we entered into a Commercial Manufacturing Services Agreement (the "Manufacturing Agreement") with Cognate BioServices, Inc. ("Cognate") to supersede the Development and Manufacturing Agreement that was entered into with Cognate in August 2015 and amended in December 2017, May 2018, November 2018, June 2019 and November 2019. Pursuant to the Manufacturing Agreement, Cognate provides manufacturing services for certain of our product candidates. The initial term of the Manufacturing Agreement is from January 1, 2020 until December 31, 2021 and is renewable with Cognate's approval for an additional one-year period. We may terminate the Manufacturing Agreement for convenience on six months' written notice to Cognate, or immediately if Cognate is unable to perform the services under the Manufacturing Agreement or fails to obtain or maintain certain necessary approvals. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of services for at least 90 days.

7. Commitments and Contingencies

License and Collaboration Agreements

Potential payments related to our license and collaboration agreements, including milestone and royalty payments, are detailed in Note 6.

Other Research and Development Agreements

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for pre-clinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination on notice. As of June 30, 2020 and December 31, 2019, there were no amounts accrued related to contract termination charges or minimum purchase volumes not being met.

Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record liabilities for these agreements as of June 30, 2020 and December 31, 2019.

Contingencies

From time to time, we may be involved in legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business or otherwise. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on our results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on us because of the defense costs, diversion of management resources and other factors. We are not currently involved in any material legal proceedings.

8. Stockholders' Equity

Our authorized capital stock consists of 520,000,000 shares, all with a par value of $0.0001 per share, of which 500,000,000 shares are designated as common stock and 20,000,000 shares are designated as preferred stock. There were no shares of preferred stock outstanding as of June 30, 2020 and December 31, 2019.

Equity Offerings

In the second quarter of 2020, we issued and sold 12,633,039 shares of common stock at a public offering price of $11.32 per share and pre-funded warrants to purchase 2,866,961 shares of common stock at a public offering price of $11.3199 per warrant in an underwritten public offering pursuant to a shelf registration on Form S-3. We granted the underwriters an option to purchase up to 2,325,000 additional shares of our common stock at a public offering price of $11.32, less underwriting discounts and commissions. The full option was exercised by the underwriters in June 2020. The gross proceeds from this public offering were $201.8 million, resulting in net proceeds of $189.3 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

Each pre-funded warrant entitles the holder to purchase one share of common stock at an exercise price of $0.0001 per share and expires seven years from the date of issuance. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise ("Maximum Ownership Percentage"). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%. As of June 30, 2020, none of these pre-funded warrants have been exercised, and all 2,866,961 pre-funded warrants were outstanding.

As part of our July 2019 underwritten public offering, we also issued and sold pre-funded warrants to purchase 2,945,026 shares of common stock with terms similar to those above. As of June 30, 2020, pre-funded warrants to purchase 2,888,526 shares of our common stock were outstanding.

ATM Facilities

In February 2019, we entered into a sales agreement (the "2019 ATM Facility") with Cowen and Company, LLC ("Cowen"), which provides for the sale, in our sole discretion, of shares of our common stock, in the aggregate offering price of up to $100.0 million through Cowen, as our sales agent. The issuance and sale of these shares by us pursuant to the 2019 ATM Facility are deemed "at the market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), and are registered under the Securities Act. We pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2019 ATM Facility.

In February 2020, we entered into a new sales agreement (the "2020 ATM Facility") with Cowen, which provides for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, as our sales agent. The 2020 ATM Facility is separate from and does not replace the 2019 ATM Facility in any way. The issuance and sale of these shares by us pursuant to the 2020 ATM Facility are deemed "at the market" offerings and are registered under the Securities Act of 1933, as amended. We will pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2020 ATM Facility.

During the three months ended June 30, 2020, we did not sell any common stock under the ATM facilities. During the six months ended June 30, 2020, we sold an aggregate of 1,528,216 shares of common stock under the 2019 ATM Facility, at an average price of $15.50 per share, for gross proceeds of $23.7 million and net proceeds of $23.0 million, after deducting commissions and other offering expenses payable by us. On January 3, 2020, we received net proceeds of approximately $1.2 million from sales of shares of common stock under the 2019 ATM Facility that occurred during December 2019. As of June 30, 2020, $25.9 million and $100.0 million of common stock remained available to be sold under the 2019 ATM Facility and 2020 ATM Facility, respectively, subject to certain conditions as specified in the sales agreements.

Equity Incentive Plans

Under the terms of the 2014 Equity Incentive Plan, as amended ("2014 EIP"), we may grant stock options, restricted stock awards ("RSAs") and RSUs to employees, directors, consultants and other service providers. RSUs generally vest over four years. In 2020, we granted performance-based awards to certain of our employees that provide for the issuance of common stock if specified Company performance criteria related to our clinical programs are achieved. The number of performance-based awards that ultimately vests depends upon if, when and which performance criteria are achieved, as well as the employee's continuous service, as defined in the 2014 EIP, through the date of vesting. The fair value of performance-based RSUs is determined as the closing stock price on the date of grant.

Stock options are granted at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that the exercise price of an option granted to a 10% shareholder cannot be less than 110% of the estimated fair value of the shares on the date of grant. Options granted generally vest over four years and expire in seven to ten years. As of June 30, 2020, a total of 14,127,804 shares of common stock were reserved for issuance under the 2014 EIP, of which 2,213,656 shares were available for future grant and 11,914,148 shares were subject to outstanding options and RSUs, including performance-based awards.

In February 2018, we adopted the 2018 Inducement Plan ("Inducement Plan"), under which we may grant options, stock appreciation rights, RSAs and RSUs to new employees. As of June 30, 2020, 1,141,086 shares of common stock were reserved for issuance under the Inducement Plan, of which 170,773 shares were available for future grant and 970,313 shares were subject to outstanding options and RSUs.

Restricted Stock Units

The following is a summary of RSU activity under our 2014 EIP and Inducement Plan:

	RSUs	
	Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2019	1,910,764	$ 26.93
Granted	3,657,440	$ 11.93
Forfeited	(408,614)	$ 19.75
Vested	(771,145)	$ 22.80
Unvested as of June 30, 2020	4,388,445	$ 15.82

As of June 30, 2020, there was $54.0 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.7 years. This excludes unrecognized stock-based compensation expense for performance-based RSUs that were deemed not probable of vesting in accordance with U.S GAAP.

Stock Options

The following is a summary of stock option activity under our 2014 EIP and Inducement Plan. The table below also includes the activity relating to options for 275,000 shares of our common stock which were issued in 2017 outside of these plans:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	6,934,262	$ 28.25		
Granted	2,341,925	11.63		
Exercised	(118,719)	13.52		
Forfeited or expired	(661,452)	31.15		
Outstanding as of June 30, 2020	8,496,016	$ 23.65	6.6	$ 8,270

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on June 30, 2020 and the exercise price of outstanding, in-the-money options. As of June 30, 2020, there was $63.3 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.9 years.

Reserved Shares

The following shares of common stock were reserved for future issuance under our equity incentive plans as of June 30, 2020:

	Total Shares Reserved
2014 Equity Incentive Plan	14,127,804
2018 Inducement Plan	1,141,086
2014 Employee Stock Purchase Plan	1,066,654
Total reserved shares of common stock	16,335,544

Stock-based Compensation Expense

Total stock-based compensation expense related to all employee and non-employee stock awards was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Research and development	$ 8,540	$ 6,672	$ 16,190	$ 12,737
General and administrative	5,408	8,529	10,402	14,733
Total stock-based compensation expense	$ 13,948	$ 15,201	$ 26,592	$ 27,470

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes included elsewhere in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Atara Biotherapeutics is a pioneer in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies forpatients with severe diseases, including solid tumors, hematologic cancers and autoimmune disease. With our lead program in Phase 3 clinical development, Atara is the most advanced allogeneic T-cell immunotherapy company and intends to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-associated diseases or other severe diseases through incorporation of engineered chimeric antigen receptors (CARs) or T-cell receptors (TCRs). Atara is applying this one platform to create a robust pipeline. Our strategic priorities are:

- ***Tab-cel®***: Atara's most advanced T-cell immunotherapy, tab-cel® (tabelecleucel), currently in Phase 3 development for patients with Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disease (EBV+ PTLD) who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-associated hematologic malignancies and solid tumors;
- ***ATA188***: T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis;
- ***CAR T Programs***:
    - ***ATA2271***: Autologous CAR T immunotherapy targeting solid tumors expressing the tumor antigen mesothelin;
    - ***ATA3271***: Allogeneic CAR T immunotherapy targeting mesothelin; and
    - ***ATA3219***: Allogeneic CAR T targeting CD19 and being developed as a potential best-in-class product, based on a next generation 1XX co-stimulatory domain and the innate advantages of EBV T cells as the foundation for an allogeneic CAR T platform.

Our T-cell immunotherapy platform includes the capability to progress both allogeneic and autologous programs and is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, and requires a complex logistics network. For our allogeneic programs, we select the appropriate set of cells for use based on a patient's unique immune profile. In addition, our manufacturing facility is capable of producing multiple types of therapies and Atara MatchMe™, our proprietary T-cell order management platform, is being developed to select and deliver the most appropriate treatments to the healthcare teams caring for patients.

We have entered into research collaborations with leading academic institutions such as Memorial Sloan Kettering Cancer Center (MSK), the Council of the Queensland Institute of Medical Research (QIMR Berghofer) and H. Lee Moffitt Cancer Center and Research Institute (Moffitt) to acquire rights to novel and proprietary technologies and programs.

We recognize that our clinical studies may not be available to all patients and we have established expanded access and compassionate use programs in instances where there is a significant patient need.

Pipeline

Tab-cel®

Atara's most advanced T-cell immunotherapy, tab-cel®, is in Phase 3 development for the treatment of patients with EBV+ PTLD who have failed rituximab or rituximab plus chemotherapy. Based on our market research, we estimate there were several hundred EBV+ PTLD patients who failed rituximab or rituximab plus chemotherapy in the U.S. in 2019. Tab-cel® is also under development for other EBV+ diseases with significant unmet medical need through a planned Phase 2 multi-cohort study.

