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

FORM 10-Q

☒ Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended June 30, 2020

☐ Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____.

Commission File Number: **001-37939**

MARKER THERAPEUTICS, INC.

(Name of registrant in its charter)

DELAWARE	**45-4497941**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3200 Southwest Freeway, Suite 2240 **Houston, Texas**	**77027**
(Address of principal executive offices)	(Zip Code)
(713) 400-6400	
(Issuer's telephone number)	

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 $0.001 per share	MRKR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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, non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "accelerated filer", "large accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of July 31, 2020, the Company had 46,617,632 shares of common stock issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

MARKER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (Unaudited)	December 31, 2019 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,124,187	$ 43,903,949
Prepaid expenses and deposits	2,632,514	1,526,442
Interest receivable	3,440	56,189
Total current assets	34,760,141	45,486,580
Non-current assets:		
Property, plant and equipment, net	1,592,094	417,528
Construction in progress	2,629,141	—
Right-of-use assets, net	9,542,228	455,174
Total non-current assets	13,763,463	872,702
Total assets	**$ 48,523,604**	**$ 46,359,282**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 4,528,021	$ 1,757,680
Lease liability	456,065	204,132
Warrant liability	—	31,000
Total current liabilities	4,984,086	1,992,812
Non-current liabilities:		
Lease liability, net of current portion	9,025,273	280,247
Total non-current liabilities	9,025,273	280,247
Total liabilities	14,009,359	2,273,059
Commitments and contingencies (see Note 10)	—	—
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value, 150 million shares authorized, 46.6 million and 45.7 million shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	46,617	45,728
Additional paid-in capital	374,828,385	371,573,909
Accumulated deficit	(340,360,757)	(327,533,414)
Total stockholders' equity	34,514,245	44,086,223
Total liabilities and stockholders' equity	**$ 48,523,604**	**$ 46,359,282**

See accompanying notes to these unaudited condensed consolidated financial statements.

MARKER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Grant income	$ 466,785	$ —	$ 466,785	$ —
Total revenues	466,785	—	466,785	—
Operating expenses:				
Research and development	4,277,052	3,152,445	8,093,670	5,985,140
General and administrative	2,547,289	2,721,120	5,374,284	5,526,895
Total operating expenses	6,824,341	5,873,565	13,467,954	11,512,035
Loss from operations	(6,357,556)	(5,873,565)	(13,001,169)	(11,512,035)
Other income (expense):				
Change in fair value of warrant liabilities	—	(7,000)	31,000	(16,000)
Interest income	15,857	310,174	142,826	638,719
Net loss	**$ (6,341,699)**	**$ (5,570,391)**	**$ (12,827,343)**	**$ (10,889,316)**
Net loss per share, basic and diluted	$ (0.14)	$ (0.12)	$ (0.28)	$ (0.24)
Weighted average number of common shares outstanding	46,572,739	45,501,078	46,328,561	45,483,513

See accompanying notes to these unaudited condensed consolidated financial statements.

MARKER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)

	For the Three Months Ended June 30, 2020				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at April 1, 2020	**46,532,522**	**$ 46,532**	**$ 373,467,697**	**$ (334,019,058)**	**$ 39,495,171**
Stock-based compensation	85,110	85	1,360,688	—	1,360,773
Net loss	—	—	—	(6,341,699)	(6,341,699)
Balance at June 30, 2020	**46,617,632**	**$ 46,617**	**$ 374,828,385**	**$ (340,360,757)**	**$ 34,514,245**

	For the Six Months Ended June 30, 2020				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2020	**45,728,831**	**$ 45,728**	**$ 371,573,909**	**$ (327,533,414)**	**$ 44,086,223**
Warrants exercised for cash	458,334	459	549,541	—	550,000
Issuance of common stock as commitment fee for future financing	345,357	345	(345)	—	—
Stock-based compensation	85,110	85	2,705,280	—	2,705,365
Net loss	—	—	—	(12,827,343)	(12,827,343)
Balance at June 30, 2020	**46,617,632**	**$ 46,617**	**$ 374,828,385**	**$ (340,360,757)**	**$ 34,514,245**

	For the Three Months Ended June 30, 2019				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at April 1, 2019	**45,484,483**	**$ 45,484**	**$ 366,989,803**	**$ (311,424,375)**	**$ 55,610,912**
Stock-based compensation	29,040	29	1,363,238	—	1,363,267
Net loss	—	—	—	(5,570,391)	(5,570,391)
Balance, June 30, 2019	**45,513,523**	**$ 45,513**	**$ 368,353,041**	**$ (316,994,766)**	**$ 51,403,788**

	For the Six Months Ended June 30, 2019				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2019	**45,440,704**	**$ 45,440**	**$ 365,400,748**	**$ (306,105,450)**	**$ 59,340,738**
Stock options exercised for cash	11,980	12	57,732	—	57,744
Warrants exercised for cash	1,799	2	5,377	—	5,379
Stock-based compensation	59,040	59	2,889,184	—	2,889,243
Net loss	—	—	—	(10,889,316)	(10,889,316)
Balance, June 30, 2019	**45,513,523**	**$ 45,513**	**$ 368,353,041**	**$ (316,994,766)**	**$ 51,403,788**

See accompanying notes to these unaudited condensed consolidated financial statements.

MARKER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	For the Six Months Ended June 30,	
	2020	**2019**
Cash Flows from Operating Activities:		
Net loss	$ (12,827,343)	$ (10,889,316)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	124,627	39,811
Changes in fair value of warrant liabilities	(31,000)	16,000
Stock-based compensation	2,705,365	2,889,243
Amortization on right-of-use assets	96,973	89,178
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(1,106,072)	(349,750)
Interest receivable	52,749	10,023
Accounts payable and accrued expenses	2,770,341	225,135
Lease liability	(187,068)	(89,907)
Net cash used in operating activities	(8,401,428)	(8,059,583)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(1,299,193)	(305,382)
Purchase of construction in progress	(2,629,141)	—
Net cash used in investing activities	(3,928,334)	(305,382)
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	—	57,744
Proceeds from exercise of warrants	550,000	5,379
Net cash provided by financing activities	550,000	63,123
Net decrease in cash	(11,779,762)	(8,301,842)
Cash and cash equivalents at beginning of the period	43,903,949	61,746,748
Cash and cash equivalents at end of the period	$ 32,124,187	$ 53,444,906

	For the Six Months Ended June 30,	
	2020	**2019**
Supplemental schedule of non-cash financing activities:		
Issuance of common stock as commitment fee for future financing	$ 345	$ —
Recognition of right-of-use assets and lease liability from new operating lease agreements	$ 9,184,027	$ —

See accompanying notes to these unaudited condensed consolidated financial statements.

MARKER THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2020
(Unaudited)

NOTE 1: NATURE OF OPERATIONS

Marker Therapeutics, Inc., a Delaware corporation (the "Company" or "we"), is a clinical-stage immuno-oncology company specializing in the development and commercialization of novel T cell-based immunotherapies and innovative peptide-based vaccines for the treatment of hematological malignancies and solid tumor indications. The Company's MultiTAA T cell technology is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens, which are tumor targets, and kill tumor cells expressing those targets. These T cells are designed to recognize multiple tumor targets to produce broad spectrum anti-tumor activity.