While clinical study operations and the opening of additional Phase 3 study sites in the United States, Canada and Europe have been impacted by the spread of COVID-19, most sites are currently open for patient enrollment, and we believe we remain on track to initiate a biologics license application (BLA) submission for patients with EBV+ PTLD by the end of 2020. We continue to advance development of tab-cel® in Phase 3 for patients with EBV+ PTLD, for which the Company has obtained Breakthrough Therapy Designation (BTD) in the U.S. and PRIority MEdicines (PRIME) designation in the European Union (EU). We plan to conduct an interim analysis for the Phase 3 study in the third quarter of 2020 and to discuss the totality of tab-cel® data with the U.S. Food and Drug Administration (FDA) in a pre-BLA meeting prior to initiating the BLA submission. We remain in active discussions with the Pediatric Committee (PDCO) of the European Medicines Agency (EMA) regarding a Pediatric Investigation Plan (PIP). Following discussion with the PRIME team and after EMA approval of the PIP, we plan to submit a tab-cel® EU marketing authorization application for patients with EBV+ PTLD in 2021.

In 2019, after discussion and alignment with regulators, we combined MATCH and ALLELE into a single study (which we now refer to as the ALLELE study) that now consists of a hematopoietic cell transplants (HCT) cohort for EBV+ PTLD patients who have failed rituximab, and a single solid organ transplant (SOT) cohort for EBV+ PTLD patients who have failed rituximab with both chemotherapy and non-chemotherapy prior treatment experience. Additionally, we expect to expand the ALLELE study geographically to include clinical sites outside the U.S. We have submitted clinical trial applications (CTAs) to several European countries to enable opening European clinical sites in 2020, and our CTAs in the United Kingdom, France, Germany, Spain, Austria and Belgium have been approved.

We continue to pursue development of tab-cel® in earlier lines of therapy, including in our planned Phase 2 multi-cohort study. We expect to initiate enrollment in the second half of 2020 for a Phase 2 multi-cohort study of tab-cel® with the goal of expanding the potential label in PTLD and closely related diseases. We intend to focus on extending further into immunodeficiency-associated lymphoproliferative diseases (IA-LPDs) as the next step in the tab-cel® life cycle plan given the commonality of their EBV-driven mechanism of disease in immunocompromised patients, high unmet medical need and positive clinical data to date with tab-cel®. The multi-cohort study will evaluate both treatment-naïve and previously treated patients in six patient populations, including two cohorts with the potential to address front-line EBV+PTLD patients with significant unmet need as well as two cohorts with the potential to address EBV+ LPDs arising out of primary or acquired immune deficiencies, including EBV+ acquired immunodeficiency-associated lymphoproliferative disease (EBV+ AID-LPD) and EBV+ primary immunodeficiency-associated lymphoproliferative disease (EBV+ PID-LPD).

Our Phase 1b study of tab-cel® in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated nasopharyngeal carcinoma (NPC) achieved its safety endpoints and stable disease in a subset of patients. These data will be presented at an appropriate forum in the future. Based on a strategic prioritization to expand tab-cel® business potential through the significant opportunity in IA-LPDs, we will now focus our tab-cel® efforts on the initiation of the multi-cohort Phase 2 study and the planned BLA initiation in EBV+ PTLD. At this time, we will not initiate the Phase 2 portion of the NPC study in combination with pembrolizumab. We intend to generate additional translational data in NPC to further inform our strategy on this patient population.

ATA188

Atara is also developing ATA188, a T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). In the fourth quarter of 2017, we initiated an open label, single arm, multi-center, multi-national Phase 1 study with allogeneic ATA188 for patients with progressive MS (PMS). The primary objective of this Phase 1 study is to assess the safety of ATA188 in patients followed for at least one year after the first dose. Key secondary endpoints in the study include measures of clinical improvement, using recognized scales for MS symptoms, function and disability including Expanded Disability Status Scale (EDSS) Fatigue Severity Score, MS Impact Scale-29 (physical), Timed 25-Foot Walk (T25FW), 9-Hole Peg Test, 12-Item MS Walking Scale (MSWS-12) and Visual Acuity. Enrollment for the fourth and final Phase 1 dose escalation cohort was completed in the third quarter of 2019 and we presented initial efficacy and updated safety results from this study in September 2019 at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). These results were based on data as of July 29, 2019, and showed that across four planned dose cohorts, ATA188 was well tolerated in PMS patients, with no evidence of cytokine release syndrome, graft versus host disease or dose-limiting toxicities.

Safety and sustained disability improvement 12-month data for cohorts 1-3, and six-month data for cohort 4, were presented as a late-breaking e-poster presentation at the 2020 European Academy of Neurology Virtual Congress (EAN) held in May 2020. All patients in cohorts 1-3 showing sustained disability improvement (SDI) at six months maintained improvement at 12 months, and there was a higher proportion of patients showing SDI with increasing dose. SDI is defined as clinically significant improvement in EDSS or T25FW observed at two consecutive time points. While these data will need to be confirmed in a double-blind, placebo-controlled, randomized study, they indicate the potential for the first treatment option in progressive MS to halt or reverse the progression of disease. We believe these results align with the body of evidence supporting the important role of EBV-infected B cells in the chronic autoimmune pathology of MS. ATA188 was well-tolerated in patients with progressive forms of MS and no dose-limiting toxicities or fatal adverse events were reported. ATA188 treatment showed no clinically meaningful effect on cytokine levels and no dose-related safety trends were identified. Rhinorrhea (runny nose) was the only treatment-related event that occurred in more than one subject. We are re-treating patients with cohort 3 dose in the open-label extension (OLE) of the Phase 1a study and expect to present preliminary OLE data in an appropriate forum in the second half of 2020. Additionally, we expect to present 12-month clinical results for cohort 4 in an appropriate forum in the second half of 2020.

Following a six-month assessment of patients in cohort 3 of this study, we selected this cohort 3 dose to initiate the randomized, double-blind, placebo-controlled trial (RCT) evaluating the efficacy and safety of ATA188 in patients with progressive forms of MS. The study design allows for addition of the cohort 4 dose, if desired, based on the 12-month data for cohort 4 that will be available in the third quarter of 2020. This study enrolled its first patient in June 2020. In addition to measuring change in disability measures compared to baseline, especially SDI over time, the study will also include multiple measures of patients' function as well as various biomarkers.

ATA2271/ATA3271

Atara's next-generation CAR T immunotherapy programs include ATA2271 targeting mesothelin, which is a tumor antigen expressed on a number of solid tumors including mesothelioma, ovarian cancer, pancreatic cancer, non-small cell lung cancer and other tumors over-expressing mesothelin. ATA2271 is designed to improve efficacy persistence, and durability of response versus CD28/CD3z-based CARs by using a novel 1XX CAR co-stimulatory signaling domain and cell intrinsic checkpoint inhibition technology with a PD-1 dominant negative receptor (DNR).

Data from investigational new drug (IND) enabling studies for ATA2271 were presented at the American Association for Cancer Research (AACR) Virtual Meeting II in June 2020. These data support the first application of the combination of 1XX co-stimulatory domain and cell intrinsic checkpoint inhibition technology with a PD-1 DNR that are associated with less cell exhaustion, improvements in functional persistence, serial cell killing and in vivo efficacy, which was maintained through multiple tumor re-challenges when compared with first-generation CD28/CD3z-based mesothelin CAR. Our ATA2271 collaborators at MSK recently submitted an IND application to the FDA for patients with advanced mesothelioma.

We are also developing and have initiated IND-enabling studies for ATA3271, an off-the-shelf, allogeneic CAR T immunotherapy targeting mesothelin using a novel combination of 1XX CAR co-stimulatory signing domain and cell intrinsic checkpoint inhibition technology with a PD-1 DNR through our EBV T-cell platform.

ATA3219

We are also developing ATA3219, an off-the-shelf, allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies as a potential best-in-class therapy, using our next-generation 1XX CAR co-stimulatory domain and EBV T-cell platform.

In February 2020, an academic off-the-shelf, allogeneic CD19 CAR T clinical study using an allogeneic EBV T-cell construct and CD28/CD3z co-stimulatory domain for patients with relapsed/refractory B-cell malignancies was presented at the 2020 Transplantation and Cellular Therapy (TCT) Meetings. Findings from this study provided initial clinical proof-of-principle that an EBV T-cell platform has the potential to generate off-the-shelf, allogeneic CAR T immunotherapies with high response rates, durable responses and low risk of toxicity that can be rapidly delivered to patients.

We have initiated IND-enabling studies for ATA3219 and anticipate filing an IND in 2021.

Additional Programs and Platform Expansion Activities

In addition to the prioritized programs described above, we have a number of preclinical programs. For example, in August 2018, we entered into a strategic collaboration with Moffitt. As part of this relationship, we agreed to collaborate with Moffitt to develop multi-targeted CAR T immunotherapies designed to address cancers with diverse cell types that often become resistant to treatment, such as acute myeloid leukemia (AML) (ATA2321) and B-cell malignancies (ATA2431), and to make certain milestone and royalty payments associated with the collaboration targets. In addition, the collaboration includes the use of novel CAR T intracellular co-stimulatory domains that may improve CAR T proliferation when responding to an appropriate antigen and enhance CAR T persistence by reducing T-cell exhaustion.

We believe our platform will have utility beyond the current set of targets to which it has been directed.We continue to evaluate additional product candidates, including those derived from collaborations with our partners. We expect to further research and develop additional cellular therapies, which may include T-cell programs targeted against other antigens as well as engineered T-cell immunotherapies such as CAR T-cell programs. We believe that viral antigens are well suited to adoptive immunotherapy given that people with normal immune systems are able to mount robust responses to these viral targets, but immunocompromised patients and some cancer patients are not. We also continue to evaluate opportunities to license or acquire additional product candidates or technologies to enhance our existing platform.

Manufacturing

Our manufacturing facility in Thousand Oaks, California has the flexibility to manufacture multiple T-cell and CAR T immunotherapies while integrating research and process science functions to enable increased collaboration for rapid product development. Our research and development and process and analytical development labs are currently supporting preclinical development activities. Our facility is designed to global regulatory standards, and the required facility commissioning and qualification activities to support clinical manufacturing are complete. We are in the process of completing our facility's commercial production qualification activities for tab-cel® while building inventory according to our commercial product supply strategy.

We continue to scale our EBV T-cell manufacturing platform to improve product yields from a single donor leukapheresis and have generated data confirming the use of stirred-tank perfusion bioreactors to improve yield and cell growth productivity. We believe our scale-up technology can potentially be a key enabler to deliver biologic-like cost of goods manufactured and could be leveraged across our portfolio, including our CAR T programs.

In addition to our manufacturing facility, we also work with Cognate BioServices, Inc. (Cognate) pursuant to a Commercial Manufacturing Services Agreement (the Manufacturing Agreement) that we entered into in December 2019. Pursuant to the Manufacturing Agreement, Cognate provides manufacturing services for certain of our product candidates. The initial term of the Manufacturing Agreement runs until December 31, 2021 and is renewable with Cognate's approval for an additional one-year period. We may terminate the Manufacturing Agreement for convenience on six months' written notice to Cognate, or immediately if Cognate is unable to perform the services under the Manufacturing Agreement or fails to obtain or maintain certain necessary approvals. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of services for at least 90 days.

COVID-19 Business Update

We continue to closely monitor the impact of the ongoing COVID-19 pandemic on our business and operations and have taken steps to ensure the health and safety of our employees, staff, clinical site staff and patients and to maintain business continuity. Based on guidance issued by federal, state and local authorities, we have temporarily transitioned most of our employees and staff to a remote, work- from- home model, while maintaining essential in-person manufacturing and laboratory functions in order to advance key research, development and manufacturing priorities. We implemented safety protocols and procedures to support our onsite employees and staff.

In addition to implementing measures to protect the health and safety of our employees and staff, our clinical study and operational teams are working closely with clinical sites to ensure the safety of site staff and patients as well as preserve data integrity and access to treatment as appropriate. Where needed, remote study visits, leveraged tele-medicine, home health care, and other methods have been established to ensure continuity of care for patients while preserving key endpoint data.

To date, the COVID-19 pandemic has not materially impacted our or our partners' clinical, research and development, regulatory and manufacturing operations or timelines. We have experienced some transient delays in clinical trial site initiation and patient enrollment in certain of our clinical trials as a result of the evolving impact of the ongoing COVID-19 pandemic. For example, due to the COVID-19 pandemic, in April 2020 we temporarily paused the screening and enrollment of patients in our RCT for ATA188. We were able to resume such activities and enrolled the first patient in the study in June 2020. Our Phase 3 clinical trial of tab-cel® in patients with EBV+ PTLD has not been adversely impacted by the ongoing COVID-19 pandemic.

The full extent to which the COVID-19 pandemic may impact our business and operations is subject to future developments which are uncertain and difficult to predict. Further quarantines, shelter-in-place or similar restrictions and other actions taken or imposed by foreign, federal, state and local governments could adversely impact our or our partners' clinical, research and development, regulatory and manufacturing operations or timelines. We continue to monitor the impact of the COVID-19 pandemic on our business and operations and will seek to adjust our activities as appropriate.

For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and operations, see the section titled "Risk Factors" under Part II, Item 1A in this Quarterly Report on Form 10-Q.

Financial Overview

We have a limited operating history. Since our inception in 2012, we have devoted substantially all of our resources to identify, acquire and develop our product candidates, including conducting preclinical and clinical studies, acquiring or manufacturing materials for clinical studies, constructing our manufacturing facility and providing general and administrative support for these operations.

Our net losses were $151.0 million and $140.6 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $968.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. As of June 30, 2020, our cash, cash equivalents and short-term investments totaled $347.7 million, which we intend to use to fund our operations. In the second quarter of 2020, we completed an underwritten public offering of shares of common stock and pre-funded warrants and received aggregate net proceeds of $189.3 million.

Revenues

We have never generated revenues and have incurred losses since inception. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties.

Research and Development Expenses

The largest component of our total operating expenses since inception has been our investment in research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development employees, including stock-based compensation; expenses incurred under agreements with contract research organizations and investigative sites that conduct preclinical and clinical studies; the costs of acquiring and manufacturing clinical study materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs; and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

We plan to continue investment in the development of our product candidates. Our current planned research and development activities include the following:

- continuing to initiate sites and enroll patients in our Phase 3 clinical study of tab-cel® for the treatment of patients with EBV+ PTLD after HCT and SOT who have failed rituximab;
- process development, testing and manufacturing of drug supply to support clinical studies and IND-enabling studies;
- continuing development of ATA188 in progressive MS;
- continuing to develop product candidates based on our next-generation CAR T programs;

- continuing to develop our product candidates in additional indications, including tab-cel® for EBV+ cancers;
- continuing to develop other pre-clinical product candidates; and
- leveraging our relationships and experience to in-license or acquire additional product candidates or technologies.

In addition, we believe it is important to invest in the development of new product candidates to continue to build the value of our product candidate pipeline and our business. We plan to continue to advance our most promising early product candidates into preclinical development with the objective to advance these early-stage programs to human clinical studies over the next several years.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs, and timing of clinical studies and development of our product candidates will depend on a variety of factors, including:

- the availability of qualified drug supply for use in our ongoing Phase 3 or other clinical studies;
- the scope, rate of progress, and expenses of our ongoing clinical studies, potential additional clinical studies and other research and development activities;
- the potential review or reanalysis of our clinical study results;
- future clinical study results;
- uncertainties in clinical study enrollment rates or discontinuation rates of patients, including any potential impact of the COVID-19 pandemic;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- changing medical practice patterns related to the indications we are investigating;
- significant and changing government regulation;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the recent outbreak of COVID-19; and
- the timing and receipt of any regulatory approvals, as well as potential post-market requirements.

The process of conducting the necessary clinical research to obtain approval from the FDA and other regulators is costly and time consuming and the successful development of our product candidates is highly uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section of this report titled “1A. Risk Factors.” As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and benefits for legal, human resources, finance, commercial and other general and administrative employees, including stock-based compensation; professional services costs, including legal, patent, human resources, audit and accounting services; other outside services and consulting costs, including those related to pre-commercial activities; and information technology and facilities costs.

Interest and Other Income, net

Interest and other income, net consists primarily of interest earned on our cash, cash equivalents and short-term investments.

Critical Accounting Policies and Significant Judgments and Estimates

Except for the adoption of ASU No. 2016-13, as amended, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, and ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, and ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income* Taxes, none of which had a material impact to us as disclosed in Note 2 to our condensed consolidated financial statements, there have been no significant changes to our critical accounting policies and significant judgments and estimates during the six months ended June 30, 2020 from those disclosed in our management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 27, 2020.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2020 and 2019

Research and development expenses

Research and development expenses consisted of the following costs, by program, in the periods presented:

	Three Months Ended June 30,		Increase	Six Months Ended June 30,		Increase
	2020	2019	(Decrease)	2020	2019	(Decrease)
	(in thousands)			(in thousands)		
Tab-cel® expenses	$ 14,905	$ 11,252	$ 3,653	$ 29,703	$ 22,891	$ 6,812
ATA188, CAR T and other program expenses	6,097	9,102	(3,005)	10,212	15,208	(4,996)
Employee and overhead expenses	40,558	31,897	8,661	79,304	62,820	16,484
Total research and development expenses	$ 61,560	$ 52,251	$ 9,309	$ 119,219	$ 100,919	$ 18,300

Tab-cel® expenses were $14.9 million and $29.7 million in the three and six months ended June 30, 2020, respectively, as compared to $11.3 million and $22.9 million in the comparative 2019 periods. The increases were primarily due to increased production activity, as well as process performance qualification activities at our manufacturing facility.

ATA188, CAR T and other program expenses were $6.1 million and $10.2 million in the three and six months ended June 30, 2020, respectively, as compared to $9.1 million and $15.2 million in the comparative 2019 periods. The decreases were primarily related to lower clinical study, manufacturing and other outside services costs for programs that are no longer in active development.

Employee and overhead expenses were $40.6 million and $79.3 million in the three and six months ended June 30, 2020, respectively, as compared to $31.9 million and $62.8 million in the comparative 2019 periods. The increases were primarily due to higher compensation-related costs from increased headcount and higher facility-related costs in support of our continuing expansion of research and development activities. Relative to the 2019 comparative period, for the three months ended June 30, 2020, payroll and related costs increased by $7.1 million, facility-related costs increased by $1.6 million and outside services costs remained consistent. Relative to the 2019 comparative period, for the six months ended June 30, 2020, payroll and related costs increased by $13.3 million, facility-related costs increased by $2.9 million and outside services costs remained consistent.

Total research and development expenses for the three and six months ended June 30, 2020 have not been significantly impacted as a result of the COVID-19 pandemic.

General and administrative expenses

	Three Months Ended June 30,		Increase	Six Months Ended June 30,		Increase
	2020	2019	(Decrease)	2020	2019	(Decrease)
	(in thousands)			(in thousands)		
General and administrative expenses	$ 16,392	$ 23,284	$ (6,892)	$ 33,430	$ 42,507	$ (9,077)

General and administrative expenses decreased to $16.4 million and $33.4 million in the three and six months ended June 30, 2020, respectively, as compared to $23.3 million and $42.5 million in the comparative 2019 periods. The decreases in 2020 were primarily due to decreases in outside services costs and lower non-cash stock-based compensation expenses. Total general and administrative expenses for the three and six months ended June 30, 2020 have not been significantly impacted as a result of the COVID-19 pandemic.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012, we have funded our operations primarily through the issuance of common and preferred stock and pre-funded warrants to purchase common stock.

In the second quarter of 2020, we completed an underwritten public offering of 14,958,039 shares, inclusive of the exercise of the full option granted to the underwriters, of common stock at a public offering price of $11.32 per share and pre-funded warrants to purchase 2,866,961 shares of common stock at a public offering price of $11.3199 per warrant. We received net proceeds of approximately $189.3 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

In February 2019, we entered into a sales agreement (the 2019 ATM Facility) with Cowen and Company, LLC (Cowen), which provides for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, as our sales agent. The issuance and sale of these shares by us pursuant to the 2019 ATM Facility are deemed "at the market" offerings defined in Rule 415 under the Securities Act of 1933, as amended (the Securities Act), and are registered under the Securities Act. We pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2019 ATM Facility.

In February 2020, we entered into a new sales agreement (the "2020 ATM Facility") with Cowen, which provides for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, as our sales agent. The 2020 ATM Facility is separate from and does not replace the 2019 ATM Facility in any way. The issuance and sale of these shares by us pursuant to the 2020 ATM Facility are deemed "at the market" offerings and are registered under the Securities Act of 1933, as amended. We will pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2020 ATM Facility.