NOTE 2: BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results.

The results for the condensed consolidated statement of operations are not necessarily indicative of results to be expected for the year ending December 31, 2020 or for any future interim period. The condensed consolidated balance sheet at June 30, 2020 has been derived from unaudited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2019 and notes thereto included in the Company's annual report on Form 10-K filed on March 12, 2020.

NOTE 3: LIQUIDITY AND FINANCIAL CONDITION

As of June 30, 2020, the Company had cash and cash equivalents of approximately $32.1 million. The Company's activities since inception have consisted principally of acquiring product and technology rights, raising capital, and performing research and development. Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things, its ability to access potential markets; secure financing; successfully progress its product candidates through preclinical and clinical development; obtain regulatory approval of one or more of its product candidates; maintain and enforce intellectual property rights; develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances and collaborations. From inception, the Company has been funded by a combination of equity and debt financings.

The Company expects to continue to incur substantial losses over the next several years during its development phase. To fully execute its business plan, the Company will need to complete certain research and development activities and clinical trials. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities will span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through issuances of debt and equity securities and, in the longer term, revenue from sales of its product candidates, if approved.

Based on the Company’s revised clinical and research and development plans and its revised timing expectations related to the progress of its programs, and buildout of manufacturing and research facilities, and expansion of the Company’s corporate headquarters, discussed in Footnotes #7 and #10 below, the Company expects that its cash and cash equivalents as of June 30, 2020 will enable the Company to fund its operating expenses and capital expenditure requirements into the second quarter of 2021, as such these factors raise substantial doubt regarding the Company's ability to continue as a going concern. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could utilize its available capital resources sooner than it currently expects. Furthermore, the Company's operating plan may change, and it may need additional funds sooner than planned in order to meet operational needs and capital requirements for product development and commercialization. Because of the numerous risks and uncertainties associated with the development and commercialization of the Company's product candidates and the extent to which the Company may enter into additional collaborations with third parties to participate in their development and commercialization, the Company is unable to estimate the amounts of increased capital outlays and operating expenditures associated with its current and anticipated clinical trials. The Company's future funding requirements will depend on many factors, as it:

- initiates or continues clinical trials of its product candidates;
- continues the research and development of its product candidates and seeks to discover additional product candidates;
- seeks regulatory approvals for any product candidates that successfully complete clinical trials;
- maintains and enforces intellectual property rights;
- establishes sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates that may receive regulatory approval;
- evaluates strategic transactions the Company may undertake; and
- enhances operational, financial and information management systems and hires additional personnel, including personnel to support development of product candidates and, if a product candidate is approved, commercialization efforts.

These factors raise substantial doubt regarding the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which implies that the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

In addition to the foregoing, based on the Company’s current assessment, the Company does not expect any material impact on its long-term liquidity due to the COVID-19 pandemic. However, the Company will continue to assess the effect of the pandemic on its operations, including its clinical programs. The extent to which the COVID-19 pandemic will impact the Company’s business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing the Company’s ability to access capital, which could in the future negatively affect the Company’s liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Company’s business and the value of its common stock.

NOTE 4: SIGNIFICANT ACCOUNTING POLICIES

Property and equipment - Construction in Progress

On June 26, 2020, the Company entered into a lease for a manufacturing facility in Houston, Texas. In connection with the manufacturing facility, the Company has incurred costs pursuant to an agreement with a vendor to design, engineer, build and eventually install modular cleanrooms in a manufacturing facility. $2.6 million is recorded in fixed assets - construction in progress on the balance sheet as of June 30, 2020. Upon completion of the facility's construction, all costs associated with the buildout will be recorded as manufacturing equipment and amortized over the estimated useful life of the facility.

New Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed, the Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on its financial position or results of operations upon adoption.

Recent Accounting Standards Not Yet Adopted

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its condensed consolidated financial statements and related disclosures.

NOTE 5: NET LOSS PER SHARE

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per common share is computed similarly to basic loss per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

The following table sets forth the computation of net loss per share for the three and six months ended June 30, 2020 and 2019, respectively:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (6,341,699)	$ (5,570,391)	$ (12,827,343)	$ (10,889,316)
Denominator:				
Weighted average common shares outstanding	46,572,739	45,501,078	46,328,561	45,483,513
Net loss per share data:				
Basic and Diluted	$ (0.14)	$ (0.12)	$ (0.28)	$ (0.24)

The following securities, rounded to the nearest thousand, were not included in the diluted net loss per share calculation because their effect was anti-dilutive for the periods presented:

	For the Six Months Ended June 30,	
	2020	2019
Common stock options	5,842,000	4,568,000
Common stock purchase warrants	21,381,000	22,979,000
Common stock warrants - liability treatment	—	27,000
Potentially dilutive securities	27,223,000	27,574,000

NOTE 6: PROPERTY AND EQUIPMENT

Property and equipment consist of the following as of June 30, 2020 and December 31, 2019, respectively:

	Estimated Useful Lives	June 30, 2020	December 31, 2019
Lab equipment	5 Years	$ 1,065,000	$ 111,000
Manufacturing equipment	5 Years	—	—
Computers, equipment and software	3-5 Years	299,000	211,000
Office furniture	5 Years	179,000	178,000
Leasehold improvements	Lesser of lease term or estimated useful life	279,000	23,000
Total		1,822,000	523,000
Less: accumulated depreciation		(230,000)	(105,000)
Construction in progress		2,629,000	—
Total fixed assets, net		$ 4,221,000	$ 418,000

Depreciation expense for the three months ended June 30, 2020 and 2019 was approximately $0.09 million and $0.03 million, respectively. Depreciation expense for the six months ended June 30, 2020 and 2019 was approximately $0.1 million and $0.04 million, respectively.

On June 26, 2020, the Company entered into a lease for a manufacturing facility in Houston, Texas. In connection with the manufacturing facility, the Company has incurred costs pursuant to an agreement with a vendor to design, engineer, build and eventually install modular cleanrooms in a manufacturing facility. $2.6 million is recorded in fixed assets - construction in progress on the balance sheet as of June 30, 2020. Upon completion of the facility's construction, all costs associated with the buildout will be recorded as manufacturing equipment and amortized over the estimated useful life of the facility.

In connection with the research facility that the Company opened during the second quarter of 2020, the Company incurred approximately $1.0 million of costs acquiring necessary lab equipment to carry out its experiments.

NOTE 7: LEASES

On March 23, 2020, the Company entered into an agreement to expand its corporate headquarters in Houston, Texas, which is expected to commence in the third or fourth quarter of 2020. The initial lease term is ten years with two five-year renewal options. Fixed rent payments under the initial term are approximately $5.6 million. Additionally, the Company is also responsible for its share of operating expenses.

On April 30, 2020, the Company entered into a lease for a research facility in Houston, Texas. The lease term is 71 months. Fixed rent payments under the initial term are approximately $1.1 million. In the second quarter of 2020, the Company recorded right-of use assets and related operating lease liabilities of approximately $0.9 million as result of entering into the lease for our research facility.

On June 26, 2020, the Company entered into a lease for a manufacturing facility in Houston, Texas. The initial lease term is ten years from the expected commencement date in the third quarter of 2020 with two five-year renewal options. Fixed rent payments under the initial term are approximately $11.1 million. Additionally, the Company is also responsible for its share of operating expenses. In the second quarter of 2020, the Company recorded right-of use assets and related operating lease liabilities of approximately $8.3 million as result of entering into the lease for its manufacturing facility.

The Company also leases office space under agreements classified as operating leases that expire on various dates through 2022. The Company has a remaining lease liability of $0.2 million and $0.2 million of the related right-of-use asset resulting from the lease of its corporate headquarters in Houston, Texas, which expires in 2021. In addition, the Company has a remaining lease liability of $0.2 million and $0.2 million of the related right-of-use asset from the lease of its Jacksonville, Florida office space, which expires in 2022.

Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right-of-use assets as the Company is not reasonably certain to exercise the options. Variable expenses generally represent the Company's share of the landlord's operating expenses. The Company does not act as a lessor or have any leases classified as financing leases.

The Company excludes short-term leases having initial terms of 12 months or less from the new accounting guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term. The Company has two lease agreements, an office at the Florida Atlantic Research and Development Authority and laboratory space located at the Texas Medical Center in Houston, which are included in short-term lease expense below.

At June 30, 2020, the Company had operating lease liabilities of approximately $9.5 million and right-of-use assets of approximately $9.5 million, which were included in the condensed consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases for the three and six months ended June 30, 2020 and 2019, respectively:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease expense summary:				
Operating lease expense	$ 103,000	$ 55,000	$ 158,000	$ 110,000
Short-term lease expense	3,000	24,000	22,000	46,000
Variable lease expense	5,000	23,000	16,000	38,000
Total	$ 111,000	$ 102,000	$ 196,000	$ 194,000

Other information:	
Operating cash flows - operating leases	$ 248,000
Weighted-average remaining lease term as of June 30, 2020 – operating leases	9.6
Weighted-average discount rate as of adoption date – operating leases	5.6 %

Maturities of the Company's operating leases, excluding short-term leases, are as follows:

Six months ended December 31, 2020	$ 286,000
Year ended December 31, 2021	1,379,000
Year ended December 31, 2022	1,253,000
Year ended December 31, 2023	1,219,000
Year ended December 31, 2024	1,254,000
Thereafter	7,114,000
Total	12,505,000
Less present value discount	(3,024,000)
Operating lease liabilities included in the Condensed Consolidated Balance Sheet at June 30, 2020	$ 9,481,000

NOTE 8: ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following as of June 30, 2020 and December 31, 2019, respectively:

	June 30, 2020	December 31, 2019
Accounts payable	$ 2,808,000	$ 993,000
Compensation and benefits	858,000	323,000
Professional fees	686,000	94,000
Technology license fees	50,000	105,000
Other	126,000	243,000
Total accounts payable and accrued liabilities	$ 4,528,000	$ 1,758,000

NOTE 9: WARRANT LIABILITY AND FAIR VALUE MEASUREMENTS

During the six months ended June 30, 2020, all of the Company's common stock purchase warrants previously treated as a liability expired.

A summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's common stock purchase warrants that are categorized within Level 3 of the fair value hierarchy for the six months ended June 30, 2020 and 2019 is as follows:

	Weighted Average Inputs For the Six Months Ended June 30,	
	2020	2019
Exercise price	$ —	$ 9.72
Contractual term (years)	0	0.58
Volatility (annual)	—	78 %
Risk-free rate	—	2 %
Dividend yield (per share)	—	0 %

Financial Liabilities Measured at Fair Value on a Recurring Basis

Financial liabilities measured at fair value on a recurring basis are summarized below and disclosed on the balance sheet under Warrant liability:

	Fair value measured at June 30, 2020			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Fair value at June 30, 2020
Warrant liability	$ —	$ —	$ —	$ —

	Fair value measured at December 31, 2019			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Fair value at December 31, 2019
Warrant liability	$ —	$ —	$ 31,000	$ 31,000

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices included in Level 1, that are observable either directly or indirectly; and

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

There were no transfers between Level 1, 2 or 3 during the six months ended June 30, 2020.

The following table presents changes in Level 3 liabilities measured at fair value for the six months ended June 30, 2020:

	Warrant Liability
Balance - January 1, 2020	$ 31,000
Change in fair value of warrant liability	(31,000)
Balance - June 30, 2020	$ —

NOTE 10: COMMITMENTS AND CONTINGENCIES

An arbitration proceeding was brought against the Company before the Financial Industry Regulatory Authority, Inc. by a broker seeking to be paid approximately $1 million as compensation for two 2018 transactions, a warrant conversion and a private placement brokered by another broker. The broker's claims are based on a placement agent agreement for a private placement it brokered in 2017, under which it alleges it is entitled to compensation for the 2018 transactions. The Company believes it has defenses to all of the allegations and intends to vigorously defend itself in this matter.

As discussed in Footnotes #6 and #7, on March 26, 2020 the Company entered into an agreement with a vendor to design, engineer, build and eventually install modular cleanrooms in a manufacturing facility in Houston, Texas, which the Company expects to lease with a commencement date in the third quarter of 2020. The total fees for this project to be substantially completed by December 31, 2020 are estimated to be $6.0 million. As of June 30, 2020, the Company has recorded $2.6 million of construction in progress costs associated with the building of the cleanrooms.

NOTE 11: STOCKHOLDERS' EQUITY

Common Stock Transactions

Exercise of Stock Warrants

During the six months ended June 30, 2020, certain outstanding warrants were exercised for 458,334 shares of common stock providing aggregate proceeds to the Company of approximately $0.6 million.

Board Compensation

During the six months ended June 30, 2020, the Company issued an aggregate of 85,110 shares of common stock to its non-employee directors. The fair value of the common stock of approximately $0.2 million was recognized as a component of stock-based compensation expense in general and administrative expenses.

Aspire Capital

On February 28, 2020, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $30.0 million of shares of the Company's common stock over the 30-month term of the purchase agreement. In consideration for entering into the purchase agreement, the Company issued to Aspire Capital 345,357 shares of the Company's common stock as a commitment fee. The Company recorded the commitment fee to additional paid in capital. As of June 30, 2020, Aspire Capital had not purchased any shares under the Purchase Agreement.

The Company may request daily up to 0.1 million shares to be purchased with a maximum purchase commitment of 9.2 million shares over the term of the arrangement. The purchase price will generally be 97% of the stock price on the date of purchase.

Share Purchase Warrants

A summary of the Company's share purchase warrants as of June 30, 2020 and changes during the period is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value
Balance - January 1, 2020	**22,664,000**	**$ 4.71**	**3.33**	**$ 954,000**
Exercised for cash	(458,000)	1.20	—	—
Expired or cancelled	(825,000)	7.10	—	—
Balance - June 30, 2020	**21,381,000**	**$ 4.69**	**3.03**	**$ —**

NOTE 12: STOCK-BASED COMPENSATION

Stock Options

Award of 2019 Performance Bonuses and 2020 Equity Incentive Awards

On March 10, 2020, upon the recommendation of the compensation committee and pursuant to the Company's 2014 Omnibus Stock Ownership Plan, the Company's board of directors approved a total of 1,170,000 options to purchase the Company's common stock as (i) performance bonuses for 2019 performance and (ii) equity-based incentive awards to the Company's executive officers. Each option award was granted with an exercise price of $2.12 per share, the closing price of the Company's common stock on the Nasdaq Global Market on March 10, 2020, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such executive officer's continued service on the applicable vesting date. Additionally, on March 10, 2020, the Company issued 111,000 options to purchase the Company's common stock to other employees of the Company as equity-based incentive awards. Each option award was granted with an exercise price of $2.12 per share, the closing price of the Company's common stock on the Nasdaq Global Market on March 10, 2020, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such executive officer's continued service on the applicable vesting date.