During the three months ended June 30, 2020, we did not sell any common stock under the ATM facilities. During the six months ended June 30, 2020, we sold an aggregate of 1,528,216 shares of common stock under the 2019 ATM Facility, at an average price of $15.50 per share for net proceeds of $23.0 million, after deducting commissions and other offering expenses payable by us. On January 3, 2020, we received net proceeds of approximately $1.2 million from sales of shares of our common stock under the 2019 ATM Facility that occurred during December 2019. As of June 30, 2020, $25.9 million and $100.0 million of common stock remained available to be sold under the 2019 ATM Facility and 2020 ATM Facility, respectively, subject to certain conditions as specified in the agreements.

We have incurred losses and negative cash flows from operations in each year since inception. As of June 30, 2020, we had an accumulated deficit of $968.9 million. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products. As such, we anticipate that we will continue to incur losses in the foreseeable future. Additionally, as a result of the COVID-19 outbreak, we have experienced, and may experience in the future, disruptions that could severely impact our business, preclinical studies and clinical trials. We expect that our operating expenses will continue to increase. As a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings including by utilizing our ATM facilities, through potential collaborations, partnering or other strategic arrangements, or a combination of the foregoing. However, 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 consequence, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. We may face similar difficulties in obtaining funding through debt financing or other arrangements. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses or other rights on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash, cash equivalents and short-term investments are held in bank and custodial accounts and consist of money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities. We expect that existing cash, cash equivalents and short-term investments as of June 30, 2020 will be sufficient to fund our planned operations into 2022.

Our cash, cash equivalents and short-term investments balances as of the dates indicated were as follows:

	June 30, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 74,511	$ 74,317
Short-term investments	273,201	184,792
Total cash, cash equivalents and short-term investments	$ 347,712	$ 259,109

Cash Flows

Comparison of the Six Months Ended June 30, 2020 and 2019

The following table details the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (123,680)	$ (124,789)
Investing activities	(91,398)	117,849
Financing activities	215,272	5,401
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 194	$ (1,539)

Operating activities

Net cash used in operating activities was $123.7 million in the 2020 period as compared to $124.8 million in the 2019 period. The decrease of $1.1 million was primarily due to decreased working capital usage and a decrease in accretion of investment discounts, partially offset by a $10.4 million increase in net loss.

Investing activities

Net cash used in investing activities in the 2020 period consisted of $228.2 million used to purchase available-for-sale securities and $3.4 million in purchases of property and equipment, partially offset by $140.2 million received from maturities and sales of available-for-sale securities. Net cash provided by investing activities in the 2019 period consisted primarily of $136.9 million received from maturities and sales of available-for-sale securities, partially offset by $17.6 million used to purchase available-for-sale securities and $1.5 million in purchases of property and equipment.

Financing activities

Net cash provided by financing activities in the 2020 period consisted primarily of $189.6 million of net proceeds received from the underwritten public offering of common stock and pre-funded warrants, $24.2 million of net proceeds received from the 2019 ATM Facility and $3.2 million of net proceeds from employee stock award transactions, partially offset by $1.4 million of taxes paid related to the net share settlement of RSUs. Net cash provided by financing activities in the 2019 period consisted primarily of $7.6 million net proceeds from the 2019 ATM Facility and $4.7 million of net proceeds from employee stock award transactions, partially offset by $6.7 million of taxes paid related to the net share settlement of RSUs.

Operating Capital Requirements and Plan of Operations

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the accumulated losses to increase as we continue the development of and seek regulatory approvals for our product candidates and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need to raise substantial additional funding in connection with our continuing and expected expansion of our operations.

We expect that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations into 2022. In order to complete the process of obtaining regulatory approval for any of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. In addition, we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings, through potential collaborations, partnering or other strategic arrangements, or a combination of the foregoing.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, costs and results of our ongoing and planned clinical and preclinical studies for our product candidates, including any potential impact of the COVID-19 pandemic;
- our success in establishing and scaling commercial manufacturing capabilities;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- subject to receipt of regulatory approval, costs associated with the commercialization of our product candidates and the amount of revenues received from commercial sales of our product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights;
- the extent to which we in-license or acquire other products and technologies; and
- the timing of capital expenditures, including the qualification of our manufacturing facility.

Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We expect to continue to seek access to the equity and debt capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses or other rights on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty, political change and other factors, including the ongoing COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we will be forced to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates.

Contractual Obligations and Commitments

We lease our corporate headquarters in South San Francisco, California under a non-cancellable lease agreement for approximately 13,670 square feet of office space. The lease expires in May 2021.

In February 2017, we entered into a lease agreement for approximately 90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California. The initial 15-year term of this lease commenced in February 2018, and the contractual obligations during the initial term are $16.4 million in aggregate. We have the option to extend this lease for two additional periods of ten and nine years, respectively, after the initial term. In connection with this lease, we were required to issue a letter of credit in the amount of $1.2 million to the landlord, which is recorded as long-term restricted cash in our condensed consolidated balance sheet.

In November 2018, we entered into a lease agreement for approximately 51,160 square feet of office space in Thousand Oaks, California. The initial term of this lease expires in February 2026. The contractual obligations during the initial term are $8.5 million in aggregate. We have the option to extend the lease for an additional period of five years after the initial term.

In May 2019, we entered into a new lease agreement for our approximately 8,800 square feet of office and lab space in Aurora, Colorado. The term of this lease expires in April 2024. The contractual obligations during the lease term are $1.1 million in aggregate.

Our contractual obligations primarily consist of our obligations under non-cancellable operating and finance leases and contracts we enter into in the normal course of business with clinical research organizations for clinical studies, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies and supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, with the exception of one of our contract manufacturing agreements which we may terminate for convenience upon six months' written notice. There have been no material changes to our contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

During the six months ended June 30, 2020, there were no material changes to our interest rate risk disclosures, market risk disclosures and foreign currency exchange rate risk disclosures reported in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 27, 2020.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2020. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of June 30, 2020 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the six months ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation to minimize the impact to the design and operating effectiveness of our internal controls.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Investors should carefully consider all of the risk factors and uncertainties described below, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated and combined financial statements and related notes, before investing in our common stock.

The risks described below may not be the only ones relating to our company and additional risks that we currently believe are immaterial may also affect us.If any of these risks, including those described below, materialize, our business, competitive position, reputation, financial condition, results of operations, cash flows and future prospects could be seriously harmed. In these circumstances, the market price of our common stock could decline, and investors may lose all or a part of their investment.

Risks Related to Our Financial Results and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that product candidates will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales or otherwise to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the six months ended June 30, 2020, we reported a net loss of $151.0 million and we had an accumulated deficit of $968.9 million as of June 30, 2020.

We do not expect to generate revenues for the foreseeable future, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, in-license or develop, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fails in clinical studies or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We anticipate that our expenses will increase in the future as we continue to invest in research and development of our existing product candidates, investigate and potentially acquire new product candidates and expand our manufacturing and commercialization activities.

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

Our company was formed in August 2012. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights and conducting product development activities for our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical studies, obtain regulatory approval, consistently manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization for any of our product candidates. In addition, the adoptive immunotherapy technology underlying our T-cell product candidates, including our next-generation CAR T programs, is new and largely unproven. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may not be as accurate as they could be if we had a longer operating history or approved products on the market.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, any of our quarterly or annual periods' results are not indicative of future operating performance.

We currently have no source of revenues. We may never generate revenues or achieve profitability.

To date, we have not generated any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including any of our current product candidates, and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical studies with positive results;
- complete and submit regulatory submissions to the FDA, EMA or other agencies and obtain regulatory approval for indications for which there is a commercial market;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- develop manufacturing and distribution processes for our novel T-cell immunotherapy product candidates;
- develop commercial quantities of our products at acceptable cost levels;
- establish and maintain adequate supply of our products, including cell lines with sufficient breadth to treat patients;
- establish and maintain manufacturing relationships with reliable third parties or qualify our manufacturing facility such that we can maintain the supply of our products by ensuring adequate, manufacturing of bulk drug substances and drug products in a manner that is compliant with global legal requirements;
- achieve market acceptance of our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property portfolio;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice, treatment guidelines or a reduction in the incidence of the addressable disease, we may not generate significant revenues from sales of our products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our T-cell immunotherapy product candidates, and the advancement and expansion of our preclinical research pipeline. We also expect to continue to expend resources for the development and manufacturing of product candidates and the technology we have licensed or have an exclusive right to license from our partners. These expenditures will include costs associated with research and development, potentially acquiring or licensing new product candidates or technologies, conducting preclinical and clinical studies and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. Under the terms of our license agreements with each of our partners, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize on our own. In addition, other unanticipated costs may arise. Because the design and outcome of our ongoing, planned and anticipated clinical studies is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates, if clinical studies are successful, including any costs from post-market requirements;
- the cost of commercialization activities for our product candidates, if any of these product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates for clinical studies in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to develop, acquire or in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing technologies or other adverse market developments.

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations into 2022. As of June 30, 2020, we had total cash, cash equivalents and short-term investments of $347.7 million. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We do not have any committed external source of funds. While we expect to continue to opportunistically seek access to additional fundsthrough additional public or private equity offerings or debt financings, through potential collaborations, partnering or other strategic arrangements, or a combination of the foregoing, additional funds may not be available when we need them on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of common stock, resulting from the ongoing COVID-19 pandemic. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us.

We may seek required additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or if existing holders of warrants exercise their rights to purchase common stock, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. To the extent equity valuations, including the trading price of our common stock, are depressed as a result of economic disruptions and uncertainty concerning the COVID-19 pandemic or other factors, the potential magnitude of this dilution will increase. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses or other rights on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or take other actions that are adverse to our business.

Risks Related to the Development of Our Product Candidates

We are early in our development efforts and have only a small number of product candidates in clinical development. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be materially harmed.