The above awards were in addition to stock option awards issued during the six months ended June 30, 2020 to new employees upon their commencement of employment with the Company.

A summary of the Company's stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2020	4,983,000	$ 7.79	$ 18,000	8.9
Granted	1,371,000	2.13	—	9.7
Cancelled	(512,500)	9.13	—	—
Outstanding as of June 30, 2020	5,841,814	$ 6.34	$ 14,000	8.7
Options vested and exercisable	1,793,460	$ 7.70	$ —	8.3

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company's share-based compensation plans. The weighted average assumptions used in calculating the fair values of stock options that were granted during the six months ended June 30, 2020 was as follows:

	For the Six Months Ended June 30, 2020
Exercise price	$ 2.13
Expected term (years)	6.0
Expected stock price volatility	109 %
Risk-free rate of interest	1 %
Expected dividend rate	0 %

The following table sets forth stock-based compensation expenses recorded during the respective periods:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Stock Compensation expenses:				
Research and development	$ 528,000	$ 593,000	$ 1,309,000	$ 1,280,000
General and administrative	833,000	770,000	1,396,000	1,609,000
Total stock compensation expenses	$ 1,361,000	$ 1,363,000	$ 2,705,000	$ 2,889,000

At June 30, 2020, the total stock-based compensation cost related to unvested awards not yet recognized was $12.9 million. The expected weighted average period compensation costs to be recognized was approximately 3.0 years. Future option grants will impact the compensation expense recognized.

NOTE 13: GRANT INCOME

During the six months ended June 30, 2020, the Company received $0.5 million of a grant awarded to the Mayo Foundation from the U.S. Department of Defense to fund the Phase 2 clinical trial of TPIV100 for the treatment of HER2/neu breast cancer. The portion of the grant the Company received compensated the Company for clinical supplies manufactured by the Company for the clinical trial. In accordance with Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers (Topic 606)" issued by the Financial Accounting Standards Board, the Company recorded the $0.5 million of grant income as revenue. The Company did not record any grant income during the six months ended June 30, 2019.

NOTE 14: RELATED PARTY TRANSACTIONS

The following table sets forth related party transaction expenses recorded for the three and six months ended June 30, 2020 and 2019, respectively.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 193,000	$ 112,000	$ 447,000	$ 237,000
Total	$ 193,000	$ 112,000	$ 447,000	$ 237,000

The detailed information for the table above is below.

Sponsored Research Agreements with The Baylor College of Medicine ("BCM"). On November 16, 2018 and February 1, 2020, in furtherance of the BCM License Agreement and as contemplated by the terms thereof, the Company entered in Sponsored Research Agreements ("SRAs") with BCM, which provided for the conduct of research for the Company by credentialed personnel at BCM's Center for Cell and Gene Therapy.

The following table sets forth related party transaction expenses recorded in connection with the SRAs for the three and six months ended June 30, 2020 and 2019, respectively.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 11,000	$ 8,000	$ 46,000	$ 22,000
Total	$ 11,000	$ 8,000	$ 46,000	$ 22,000

Clinical Supply Agreement with BCM. On September 9, 2019, in furtherance of the BCM License Agreement and as contemplated by the terms thereof, the Company entered in a Clinical Supply Agreement ("CSA") with BCM, which provided for BCM to provide to the Company multi tumor antigen specific products.

The following table sets forth related party transaction expenses recorded in connection with the CSA for the three and six months ended June 30, 2020 and 2019, respectively.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 100,000	$ —	$ 200,000	$ —
Total	$ 100,000	$ —	$ 200,000	$ —

Workforce Grant Agreement with BCM. On October 5, 2019, in furtherance of the BCM Clinical Supply Agreement and as contemplated by the terms thereof, the Company entered in a Workforce Grant Agreement ("WGA") with BCM, which provided for BCM to provide to the Company manpower costs of projects for manufacturing, quality control testing and validation run activities.

The following table sets forth related party transaction expenses recorded in connection with the WGA for the three and six months ended June 30, 2020 and 2019, respectively.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 47,000	$ —	$ 147,000	$ —
Total	$ 47,000	$ —	$ 147,000	$ —

Purchases from Bio-Techne Corporation. The Company is currently utilizing Bio-Techne Corporation and one of its brands for the purchases of reagents, primarily cytokines. Mr. David Eansor is a member of the Company's board of directors and is serving as the President of the Protein Sciences Segment of Bio-Techne Corporation.

The following table sets forth related party transaction expenses recorded in connection with Bio-Techne Corporation for the three and six months ended June 30, 2020 and 2019, respectively.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 35,000	$ 18,000	$ 54,000	$ 39,000
Total	$ 35,000	$ 18,000	$ 54,000	$ 39,000

Consulting Agreement with Dr. Juan Vera. On October 19, 2018, after the closing of the Company’s merger, the Company entered into a consulting agreement with Dr. Juan Vera, a member of the Company’s board of directors, to serve as the Company’s Chief Development Officer. On September 1, 2019, Dr. Vera became an employee of the Company and his consulting agreement was terminated.

During the three and six months ended June 30, 2019, the Company incurred approximately $88,000 and $175,000, respectively, of expenses under Dr. Vera’s consulting agreement.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we "believe", "expect", "anticipate", "plan", "target", "intend" and similar expressions should be considered forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including factors discussed in this section and elsewhere in this Quarterly Report on Form 10-Q, and the risks discussed in our other filings with the SEC. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis, judgment, belief or expectation only as the date hereof. We assume no obligation to update these forward-looking statements to reflect events or circumstance that arise after the date hereof.

As used in this quarterly report: (i) the terms "we", "us", "our", "Marker" and the "Company" mean Marker Therapeutics, Inc. and its wholly owned subsidiaries, Marker Cell Therapy, Inc. and GeneMax Pharmaceuticals Inc. which wholly owns GeneMax Pharmaceuticals Canada Inc., unless the context otherwise requires; (ii) "SEC" refers to the Securities and Exchange Commission; (iii) "Securities Act" refers to the Securities Act of 1933, as amended; (iv) "Exchange Act" refers to the Securities Exchange Act of 1934, as amended; and (v) all dollar amounts refer to United States dollars unless otherwise indicated.

The following should be read in conjunction with our unaudited condensed consolidated interim financial statements and related notes for the six months ended June 30, 2020 included in this Quarterly Report.

Company Overview

We are a clinical-stage immuno-oncology company specializing in the development and commercialization of novel T cell-based immunotherapies and innovative peptide-based vaccines for the treatment of hematological malignancies and solid tumor indications. We developed our lead product candidates from our MultiTAA-specific T cell technology, which is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens, or TAAs, which are tumor targets, and then kill tumor cells expressing those targets. These T cells are designed to recognize multiple tumor targets to produce broad spectrum anti-tumor activity. We are advancing two pipelines of product candidates as part of our MultiTAA-specific T cell program: the autologous T cells for the treatment of lymphoma, multiple myeloma, or MM, and selected solid tumors and the allogeneic T cells for the treatment of acute myeloid leukemia, or AML, and acute lymphoblastic leukemia, or ALL. Because we do not genetically engineer the MultiTAA-specific T cell therapies, we believe that our product candidates are easier and less expensive to manufacture, have lower toxicities than current engineered chimeric antigen receptor, or CAR-T, and T cell receptor-based therapies and may provide patients with meaningful clinical benefit. We are also developing innovative peptide-based immunotherapeutic vaccines for the treatment of metastatic solid tumors.

We are pursuing post-transplant AML as the lead indication for our first company-sponsored MultiTAA-specific T cell program. The MultiTAA-specific T cell therapy has been well tolerated in an ongoing Phase 1 clinical trial conducted by our strategic partner Baylor College of Medicine, or BCM. As reported in March 2019, eleven of the thirteen patients in the adjuvant disease setting dosed with the MultiTAA-specific T cell therapy after receiving an allogeneic stem cell transplant survived, ranging from 6 weeks to 2.5 years post-infusion, with nine of these remaining patients in continuing complete remission, or CCR. Survival of the six patients with active disease ranged from 4 to 21 months, as compared to a historical survival rate of approximately 4.5 months for patients who receive the standard of care post-transplant.

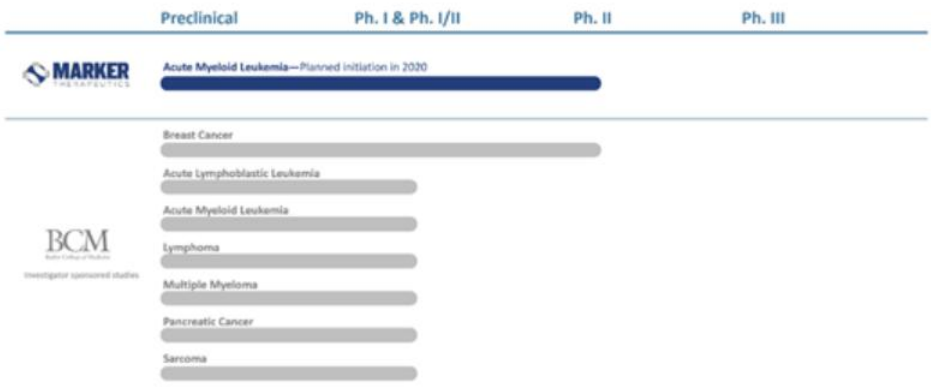
We submitted an investigational new drug, or IND, application to the United States Food and Drug Administration, or the FDA, to initiate a Phase 2 clinical trial of MultiTAA-specific T cell therapy, which we refer to as MT-401 (zelenoleucel), in post-allogeneic hematopoietic stem cell transplant patients with AML in both the adjuvant and active disease setting. The dose administered in this multicenter trial is the approximate flat dose equivalent of the current maximum tolerated dose from the ongoing Phase 1 trial. In the adjuvant setting, patients will be randomized to either MultiTAA-specific T cell therapy at approximately 90 days post-transplant versus standard of care observation, while the active disease patients will receive MT-401 following relapse post-transplant as part of a single-arm group. In February 2020, we announced that the FDA has permitted us to initiate our Phase 2 clinical trial beginning with a safety lead-in portion of the trial. We expect that we will be delayed in initiating this trial per previously communicated timelines due to the COVID-19 pandemic. See "—Clinical Program Updates." In April 2020, the FDA granted orphan drug designation to MT-401 for the treatment of AML after receiving an allogenic stem cell transplant.

We reported interim data for an ongoing Phase 1/2 clinical trial of the MultiTAA-specific T cell therapy for the treatment of pancreatic adenocarcinoma being conducted by BCM. In this trial, we have observed a clinical benefit correlated with the post-infusion detection of tumor-reactive T cells in patient peripheral blood and within tumor biopsy samples in patients in the tumor-resection arm of the trial. These T cells exhibited activity against both targeted antigens and non-targeted TAAs, indicating induction of antigen spreading. To date, we have not observed any cytokine release syndrome or neurotoxicity in this trial.

We are also evaluating the MultiTAA-specific T cell therapies in a Phase 2 clinical trial for the treatment of breast cancer and in Phase 1 clinical trials for the treatment of ALL, lymphoma, MM and sarcoma, all of which are being conducted by BCM. As of December 2019, the MultiTAA-specific T cell therapies have been generally well tolerated by all of the patients enrolled in clinical trials in hematological and solid tumor indications with no incidents of cytokine release syndrome or neurotoxicity, which are frequently associated with CAR-T therapies. Our ongoing clinical trials may be also affected by the COVID-19 pandemic. Based on our observations in clinical trials in AML, pancreatic cancer, lymphoma, ALL and MM, we believe that the MultiTAA-specific T cell therapies have the potential to mediate a meaningful anti-tumor effect, as well as significant in vivo expansion of T cells. We may initiate additional Phase 2 clinical trials investigating other indications in addition to our planned Phase 2 trial in post-transplant AML patients.

Pipeline

Our clinical-stage pipeline, including clinical trials being conducted by BCM and other partners, is set forth below:



Clinical Program Updates

MT-401 (zelenoleucel) for the Treatment of Post-Transplant AML

In February 2020, we announced that the FDA lifted the clinical hold on the Phase 2 clinical trial investigating the safety and efficacy of MT-401 for the treatment of patients with AML post-transplant permitting us to initiate the trial with the safety lead-in portion that is expected to enroll approximately six patients. Three patients will be dosed with MT-401 manufactured with the legacy reagent used in the Phase 1 trial, and three patients will be dosed with MT-401 manufactured using a new reagent from an alternative supplier. We anticipate using this supplier for clinical and commercial manufacturing of MT-401. The FDA placed a partial clinical hold on the trial for the use of the MT-401 product manufactured using one of the reagents supplied by the alternative supplier until the final data and certificate of analysis for the reagent are reviewed and accepted by the FDA. As a result of the COVID-19 pandemic, we may be delayed in our ability to enroll the first three patients in the safety lead-in portion of the trial, but we continue to work to identify clinical trial sites. Further, our alternate supplier has notified us that they will also be delayed in providing the new reagent for MT-401, along with the final data and certificate of analysis required by the FDA to satisfy the requirements for lifting the partial hold. Accordingly, we expect that we will be delayed in initiating the Phase 2 trial per previously communicated timelines.

Interim Results of Phase 1 Trial of MultiTAA-specific T cell Therapy for the Treatment of Pancreatic Adenocarcinoma

In May 2020, we reported additional interim data of a cohort of patients receiving MultiTAA-specific T cell therapy in combination with standard-of-care chemotherapy in the first-line setting (Arm A). Arm A is evaluating the safety and potential efficacy of using MultiTAA-specific T cells in the first line setting for chemo-responsive patients with locally advanced or metastatic pancreatic adenocarcinoma. Patients in Arm A receive at least three months of standard-of-care chemotherapy (gemcitabine/nab-paclitaxel or FOLFIRINOX) - the period during which a response to chemotherapy would typically occur - before receiving up to six administrations of MultiTAA-specific T cells in conjunction with chemotherapy.