We are early in our development efforts, and only a small number of our product candidates are in clinical development. The majority of our product candidates are currently in preclinical development. We have invested substantial resources in identifying and developing potential product candidates, conducting preclinical and clinical studies, manufacturing activities and preparing for the potential commercial launch of our product candidates. Our ability to generate revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on many factors, including the following:

- completion of preclinical and clinical studies with positive results;
- receipt of regulatory approvals from applicable authorities;
- protecting our rights in our intellectual property portfolio, including by obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing or making arrangements with third-party manufacturers or qualifying our own manufacturing facility for clinical and commercial manufacturing purposes;
- developing manufacturing and distribution processes for our novel T-cell product candidates and next-generation CAR T programs;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our products, if approved by applicable regulatory authorities, whether alone or in collaboration with others;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other therapies;
- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which could materially harm our business.

Our business and operations have been affected by and could be materially and adversely affected in the future by the effects of health epidemics and pandemics, including the evolving and ongoing effects of the COVID-19 pandemic. The COVID-19 pandemic continues to impact our business and operations and could materially and adversely affect our business and operations in the future, as well as the businesses and operations of third parties on which we rely.

Our business could be adversely affected by health epidemics and pandemics, including the ongoing COVID-19 pandemic, which has presented a substantial public health and economic challenge around the world and has affected, and continues to affect, our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The COVID-19 pandemic has resulted in transient, episodic travel and other restrictions to reduce the spread of the disease and included a California executive order and many other foreign, state and local orders (including in locations where we operate facilities), which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings and order cessation of non-essential travel. As a result of the ongoing COVID-19 pandemic, the work-from-home model we implemented for most of our employees remains in place. We continue to maintain essential in-person manufacturing and laboratory functions in order to advance key research, development and manufacturing priorities. In connection with these measures, we may be subject to claims based upon, arising out of, or related to COVID-19 and our actions and responses thereto, including any determinations that we may make to continue to operate or to re-open our facilities where permitted by applicable law. The effects of current and potential future state executive orders, local shelter-in-place orders, government-imposed quarantines and our work-from-home policies and other similar, and perhaps more severe, actions may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Further quarantines, shelter-in-place or similar restrictions and other actions taken by foreign, federal, state and local governments, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur or could be reinstated, related to the ongoing COVID-19 pandemic or other infectious diseases, could impact our manufacturing capabilities and third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, standard transportation channels have been impacted and we and other manufacturing, testing, product disposition, contract manufacturing organizations and external testing laboratories are subject to enhanced risk assessment and mitigation measures. In addition, there have been and may continue to be interruptions in the supply of leukapheresis collections, which supply raw materials used in our products. Our clinical trials may be affected by health epidemics and have been affected by the ongoing COVID-19 pandemic. Clinical site initiation and patient enrollment have experienced delays as a result of the ongoing COVID-19 pandemic, including due to the prioritization of hospital resources toward COVID-19 and away from clinical trials or as a result of changing practice patterns that impact the diseases our trials address. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services or if patients contract COVID-19 or are forced to quarantine. For example, while most clinical trial sites for our studies, including our Phase 3 clinical trial of tab-cel® in patients with EBV+ PTLD, remain open to enrollment for patients, some sites have limited the screening and enrollment of new patients due to governmental orders related to COVID-19, or fear of infection of COVID-19, have limited, and may continue to limit, patients' abilities to access clinical sites. COVID-19-related travel restrictions may also interrupt key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses. At the outset of the COVID-19 pandemic, we observed a temporary slow-down in stem cell and solid organ transplant volumes, which may have decreased the eligible patient population for the tab-cel® phase 3 study. In April 2020, we initiated a temporary pause in the screening and enrollment of patients in our RCT of ATA188 in patients with progressive MS. Although we were able to resume the screening and enrollment of patients in our RCT of ATA188and enrolled the first patient in the study in June 2020, the ongoing COVID-19 pandemic may require us to institute another pause in the screening and enrollment of patients in our RCT. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted.

In addition, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic and the various actions taken in response to it may be difficult to assess or predict, the pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

While we expect the ongoing COVID-19 pandemic to continue to adversely affect our business operations, the extent of the impact on our clinical development and regulatory efforts and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. In addition, to the extent the evolving effects of the ongoing COVID-19 pandemic adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

Our future success is dependent on the regulatory approval of our product candidates.

We do not have any products that have gained regulatory approval. Currently, our prioritized clinical-stage product candidates include tab-cel® and ATA188. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our product candidates in a timely manner.

We cannot commercialize product candidates in the U.S. without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical and clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

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

- disagreement with the design or conduct of our clinical studies;
- failure to demonstrate positive benefit/risk profile of the product candidate for its proposed indication;
- failure of clinical studies to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical studies;
- the insufficiency of data collected from clinical studies of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

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

In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates, such as our novel T-cell product candidates and next-generation CAR T programs, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EMA and FDA for existing autologous CAR T therapies, such as Novartis's Kymriah® and Gilead's Yescarta®, may not be indicative of what these regulators may require for approval of our therapies. Moreover, our product candidates may not perform successfully in clinical studies or may be associated with adverse events that distinguish them from that which have previously been approved, such as existing autologous CAR T therapies. For instance, allogeneic product candidates may result in adverse events not experienced with autologous products.

Our development and commercialization activities could be harmed or delayed by governmental or regulatory delays due to limitations on the availability of governmental and regulatory agency personnel to review regulatory filings or engage with us, as a result of the COVID-19 pandemic, changes to governmental regulatory requirements, policies, guidelines or priorities, reallocation, or availability of government resources, or for other reasons, which may significantly delay the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays.

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

Our T-cell immunotherapy product candidates and our next-generation CAR T programs represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.

Our future success is dependent on the successful development of T-cell immunotherapies and our next-generation CAR T programs in general and our development product candidates in particular. Because these programs, particularly our pipeline of allogeneic T-cell product candidates that are bioengineered from donors, represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing our product candidates subject us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of T-cell immunotherapies, particularly allogeneic T-cell product candidates;
- developing and deploying consistent and reliable processes for procuring blood from consenting third-party donors, isolating T cells from the blood of such donors, activating the isolated T cells against a specific antigen, characterizing and storing the resulting activated T cells for future therapeutic use, selecting and delivering a sufficient supply and breadth of appropriate partially HLA-matched cell line from among the available T-cell lines, and finally infusing these activated T cells into patients;

- utilizing these product candidates in combination with other therapies (e.g. immunomodulatory approaches such as checkpoint inhibitors), which may increase the risk of adverse side effects;
- educating medical personnel regarding the potential side effect profile of each of our product candidates, particularly those that may be unique to our allogeneic T-cell product candidates and to our next-generation CAR T programs;
- understanding and addressing variability in the quality of a donor's T cells, which could ultimately affect our ability to manufacture product in a reliable and consistent manner;
- developing processes for the safe administration of these products, including long-term follow-up and registries, for all patients who receive these product candidates;
- manufacturing our product candidates to our specifications and in a timely manner to support our clinical studies and, if approved, commercialization;
- sourcing clinical and, if approved by applicable regulatory authorities, commercial supplies for the materials used to manufacture and process these product candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities ahead of and after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of diseases beyond those initially addressed by our current product candidates.

We cannot be sure that the manufacturing processes used in connection with our T-cell immunotherapy product candidates will yield a sufficient supply of satisfactory products that are safe, pure and potent, comparable to those T cells produced by our partners historically, scalable or profitable.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical studies, or, if one of our product candidates is approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics or of patients to provide consent to receive a novel treatment despite its regulatory approval. The FDA or other applicable regulatory authorities may require specific post-market studies or additional information that communicates the benefits or risks of our products. New data may reveal new risks of our product candidates at any time prior to or after regulatory approval.

Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel therapy, may decide the therapy is too complex to adopt without appropriate training or not cost-efficient, and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

The results of preclinical studies or earlier clinical studies are not necessarily predictive of future results. Our existing product candidates in clinical studies, and any other product candidate we advance into clinical studies, may not have favorable results in later clinical studies or receive regulatory approval.

Success in preclinical studies and early clinical studies does not ensure that later clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical studies, even after seeing promising results in earlier preclinical studies or clinical studies. Despite the results reported in earlier preclinical studies or clinical studies for our product candidates, we do not know whether the clinical studies we may conduct, or clinical studies in progress, will demonstrate adequate efficacy and safety to result in regulatory approval to market tab-cel®, ATA188, any product candidates resulting from our next-generation CAR T programs or any of our other product candidates in any particular jurisdiction.

Tab-cel® has been predominantly evaluated in single-center studies under investigator-sponsored INDs held by MSK and in our EAP, utilizing different response criteria and endpoints from those we may utilize in later clinical studies. The findings may not be reproducible in late phase studies we conduct. For instance, the current protocol for our ALLELE study is designed to rule out a 20% ORR as the null hypothesis. This means that if the lower bound of the 95% confidence interval on ORR among patients receiving at least one dose of tab-cel® exceeds 20% at the end of the study, then the study would be expected to meet the primary endpoint for the treatment of PTLD. For example, assuming enrollment of 33 patients in a cohort of ALLELE, an observed ORR above approximately 37% would be expected to meet the primary endpoint for that cohort. In addition, our amended ALLELE study protocol includes an interim analysis as well as a final study analysis. Depending on discussions with regulators, we may, for example, file a marketing application on the basis of interim data from a subset of the required patients or file a marketing application on the basis of the final data. A marketing application based on interim data would impact the required ORR. If conditional marketing authorization is granted from the European Commission, we may be subject to ongoing obligations, including the need to provide additional clinical data at a later stage to confirm a positive benefit/risk balance.

For regulatory approvals of tab-cel®, we plan on using independent radiologist and/or oncologist assessment of responses which may not correlate with the investigator-reported assessments. In addition, the Phase 2 clinical studies with tab-cel® enrolled a heterogeneous group of patients with a variety of EBV-associated malignancies, including EBV+ PTLD after HCT and EBV+ PTLD after SOT. These Phase 2 studies were not prospectively designed to evaluate the efficacy oftab-cel® in the treatment of a single disease state for which we may later seek approval.

Moreover, final study results may not be consistent with interim study results. Efficacy data from prospectively designed studies may differ significantly from those obtained from retrospective subgroup analyses. In addition, clinical data obtained from a clinical study with an allogeneic product candidate may not yield the same or better results as compared to an autologous product candidate. If later-stage clinical studies do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical studies.

Interim "top line" and preliminary data from clinical studies that we or our partners may announce or share with regulatory authorities from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we or our partners may announce or share with regulatory authoritiesinterim "top line" or preliminary data from clinical studies. Interim data from completed clinical studies are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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 previously announced. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could impact the regulatory approval of, and significantly harm the prospects of any product candidate that is impacted by the applicable data.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical and clinical studies.