Between June 2018 and December 2019, 13 patients have been treated, each of whom received up to six monthly infusions of $1x10^7$ MultiTAA-specific T cells/m^2 in conjunction with ongoing first-line chemotherapy and without prior lymphodepletion. For 12 of the 13 patients, sufficient cells for all six planned doses were generated; two doses were available for the remaining patient.

- Out of the 13 evaluable patients (best overall response):
  - 4 patients experienced objective responses after administration of MultiTAA cells;
  - 1 patient experienced a radiographic complete response occurring at month 9 after starting chemotherapy;
  - 3 patients experienced partial responses per RECIST occurring at 6-9 months after starting chemotherapy;
  - 6 patients experienced stable disease;
  - 1 patient experienced a mixed response (some lesions increased in size and others decreased for a net zero change in size of tumor lesions);

- Patients had durable cancer control with 9 of the 13 patients exceeding historical control of overall survival;

- 5 patients enrolled in the study were not administered MultiTAA-specific T cells, either because of disease progression (4 patients) which made them ineligible for treatment, or because insufficient starting material from the patient was available for manufacturing (1 patient);

- Evidence of epitope-spreading was observed in all responders, suggesting that the MultiTAA T cell therapy triggered the recruitment of a broader endogenous immune system response for improved anti-tumor activity; and

- No infusion-related reactions, cytokine release syndrome or neurotoxicity was observed.

Results of Operations

In this discussion of our results of operations and financial condition, amounts, other than per-share amounts, have been rounded to the nearest thousand dollars.

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

The following table summarizes the results of our operations for the three months ended June 30, 2020 and 2019:

	For the Three Months Ended June 30,		Change	
	2020	2019		
Revenues:				
Grant income	$ 467,000	$ —	$ 467,000	0 %
Total revenues	467,000	—	467,000	0 %
Operating expenses:				
Research and development	4,277,000	3,152,000	1,125,000	36 %
General and administrative	2,547,000	2,721,000	(174,000)	(6)%
Total operating expenses	6,824,000	5,874,000	950,000	16 %
Loss from operations	(6,358,000)	(5,874,000)	(484,000)	8 %
Other income (expense):				
Change in fair value of warrant liabilities	—	(7,000)	7,000	(100)%
Interest income	16,000	310,000	(294,000)	(95)%
Net loss	**$ (6,342,000)**	**$ (5,570,000)**	**$ (772,000)**	**14 %**
Net loss per share, basic and diluted	$ (0.14)	$ (0.12)	$ (0.02)	19 %
Weighted average number of common shares outstanding	46,573,000	45,501,000	1,072,000	2 %

Revenue

Grant income

During the three months ended June 30, 2020, we received $0.5 million of a grant awarded to the Mayo Foundation from the U.S. Department of Defense to fund the Phase 2 clinical trial of TPIV100 for the treatment of HER2/neu breast cancer. The portion of the grant we received compensated us for clinical supplies manufactured by us for the clinical trial. We did not receive any grant income during the three months ended June 30, 2019.

Operating Expenses

Operating expenses incurred during the three months ended June 30, 2020 were $6.8 million compared to $5.9 million during the three months ended June 30, 2019.

Significant changes and expenditures in operating expenses are outlined as follows:

Research and Development Expenses

Research and development expenses increased by 36% to $4.3 million for the three months ended June 30, 2020, compared to $3.2 million for the three months ended June 30, 2019.

The increase of $1.1 million in 2020 was primarily attributable to the following:

- increase of $0.6 million in headcount-related expenses as we increased the number of research and development personnel,
- increase of $0.8 million in process development expenses,
- increase of $0.1 million in sponsored research expenses from BCM agreements,

- increase of $0.1 million in other expenses, and
- decrease of $0.5 million in our peptide vaccine clinical trial expenses due to the stages of ongoing clinical trials and the decreased number of active patients in such trials.

General and Administrative Expenses

General and administrative expenses were $ 2.5 million and $2.7 million for the three months ended June 30, 2020 and 2019, respectively. The decrease in general and administrative expenses was mainly comprised of a decrease in legal and professional fees.

Other Income (Expense)

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities for the three months ended June 30, 2020 was $0 as compared to $(7,000) for the three months ended June 30, 2019.

Interest Income

Interest income was $16,000 and $0.3 million for the three months ended June 30, 2020 and 2019, respectively, and was attributable to interest income relating to funds that are held in U.S. Treasury notes and U.S. government agency-backed securities. As part of the reaction to the COVID-19 pandemic, the Federal Reserve cut rates in mid-March to a range of 0.0% - 0.25%. As such, we recorded lower interest income during the three months ended June 30, 2020.

Net Loss

We recorded a net loss of $6.3 million, or a net loss per share, basic and diluted of $(0.14), during the three months ended June 30, 2020, compared to a net loss of $5.6 million, or a net loss per share, basic and diluted of $(0.12), during the three months ended June 30, 2019. The increase in our net loss during the three months ended June 30, 2020 compared to during the three months ended June 30, 2019 was due to the continued expansion of our research and development activities, increased expenses relating to current and future clinical trials, and the overall growth of our corporate infrastructure. We anticipate that we will continue to incur net losses in the future as we continue to invest in research and development activities, including clinical development of our MultiTAA T cell product candidates.

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

The following table summarizes the results of our operations for the six months ended June 30, 2020 and 2019:

	For the Six Months Ended June 30,		Change	
	2020	2019		
Revenues:				
Grant income	$ 467,000	$ —	$ 467,000	0 %
Total revenues	467,000	—	467,000	0 %
Operating expenses:				
Research and development	8,094,000	5,985,000	2,109,000	35 %
General and administrative	5,374,000	5,527,000	(153,000)	(3)%
Total operating expenses	13,468,000	11,512,000	1,956,000	17 %
Loss from operations	(13,001,000)	(11,512,000)	(1,489,000)	13 %
Other income (expense):				
Change in fair value of warrant liabilities	31,000	(16,000)	47,000	(294)%
Interest income	143,000	639,000	(496,000)	(78)%
Net loss	**$ (12,827,000)**	**$ (10,889,000)**	**$ (1,938,000)**	**18 %**
Net loss per share, basic and diluted	$ (0.28)	$ (0.24)	$ (0.04)	16 %
Weighted average number of common shares outstanding	46,329,000	45,484,000	845,000	2 %

Revenue

Grant income

During the six months ended June 30, 2020, we received $0.5 million of a grant awarded to the Mayo Foundation from the U.S. Department of Defense to fund the Phase 2 clinical trial of TPIV100 for the treatment of HER2/neu breast cancer. The portion of the grant we received compensated us for clinical supplies manufactured by us for the clinical trial. We did not receive any grant income during the six months ended June 30, 2019.

Operating Expenses

Operating expenses incurred during the six months ended June 30, 2020 were $13.5 million compared to $11.5 million during the six months ended June 30, 2019.

Significant changes and expenditures in operating expenses are outlined as follows:

Research and Development Expenses

Research and development expenses increased by 35% to $8.1 million for the six months ended June 30, 2020, compared to $6.0 million for the six months ended June 30, 2019.