We may experience delays in our ongoing or future clinical studies and we do not know whether clinical studies will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical studies of any of our product candidates on clinical hold in the future. Clinical studies may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delays in enrollment due to travel, shelter-in-place or quarantine policies, or other factors, related to the ongoing COVID-19 pandemic or other epidemics or pandemics;
- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a study design that we are able to execute;
- delay or failure in obtaining authorization to commence a study or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a study;

- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations(CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- delay or failure in obtaining institutional review board (IRB) approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical study at each site;
- withdrawal of clinical study sites from our clinical studies or the ineligibility of a site to participate in our clinical studies;
- delay or failure in recruiting and enrolling eligible subjects to participate in a study;
- delay or failure in subjects completing a study or returning for post-treatment follow-up;
- clinical sites and investigators deviating from study protocol, failing to conduct the study in accordance with regulatory requirements, or dropping out of a study;
- an FDA or other regulatory authority clinical site inspection reveals serious violations of regulations applicable to clinical investigations, which may result in requests for additional data analyses and/or rejection of data deemed unreliable;
- inability to identify and maintain a sufficient number of study sites, including because potential study sites may already be engaged in competing clinical study programs enrolling the same population;
- failure of our third-party clinical study managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new study sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign authorities, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol for a study;
- a decision by the FDA, the IRB, comparable foreign authorities, or us, or a recommendation by a data safety monitoring board or comparable foreign authority, to suspend or terminate clinical studies at any time for safety issues or for any other reason;
- unacceptable benefit/risk profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities and breadth of appropriate partially HLA matched cell lines from among the available T-cell lines to start or to use in clinical studies;
- lack of adequate funding to continue a study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical study.

Patient enrollment, a significant factor in the timing of clinical studies, is affected by many factors including:

- the size and nature of the patient population;
- the possibility that the rare diseases that many of our product candidates address are under-diagnosed;
- changing medical practice patterns or guidelines related to the diseases or conditions we are investigating;
- the severity of the disease under investigation, our ability to open clinical study sites;
- the proximity of subjects to clinical sites;
- the patient referral practices of physicians;
- the design and eligibility criteria of the clinical study;
- ability to obtain and maintain patient consents;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical studies;

- our or our partner's ability to manufacture the requisite materials for a study;
- risk that we do not have appropriately matched HLA cell lines;
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the diseases or conditions we are investigating; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the ongoing COVID-19 pandemic.

As an example, we activated additional clinical sites over the course of 2018 and increased HLA coverage during this period. As a result, enrollment in our studies was limited in the early part of 2018 and increased through the course of the year as we increased clinical sites and HLA coverage. However, in May 2019, we announced that enrollment in our Phase 3 studies of tab-cel® for patients with EBV+ PTLD was proceeding slower than anticipated. Many of our product candidates are designed to treat rare diseases, and as a result, the pool of potential patients with respect to a given disease is small. We may not be able to initiate or continue to support clinical studies of tab-cel®, ATA188 or any other product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these studies as required by the FDA or other regulatory authorities. We have also experienced a delay in clinical trial site initiation and patient enrollment in certain of our clinical trials, including our Phase 3 clinical trial of tab-cel®, as a result of the evolving impact of the ongoing COVID-19 pandemic, and if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our clinical development timelines. Even if we are able to enroll a sufficient number of patients in our clinical studies, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our studies may be delayed or our studies could become too expensive to complete.

We rely on CROs, other vendors and clinical study sites to ensure the proper and timely conduct of our clinical studies, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

If we experience delays or quality issues in the conduct, completion or termination of any clinical study of our product candidates, the approval and commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical studies will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any delays in completing our clinical studies for our product candidates may also decrease the period of commercial exclusivity. In addition, many of the factors that could cause a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical studies, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our studies could reveal an unacceptably high severity and incidence of side effects, or risks that outweigh the benefits of our product candidates. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the study or result in potential product liability claims.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of that product;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to conduct post-marketing studies;

- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

The FDA often approves new cancer therapies initially only for use in patients with relapsed or refractory metastatic disease. We expect to initially seek approval of tab-cel® and our other product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials.

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive second or later lines of therapy, and who have the potential to benefit from treatment with our product candidates, are based on our current beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or our own market research, and may prove to be incorrect, including if the COVID-19 pandemic and associated responses impact our ability to engage with key stakeholders within the transplant center in person. Further, new studies or market research may change the estimated incidence or prevalence of these diseases, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we expect our lead product candidate, tab-cel®, to initially target a small patient population that suffers from aggressive EBV+PTLD who have failed rituximab or rituximab plus chemotherapy. At the outset of the COVID-19 pandemic, we initially observed a temporary slow-down in stem cell and solid organ transplant volumes. These reductions were transient, but if a reduction in such volumes resumes, it could result in lower PTLD incidence and thus reduce the demand for tab-cel®. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. Both the FDA and the EMA have granted us orphan designation for tab-cel® for EBV+ PTLD after HCT or SOT.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not be maintained or effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a new drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

BTD by the FDA and PRIME designation by the EMA may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

Although we have obtained BTD and PRIME designation for tab-cel® for EBV+ PTLD in the U.S. and the EU, respectively, this may not lead to faster development or regulatory review and does not increase our likelihood of success. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the study can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for priority review. PRIME designation supports the development and accelerated review by the EMA of new therapies to treat patients with unmet medical need.

Designation as a breakthrough therapy is within the discretion of the FDA, and access to PRIME is at the discretion of the EMA. Receipt of a BTD or PRIME designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA or EMA review procedures, respectively, and does not assure ultimate approval by the FDA or EMA, respectively. In addition, the FDA or EMA, respectively, may later decide that the product no longer meets the conditions for qualification and rescind the BTD or PRIME designation or decide that the time period for FDA or EMA, respectively, review or approval will not be shortened.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the U.S., to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. Clinical studies accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the U.S. require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our contract manufacturing organizations (CMOs) and CROs for any post-approval clinical studies that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (cGMP), current Good Clinical Practices (GCP), current good tissue practices (cGTP) and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products.

Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the Department of Justice (the DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS), state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. will be heavily scrutinized by comparable foreign entities and stakeholders. For example, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

Regulations, guidelines and recommendations published by various government agencies and organizations may affect the use of our product candidates.

Changes to regulations, recommendations or other guidelines advocating alternative therapies for the indications we treat could result in decreased use of our products. For example, although treatment with EBV-specific T cells is recognized as a recommended treatment for persistent or progressive EBV+ PTLD as set forth in the 2017 National Comprehensive Cancer Network Guidelines, future guidelines from governmental agencies, professional societies, practice management groups, private health/science foundations and other organizations could lead to decreased ability of developing our product candidates, or decreased use of our products once approved by applicable regulatory authorities.

We may not successfully identify, acquire, develop or commercialize new potential product candidates.

Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in-license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through in-licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in-license or acquire them.

We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses.

We may desire to form strategic alliances, create joint ventures or collaborations, enter into licensing arrangements with third parties or acquire products or business, in each case that we believe will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time-consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive benefit/risk profile. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction.

Risks Related to Manufacturing

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

Concurrently with the license of our existing product candidates, we acquired manufacturing process know-how and, in some cases, inventory of process intermediates and clinical materials from our partners. Transferring manufacturing processes, testing and associated 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. Each stage is retroactively and concurrently verified to be compliant with appropriate regulations. As a result, there is a risk that all relevant know-how was not adequately transferred to us from our partners or that previous execution was not compliant with applicable regulations.

In addition, we need to conduct significant development and scale-up work to transfer these processes and manufacture each of our product candidates for various studies, clinical studies and commercial launch readiness. To the extent we elect to transfer manufacturing within our network, we are required to demonstrate that the product manufactured in the new or “receiving” facility is comparable to the product manufactured in the original or “sending” facility. The inability to demonstrate to each of the applicable regulatory authorities that comparable drug product was manufactured could delay the development of our product candidates.

The processes by which our product candidates are manufactured were initially developed by our partners for clinical purposes. We intend to evolve the existing processes with our partners to support advanced clinical studies and commercialization requirements. Developing commercially viable manufacturing processes is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical studies or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidates will be made could be adversely affected by the ongoing COVID-19 pandemic, earthquakes and other natural or man-made disasters, equipment failures, labor shortages, power failures, and numerous other factors. In addition, there have been, and there may continue to be, interruptions in the supply of leukapheresis collections related to the COVID-19 pandemic, which supply raw materials used in our product candidates. If we are unable to obtain such raw materials or other necessary raw materials in a timely manner, our business operations and manufacturing capabilities could be adversely affected.

The process of manufacturing cellular therapies is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, impact to key product quality attributes, and other supply disruptions. Product defects can also occur unexpectedly. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, these manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because our T-cell immunotherapy product candidates are manufactured from the blood of third-party donors, the process of manufacturing is susceptible to the availability of the third-party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be 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. This type of contaminations could result in delays in the manufacture of products which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects. Furthermore, our allogeneic products ultimately consist of many individual cell lines, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell line for therapeutic use in a patient requires close coordination between clinical operations, supply chain and quality assurance personnel.

Any adverse developments affecting manufacturing operations for our product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the supply of our drug product which could delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

We intend to manufacture a majority of our product candidates ourselves. Delays in receiving regulatory approvals for product candidates produced in our manufacturing facility could delay our development plans and thereby limit our ability to generate revenues.

The research and development and process and analytical development labs within our manufacturing facility in Thousand Oaks, California are currently supporting preclinical development activities. The facility commissioning and qualification activities required to support production at our facility were completed in 2018. Product-specific qualification to support clinical development is complete and commercial production qualification activities are ongoing. If the appropriate regulatory approvals for manufacturing product candidates in our facility are delayed, we may not be able to manufacture sufficient quantities of our product candidates, which would limit our development activities and our opportunities for growth.

In addition to the similar manufacturing risks described in "Risks Related to Our Dependence on Third Parties," our manufacturing facility will be subject to ongoing, periodic inspection by the FDA, EMA or other comparable regulatory agencies to ensure compliance with cGMP and GTP. Our failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical study, or may delay or prevent filing or approval of commercial marketing applications for our product candidates. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical studies, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facility. Without further investment, advances in manufacturing techniques may render our facility and equipment inadequate or obsolete.