The increase of $2.1 million in 2020 was primarily attributable to the following:

- increase of $1.4 million in headcount-related expenses as we increased the number of research and development personnel,
- increase of $1.5 million in process development expenses,
- increase of $0.1 million in sponsored research expenses from BCM agreements,
- increase of $0.2 million in other expenses, and

- decrease of $1.1 million in our peptide vaccine clinical trial expenses due to the stages of ongoing clinical trials and the decreased number of active patients in such trials.

General and Administrative Expenses

General and administrative expenses were $5.4 million and $5.5 million for the six months ended June 30, 2020 and 2019, respectively. The decrease in general and administrative expenses was mainly comprised of a decrease in legal and professional fees and other.

Other Income (Expense)

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities for the six months ended June 30, 2020 was $31,000 as compared to $(16,000) for the six months ended June 30, 2019.

Interest Income

Interest income was $0.1 million and $0.6 million for the six months ended June 30, 2020 and 2019, respectively, and was attributable to interest income relating to funds that are held in U.S. Treasury notes and U.S. government agency-backed securities. As part of the reaction to the COVID-19 pandemic, the Federal Reserve cut rates in mid-March to a range of 0.0% - 0.25%. As such, we recorded lower interest income during the six months ended June 30, 2020.

Net Loss

We recorded a net loss of $12.8 million, or a net loss per share, basic and diluted of $(0.28), during the six months ended June 30, 2020, compared to a net loss of $10.9 million, or a net loss per share, basic and diluted of $(0.24), during the six months ended June 30, 2019. The increase in our net loss during the six months ended June 30, 2020 compared to during the six months ended June 30, 2019 was due to the continued expansion of our research and development activities, increased expenses relating to current and future clinical trials, and the overall growth of our corporate infrastructure. We anticipate that we will continue to incur net losses in the future as we continue to invest in research and development activities, including clinical development of our MultiTAA T cell product candidates.

Liquidity and Capital Resources

We have not generated any revenues from product sales since inception. We have financed our operations primarily through public and private offerings of our debt and equity securities.

The following table sets forth our cash and cash equivalents and working capital as of June 30, 2020 and December 31, 2019:

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 32,124,000	$ 43,904,000
Working capital	$ 29,776,000	$ 43,494,000

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2020 and 2019:

	For the Six Months Ended June 30,	
	2020	2019
Net Cash provided by (used in):		
Operating activities	$ (8,401,000)	$ (8,060,000)
Investing activities	(3,928,000)	(305,000)
Financing activities	550,000	63,000
Net decrease in cash and cash equivalents	$ (11,779,000)	$ (8,302,000)

Operating Activities

Net cash used in operating activities during the six months ended June 30, 2020 was $8.4 million. The use of cash primarily related to our net loss of $12.8 million, in addition to the effect of changes in asset and liability accounts, including an increase in prepaid expenses and deposits of $1.1 million, an increase in accounts payable and accrued liabilities of $2.8 million, a decrease in interest receivable of $53,000 and an increase in lease liabilities of $0.3 million.

Net cash used in operating activities during the six months ended June 30, 2019 was $8.1 million. The use of cash primarily related to our net loss of $10.9 million, in addition to the effect of changes in asset and liability accounts, including an increase in prepaid expenses and deposits of $350,000, an increase in accounts payable and accrued liabilities of $225,000, a decrease in lease liabilities of $90,000 and a decrease in interest receivable of $10,000.

Investing Activities

Net cash used in investing activities was $3.9 million and $0.3 million for the purchase of property and equipment during the six months ended June 30, 2020 and 2019, respectively. The increase relates to $2.6 million in construction in progress towards the new modular cleanrooms in our manufacturing facility, an additional $1.0 million in laboratory equipment and $0.3 million in leasehold improvements at the new research facility.

Financing Activities

Net cash provided by financing activities was $550,000 during the six months ended June 30, 2020, due to the exercise of stock warrants. Net cash provided by financing activities was $63,000 during the six months ended June 30, 2019, due to the exercise of stock warrants and stock options.

Future Capital Requirements

To date, we have not generated any revenues from the commercial sale of approved drug products, and we do not expect to generate substantial revenue for at least the next several years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be compromised. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate significant revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of and seek marketing approval for our product candidates. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of June 30, 2020, we had working capital of $29.8 million, compared to working capital of $43.5 million as of December 31, 2019. Based on our revised clinical and research and development plans and our revised timing expectations related to the progress of our programs, and buildout of manufacturing and research facilities, and expansion of our corporate headquarters, we expect that our cash and cash equivalents as of June 30, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Furthermore, our operating plan may change, and we may need additional funds sooner than planned in order to meet operational needs and capital requirements for product development and commercialization. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, as we:

- initiate or continue clinical trials of our product candidates;
- continue the research and development of our product candidates and seek to discover additional product candidates;seek regulatory approvals for our product candidates if they successfully complete clinical trials;
- establish sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates that may receive regulatory approval;
- evaluate strategic transactions we may undertake; and
- enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercialization efforts.

Because all of our product candidates are in the early stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates or whether, or when, we may achieve profitability. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements.

During fiscal 2020, we have entered into agreements to buildout a manufacturing facility, to lease a research lab and to expand our corporate headquarters in Houston, Texas. A summary of these future capital requirements is below:

- On March 23, 2020, we entered into an agreement to expand our corporate headquarters in Houston, Texas, which is expected to commence in the third quarter of 2020. The initial lease term is ten years with two five-year renewal options. Fixed rent payments under the initial term are approximately $5.6 million. Additionally, we are also responsible for our share of operating expenses.

- On March 26, 2020 we entered into an agreement with a vendor to design, engineer, build and eventually install modular cleanrooms in the manufacturing facility in Houston, Texas. The total fees for this project to be substantially completed by December 31, 2020 are estimated to be $6.0 million.

- On April 30, 2020, we entered into a lease for a research facility in Houston, Texas. The lease term is 71 months. Fixed rent payments under the initial term are approximately $1.1 million. Additionally, we are also responsible for our share of operating expenses.

- On June 26, 2020, we entered into a lease for a manufacturing facility in Houston, Texas. The initial lease term is ten years from the expected commencement date in the third quarter 2020, with two five-year renewal options. Fixed rent payments under the initial term are approximately $11.1 million. Additionally, we are responsible for our share of operating expenses.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also consider new collaborations or selectively partner our technology. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing stockholders' common stock. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us. We may also be required to pay damages or have liabilities associated with litigation or other legal proceedings involving our company.

In addition to the foregoing, based on our current assessment, we do not expect any material impact on our long-term liquidity due to the COVID-19 pandemic. However, we will continue to assess the effect of the pandemic on our operations. The extent to which the COVID-19 pandemic will impact our business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread 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.

Aspire Common Stock Purchase Agreement

In February 2020, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $30.0 million of shares of our common stock over the 30-month term of the Purchase Agreement. As of June 30, 2020, Aspire Capital had not purchased any shares under the Purchase Agreement.