A number of the product candidates in our portfolio, if approvedby applicable regulatory authorities, may require significant commercial supply to meet market demand. In these cases, we may need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our product candidates in a sufficient quantity to meet future demand.

If our sole clinical or commercial manufacturing facility or our CMO is damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.

If any manufacturing facility in our manufacturing network, or the equipment in these facilities, is either damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of a facility or its equipment, we may not be able to transfer manufacturing to a third party in the time required to maintain supply. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements or may require regulatory approval before selling any products manufactured at that facility. Such an event could delay our clinical studies or reduce our commercial product sales.

Currently, we maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

Risks Related to Our Dependence on Third Parties

Maintaining clinical and commercial timelines is dependent on our end-to-end supply chain network to support manufacturing; if we experience problems with our third party suppliers we may delay development and/or commercialization of our product candidates.

We rely in part on our CMOs or our partners for the current production of our product candidates and the acquisition of materials incorporated in or used in the manufacturing or testing of our product candidates. Our CMOs or partners are not our employees, and except for remedies available to us under our agreements with our CMOs or partners, we cannot directly control whether or not they devote sufficient time and resources, including experienced staff, to the manufacturing of supply for our ongoing clinical, nonclinical and preclinical programs.

To meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of tab-cel®, ATA188, any product candidates resulting from our next-generation CAR T programs or any other product candidates, we will need to transition the manufacturing of these materials to a CMO or our own facility. Regardless of where production occurs, we will need to develop relationships with suppliers of critical starting materials or reagents, increase the scale of production and demonstrate comparability of the material produced at these facilities to the material that was previously produced. Transferring manufacturing 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 would expect additional comparability work will also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know-how and data has been adequately incorporated into the manufacturing process until the completion of studies (and the related evaluations) intended to demonstrate the comparability of material previously produced with that generated by our CMO.

If we are not able to successfully transfer and produce comparable product candidates, our ability to further develop and manufacture our product candidates may be negatively impacted.

While our manufacturing facility in Thousand Oaks, California provides us with flexibility within our manufacturing network, we still may need to identify additional CMOs for continued production of supply for some of our product candidates. Given the nature of our manufacturing processes, the number of CMOs who possess the requisite skill and capability to manufacture our T-cell immunotherapy product candidates is limited. We have not yet identified alternate suppliers in the event the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them.

Manufacturing cellular therapies is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product candidate or intermediate would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our product candidates at costs, or in sufficient quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA or comparable regulatory authorities not agree with our product candidate specifications and comparability assessments for these materials, further clinical development of our product candidate could be substantially delayed and we would incur substantial additional expenses.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial resources to meet its obligations under the manufacturing agreement, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture 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 or nonrenewal of the agreement 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 regulatory 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 limited control over our manufacturers' compliance with these regulations and standards and although we monitor our manufacturers, we depend on them to provide honest and accurate information. Any failure by our third-party manufacturers to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, 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 studies, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

We depend on third party suppliers for key materials used to produce our product candidates. Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate for an ongoing clinical study could considerably delay initiation or completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If raw materials or components cannot be purchased or fail to meet approved specifications, the commercial launch of our product candidates could be delayed, or there could be a shortage in supply, which could impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements – both that we own or possess or that are owned or possessed by our partners that are in-licensed to us – to protect the intellectual property related to our technology and product candidates. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license, many of which are critical to our intellectual property protection and our business. For example, the product candidates and platform technology we have licensed from our partners are protected primarily by patent or patent applications of our partners that we have licensed and as confidential know-how and trade secrets. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office (USPTO) and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the U.S. or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in these patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable.

Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek a license from a third party who owns intellectual property that may be useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all.

In addition, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

We and our partners have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our partners were the first to file any patent application related to a product candidate. We or our partners may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and *inter partes* and post-grant review proceedings before the USPTO the European Patent Office and other non-U.S. patent offices.

Even if granted, patents have a limited lifespan. In the U.S., the natural expiration of a patent generally occurs 20 years after it is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical studies or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates.

Furthermore, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government has certain rights to these patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to practice the invention for or on behalf of the U.S. These rights may permit the government to disclose confidential information on which we rely to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in any inventions that result from government-funded research may be subject to certain requirements to manufacture products embodying these inventions in the U.S.

If we are sued for infringing the intellectual property rights of third parties, the resulting litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and *inter partes* and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our 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 third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, patent applications covering our product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing their claims.

If we or our partners are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until the relevant patent expired. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us.

We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates.

Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. In the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any of these license agreements may require us to pay royalties and other fees that could be significant. As a result of all of the foregoing, any actual or threatened intellectual property claim could prevent us from developing or commercializing a product candidate or force us to cease some aspect of our business operations.

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

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the U.S. may be less extensive than those in the U.S. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the U.S. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the U.S., or from selling or importing infringing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the U.S. These infringing products may compete with our product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

We have in-licensed a significant portion of our intellectual property from our partners. If we breach any of our license agreements with these partners, we could lose the ability to continue the development and potential commercialization of one or more of our product candidates.

We hold rights under license agreements with our partners, including MSK, QIMR Berghofer and Moffitt that are important to our business. Our discovery and development platform is built, in part, around patent rights in-licensed from our partners. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations, we may be liable to pay damages and our counterparties may have a right to terminate the affected license. The termination of any license agreement with one of our partners would materially adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product candidates and our ability to commercialize the affected product candidates. Furthermore, a disagreement under any of these license agreements may harm our relationship with the partner, which could have negative impacts on other aspects of our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our partners may elect to initiate legal proceedings to enforce or defend our or our partners' intellectual property rights, to protect our or our partners' trade secrets or to determine the validity or scope of our intellectual property rights. Any claims that we or our partners assert against perceived infringers could also provoke these parties to assert counterclaims against us or our partners alleging that we or our partners infringe their intellectual property rights or that our intellectual property rights are invalid.

Interference or derivation proceedings provoked by third parties, brought by us or our partners, or brought by the USPTO or any non-U.S. patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, *inter partes* review, post-grant review or other pre-issuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could require us or our partners to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our partners a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Any intellectual property proceedings can be expensive and time-consuming. Our or our partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our partners can. Accordingly, despite our or our partners' efforts, we or our partners may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as in the U.S. Even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. The T-cell immunotherapy product candidates and platform technology we have licensed from our partners are protected primarily as confidential know-how and trade secrets. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the U.S. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the medical community, including hospitals and outpatient clinics.

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidates as demonstrated in clinical studies;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians and patients of the drug as a safe and effective treatment;
- the administrative and logistical burden of treating patients;
- the adoption of novel cellular therapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our products as well as competitive products;
- the development of manufacturing and distribution processes for our product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the U.S. and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. In some countries such as the U.S., greater cost-shifting from the payor to the patient is also a trend, and higher patient copayments or other administrative burdens could lead to reduced demand from patients or healthcare professionals. This could particularly be the case in a challenging economic climate, such as during the ongoing COVID-19 pandemic. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval, and ultimately our ability to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the U.S. Third-party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Current and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government's comparative effectiveness research and established a new Medicare Part D coverage gap discount program.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U.S. Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act (CARES Act), which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In January 2013, the American Taxpayer Relief Act of 2012 (the ATRA) was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There remain judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the Affordable Care Act. For example, the President signed Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While the U.S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, eliminating the implementation of certain mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In December 2018, a Texas District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. In December 2019, the U.S. Court of Appeals for the 5th Circuit upheld the Texas District Court ruling that the individual mandate was unconstitutional and remanded the case back to the Texas District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. In March 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall of 2020.

It is unclear how this litigation and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. The U.S. Congress may consider and adopt other legislation to repeal and replace all or certain elements of the Affordable Care Act. Any other executive, legislative or judicial action to "repeal and replace" all or part of the Affordable Care Act may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier. Policy changes, including potential modification or repeal of all or parts of the Affordable Care Act or the implementation of new healthcare legislation, could result in significant changes to the healthcare system which may adversely affect our business in unpredictable ways.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product candidates for which we obtain regulatory approval and our ability to set a price that we believe is fair for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product candidates, if any, may be. In the U.S., the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. For example, in the U.S., there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the U.S. presidential administration's budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. In March 2020, the administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, in May 2018, the U.S. presidential administration previously laid out a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, the presidential administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. Although some of these and other proposals may require additional authorization to become effective, members of Congress and the presidential administration have indicated that they will continue to seek new legislative or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Furthermore, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

In addition, there is significant uncertainty regarding the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our collaborators, may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Additionally, our commercial opportunities will be reduced or eliminated if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence of our current or future target diseases. Competition could result in reduced sales and pricing pressure on our product candidates, if approved by applicable regulatory authorities. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

There are currently no FDA- or EMA-approved products for the treatment ofEBV+ PTLD. However, some marketed products and therapies are used off-label in the treatment of EBV+ PTLD, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing product candidates for EBV+ PTLD and other EBV-associated diseases including: Viracta Therapeutics, Inc., which is conducting a Phase 1b/2 clinical study for nanatinostat (formerly named tractinostat, or VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV+ lymphomas, AlloVir (formerly known as ViraCyte), which has completed a Phase 2 clinical study for Viralym-M (ALVR105), an allogeneic, multi-virus T-cell product that targets six viruses including EBV and is planning to initiate several Phase 3 studies in 2020 and Tessa Therapeutics Pte Ltd., which has a Phase 3 autologous EBV-specific T-cell therapy (TT10) and a preclinical product candidate that is an allogeneic CD30-targeted CAR EBV-specific T-cell therapy.

Competition in the MS market is high with at least 18 therapies, including three generics, approved for the treatment of relapsing forms of MS (RMS), including clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in the U.S. and EU. There are many competitors in the RMS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Zeposia® (ozanimod), marketed by Bristol Myers Squibb, and Vumerity™ (diroximel fumarate), marketed by Biogen, was approved in the U.S. for the treatment of RMS, and Mayzent® (siponimod), marketed by Novartis, was approved in the EU for the same indication. There are numerous development candidates in Phase 3 studies for RMS including TG Therapeutics' anti-CD20 monoclonal antibody ublituximab and EMD Serono's BTK inhibitor, evobrutinib. Novartis and J&J have completed Phase 3 studies of their anti-CD20 monoclonal antibody, ofatumumab, and sphingosine-1-phosphate receptor 1 (S1P1) modulator, ponesimod, respectively, and have sought regulatory approval for these candidates in the U.S. and EU.

Two therapies have been approved for the treatment of non-relapsing, progressive forms of MS. Ocrevus® is approved in the U.S. and EU for the treatment of PPMS. Mitoxantrone, which is now generic, is approved to treat SPMS, without relapses, in the U.S.

The SPMS and PPMS markets have active development pipelines and additional novel agents could be approved in the future. At least one development candidate is being evaluated in Phase 3 studies for progressive forms of MS including primary and secondary progressive MS. This is AB Science's masitinib, a tyrosine kinase inhibitor. Medicinova is planning to initiate a Phase 3 study of its PDE inhibitor, ibudilast (MN166) in patients with non-relapsing secondary progressive MS.

There are currently three autologous CAR T therapies approved in the U.S. and/or EU: Novartis' Kymriah® (tisagenlecleucel) and Gilead/Kite's Yescarta® (axicabtagene ciloleucel) and Tecartus™ (brexucabtagene autoleucel). Bristol-Myers Squibb has filed BLAs to the US FDA for lisocabtagene maraleucel (liso-cel)(November 2020 PDUFA) and for idecabtagene vicleucel with bluebird bio. There are many CAR-mediated cell therapies in development, and, although the majority are autologous, they include allogeneic and off-the-shelf cell therapies. There are multiple allogeneic CAR platforms being developed with differences in approaches to minimize instances of donor cells recognizing the patient's body as foreign or rejection of the donor cells by the patient's body. These approaches include the use of gene-editing to remove the TCR and the use of cell types without a TCR. The majority of clinical stage allogeneic CAR programs utilize alpha beta T cells as the cell type and gene editing of the T-cell receptor and HLA as the preferred technology approach, however, other strategies are also in development. It is possible that some of these other approaches will have more favorable characteristics than the approach we utilize, which would result in them being favored by potential partners or customers over our products. Depending on the diseases that we target in the future, we may face competition from both autologous and allogeneic CAR therapies and other modalities (e.g. small molecules, antibodies) in the indication of interest.

Many of the approved or commonly used drugs and therapies for our current or future target diseases, includingEBV+ PTLD and MS, are well established and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs and nutritional supplements are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. We expect that, if any of our product candidates are approved, they will be priced at a significant premium over competitive generic products. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies or if they are acquired by larger companies. These third parties compete with us in recruiting and retaining qualified scientific, commercial and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

We expect the product candidates we develop will be regulated as biological products (biologics) and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the U.S. as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We are at any early stage of establishing an organization that will be responsible for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without a sufficiently scaled, appropriately timed and trained internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

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

As of June 30, 2020, we had 425 employees. We have made the decision to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates. In particular, we may need to add substantial numbers of additional personnel and other resources to support our development and potential commercialization of our product candidates. As our development and commercialization plans and strategies continue to develop, or as a result of any future acquisitions, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources will increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our preclinical and clinical studies effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

As our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and preclinical and clinical studies effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

Risks Related to Our Business Generally

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our executive officers and other key employees and the loss of the services of any of our executive officers or other key employees, including scientific, technical or management personnel, could impede the achievement of our corporate objectives.

Our success depends on our ability to recruit, retain, manage and motivate our employees. Although we enter into employment agreements or offer letters with our employees, these documents provide for “at-will” employment, which means that any of our employees could leave our employment at any time, with or without notice. Competition for skilled personnel in our industry and geographic regions is intense and may limit our ability to hire and retain qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards that vest over time. The value to employees of equity awards may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, privacy and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute, which governs our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates;
- the federal physician sunshine requirements under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, as defined by this law, and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations;
- state and foreign laws and regulations that are analogous to the federal laws and regulations described in the preceding subsections of this risk factor, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; some state laws require drug manufacturers to report information regarding pricing and marketing information related to payments and other transfers of value to physicians and other healthcare providers; some state and local laws require the registration of pharmaceutical sales representatives; and other state laws require the protection of the privacy and security of health information, which may differ from each other in significant ways and often are not preempted by HIPAA.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical studies, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical study sites or entire study programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical study participants;
- significant costs to defend the related litigation;
- substantial monetary awards to study subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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 with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, 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. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could adversely affect our business, financial condition, results of operations and prospects.

Our business and operations would suffer in the event of computer system failures or security breaches.

Our internal computer systems, and those of our partners, our CROs, our CMOs, and other business vendors on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural or man-made disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. Additionally, the increased usage of computers operated on home networks due to the shelter-in-place or similar restrictions related to the COVID-19 pandemic may make our systems more susceptible to security breaches. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical study data from completed, ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

Changes in tax laws or regulations that are applied adversely to us or our customers may have an adverse effect on our business, cash flows, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the Tax Act), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any other newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. However, given our valuation allowance position, the Tax Act is not expected to have a significant impact on our effective tax rate, cash tax expenses or net deferred tax assets.

Our ability to use net operating loss carryforwards to offset future taxable income, and our ability to use tax credit carryforwards, may be subject to certain limitations.

Our ability to use our federal and state net operating losses (NOLs) to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

As of December 31, 2019, we reported U.S. federal and state NOLs of approximately $547.7 million and $695.4 million, respectively. Our federal NOLs generated prior to 2018 aggregating to $77.1 million will continue to be governed by the NOL tax rules as they existed prior to the adoption of the Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Many states have similar laws, and our state NOLs will begin to expire in 2032. Accordingly, these federal and state NOLs could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, as modified by the CARES Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the utilization of such federal NOLs arising in taxable years beginning after 2020 is limited to 80% of current year taxable income. Not all states conform to the Tax Act or CARES Act and other states have varying conformity to the Tax Act or CARES Act.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended(the Code), our ability to utilize these NOLs and other tax attributes, such as federal tax credits, in any taxable year may be limited if we have experienced an "ownership change." Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year testing period. Similar rules may apply under state tax laws. We completed a Section 382 study of transactions in our stock through December 31, 2019 and concluded that we have experienced ownership changes since inception that we believe under Section 382 of the Code will result in limitations in our ability to use certain of our NOLs and credits. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, the amount of the NOLs and tax credit carryforwards presented in our financial statements could be limited and, in the case of NOLs generated in 2017 and before, may expire unused. Any such material limitation or expiration of our NOLs may harm our future operating results by effectively increasing our future tax obligations.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Two of our corporate locations are located in California, an area prone to earthquakes and fires. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, including, for example, the ongoing COVID-19 pandemic.

Risks Related to Ownership of Our Common Stock

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

Our stock price has fluctuated in the past and can be expected to be volatile in the future. From January 1, 2018 through June 30, 2020, the reported sale price of our common stock has fluctuated between $4.52 and $54.45 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In particular, the ongoing COVID-19 pandemic has further heightened the volatility of the stock market for biopharmaceutical companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or products or our competitors' product candidates or products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical studies of our product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;

- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other risks described in this "Risk Factors" section.

In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies, including in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and healthcare spending and delivery, including the possible repeal and/or replacement of all or portions of the Affordable Care Act or changes in tariffs and other restrictions on free trade stemming from U.S. and foreign government policies, or for other reasons, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These market fluctuations may adversely affect the trading price of our common stock.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and divert management's attention and resources, which could result in delays of our clinical studies or commercialization efforts.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and principal stockholders own a significant portion of our outstanding common stock. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock. The interests of our significant stockholders may not always coincide with the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the market price for our common stock.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, certain holders of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We have incurred and will continue to incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Stock Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted and will adopt additional rules and regulations, such as mandatory "say on pay" voting requirements, that now apply to us. Stockholder activism, the current political environment and the potential for future regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and make some activities more time-consuming and costly. To the extent these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock in one or more transactions at prices and in a manner we determine from time to time. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options or warrants, and any additional shares issued in connection with acquisitions or in-licenses, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. To the extent equity valuations, including the trading price of our common stock, are depressed as a result of economic disruptions and uncertainty concerning the COVID-19 pandemic or other factors, the potential magnitude of this dilution will increase. Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, non-employee directors and consultants. Future grants of RSUs, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock.

Some terms of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation (Certificate of Incorporation) and amended and restated bylaws (Bylaws), as well as Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include terms that:

- permit our board of directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- establish that our board of directors is divided into three classes, with each class serving three-year staggered terms, which makes it more difficult to replace a majority of our directors in a short period of time;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by our board of directors, the chairperson of our board of directors or our chief executive officer.

Any of the factors listed above may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management.

In addition, because we are incorporated in Delaware, we are governed by Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any term of our Certificate of Incorporation or Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. In the event securities or industry analysts who cover us downgrade our stock or publish unfavorable research about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	6/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	6/20/2014	
4.1	Form of Pre-Funded Warrant to Purchase Common Stock	8-K	001-36548	4.1	5/28/2020	
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification by Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1(1)	Certifications of Chief Executive Officer and Principal Financial and Accounting Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Schema Document					X
101.CAL	Inline XBRL Calculation Linkbase Document					X
101.LAB	Inline XBRL Labels Linkbase Document					X
101.PRE	Inline XBRL Presentation Linkbase Document					X
101.DEF	Inline XBRL Definition Linkbase Document.					X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, formatted in Inline XBRL.					X

(1) The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

ATARA BIOTHERAPEUTICS, INC.

Date: August 5, 2020

By: /s/ Pascal Touchon
Pascal Touchon
President and Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

By: /s/ Utpal Koppikar
Utpal Koppikar
Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Pascal Touchon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Atara Biotherapeutics, 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: August 5, 2020

/s/ Pascal Touchon
Pascal Touchon
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Utpal Koppikar certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Atara Biotherapeutics, 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: August 5, 2020

/s/ Utpal Koppikar
Utpal Koppikar
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Atara Biotherapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2020, as filed with the Securities and Exchange Commission (the "Report"), Pascal Touchon, Chief Executive Officer of the Company, and Utpal Koppikar, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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: August 5, 2020

/s/ Pascal Touchon
Pascal Touchon
Chief Executive Officer
(Principal Executive Officer)

/s/ Utpal Koppikar
Utpal Koppikar
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.