In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 345,357 shares of our common stock, or the Commitment Shares. Under the Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a Purchase Notice directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per business day, up to $30.0 million of our common stock in the aggregate at a Purchase Price equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

We and Aspire Capital also may mutually agree to increase the number of shares that may be sold to as much as an additional 2,000,000 shares per business day.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to at least 100,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, or a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock traded on its principal market on the next trading day, which we refer to as the VWAP Purchase Date, subject to a maximum number of shares we may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for our common stock traded on its principal market on the VWAP. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

The Purchase Agreement provides that we and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.25. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us but is obligated to make purchases from us as directed by us on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at its discretion, without any cost to us. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement. We expect to use any proceeds under the Purchase Agreement for working capital and general corporate purposes.

The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement will be limited to 9,232,814 shares, including the Commitment Shares, or the Exchange Cap, which represents 19.99% of our outstanding shares of common stock as of the date of the Purchase Agreement, unless stockholder approval is obtained to issue more than 19.99%. This limitation will not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued under the Purchase Agreement is equal to or greater than $2.41, which was the closing price of our shares on The Nasdaq Global Market immediately preceding the execution of the Purchase Agreement. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of The Nasdaq Global Market.

Critical Accounting Policies

The condensed consolidated financial statements are prepared in conformity with U.S. GAAP, which require the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses in the periods presented. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results could differ from the original estimates, requiring adjustments to these balances in future periods. The critical accounting estimates that affect the consolidated financial statements and the judgments and assumptions used are consistent with those described under Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2019.

Going Concern

The below excludes any potential funding provided by the $30 million Purchase Agreement with Aspire Capital.

We have no sources of revenue to provide incoming cash flows to sustain our future operations. As outlined above, our ability to pursue our planned business activities is dependent upon our successful efforts to raise additional capital.

The factors discussed above raise substantial doubt regarding our ability to continue as a going concern. Our condensed consolidated financial statements have been prepared on a going concern basis, which implies that we will continue to realize our assets and discharge our liabilities in the normal course of business. Our financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes of financial condition, revenues, expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on such evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act.

It should be noted that any system of controls is based in part upon certain assumptions designed to obtain reasonable (and not absolute) assurance as to its effectiveness, and there can be no assurance that any design will succeed in achieving its stated goals.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

(b) Changes in Internal Control Over Financial Reporting

There have been no changes in our internal controls over financial reporting during the six months ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

As of June 30, 2020, we were not a party to any legal proceedings that, in the opinion of management, are likely to have a material adverse effect on our business.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to our Business and Intellectual Property

Our business and operations are likely to be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations are likely to be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization as a global pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States that, 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 events and order cessation of non-essential travel. In response to public health directives and orders, we have implemented work-from-home policies for all employees, including at our headquarters in Houston, Texas, which is currently subject to an order that requires all non-essential businesses to cease in-person operations.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and, to date, have disrupted our ongoing research and development activities and delayed certain of 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. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements may result in control deficiencies in the preparation of our financial reports, which could be material.

Such orders may also impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

In addition, we expect that we will be delayed in initiating our Phase 2 trial of MT-401 (zelenoleucel) for post-transplant AML per previously communicated timelines due to delays in our ability to enroll the first three patients in the safety lead-in portion of the trial because of the COVID-19 pandemic and delays in receiving the new reagent for MT-401 and the final data and certificate of analysis required by the FDA to satisfy the requirements for lifting the partial hold. Our ongoing clinical trials may be also affected by the COVID-19 pandemic. Patient enrollment and clinical site initiation may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, we may be unable to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, which would adversely impact clinical trial operations

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread 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.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Form 10-Q, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

We are a development stage company with a history of operating losses, and we expect losses to continue for the indefinite future. These factors raise substantial doubt regarding our ability to continue as a going concern.

We are a clinical-stage immunotherapy company with a history of losses, and we may always operate at a loss. We expect that we will continue to operate at a loss throughout our development stage, and as a result, we may exhaust our financial resources and be unable to complete the development of our product candidates. We anticipate that our ongoing operational costs will increase significantly as we continue conducting our clinical development program. Our deficit will continue to grow during our drug development period. We have no sources of significant revenue to provide incoming cash flows to sustain our future operations. As outlined above, our ability to pursue our planned business activities depends upon our successful efforts to raise additional financing. 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 resulting from the ongoing COVID-19 pandemic.

We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future due to the substantial investment in research and development. As of June 30, 2020, we had an accumulated deficit of $ 340.4 million since inception. We expect that our cash and cash equivalents as of June 30, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2021. We expect to spend substantial additional sums on the continued administration and research and development of licensed and proprietary product candidates and technologies with no certainty that our approach and associated technologies will become commercially viable or profitable as a result of these expenditures. If we fail to raise a significant amount of capital, we may need to significantly curtail operations, allocate limited financial resources among our product candidates, or cease operations in the near future. If any of our product candidates fail in clinical trials or do not gain regulatory approval, we may never generate revenue. Even if we generate revenue in the future, we may not be able to become profitable or sustain profitability in subsequent periods.

These and other factors raise substantial doubt regarding our ability to continue as a going concern, which may create negative reactions to the price of our common stock. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Further, the perception that we may be unable to continue as a going concern may impede our ability to pursue strategic opportunities or operate our business due to concerns regarding our ability to discharge our contractual obligations. In addition, if there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, or at all.

Our future success is highly dependent upon our key personnel, and our ability to attract, retain, and motivate additional qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management, scientific, and medical personnel and consultants, including Peter Hoang, our President and Chief Executive Officer, Juan Vera, M.D., our Chief Development and Scientific Officer, and Mythili Koneru, M.D., Ph.D. our Chief Medical Officer as well as others. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm to our business. We have a priority to quickly train additional qualified scientific and medical personnel to ensure the ability to maintain business continuity. Any delays in training such personnel could delay the development, manufacture, and clinical trials of our product candidates.

Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other biotechnology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than us. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, or integrating them into our operations, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances, we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials and development of our product candidates, and unable to adequately address our management needs.

Our strategic relationship with Baylor College of Medicine, or BCM, is dependent, in part, upon our relationship with key medical and scientific personnel and advisors.

Our MultiTAA-specific T cell therapy has been developed through our collaboration with the Center for Cell and Gene Therapy at BCM, founded by Malcolm K. Brenner, M.D., Ph.D., a recognized pioneer in immuno-oncology. In addition to Dr. Brenner, our founders include Juan Vera, M.D., Ann Leen, Ph.D., Helen Heslop, M.D., DSc (Hon) and Cliona Rooney, Ph.D., who all have significant experience in this field and are all affiliated with the Center for Cell and Gene Therapy at BCM. Dr. Vera is our Chief Development Officer. In addition, Dr. Brenner, Dr. Heslop and Dr. Rooney have joined our Scientific Advisory Board.

Our strategic relationship with BCM is dependent, in part, on our relationship with these key employees and advisors, and in particular Dr. Vera. If Dr. Vera discontinues his employment with us, our relationship with BCM may deteriorate, and our business could be harmed.

We, and certain of our key medical and scientific personnel, will need additional agreements in place with BCM to expand our development, manufacture, and clinical trial efforts.

Although we have an exclusive license agreement with BCM under which we received a worldwide, exclusive license to BCM's rights in and to three patent families to develop and commercialize the MultiTAA-specific T cell product candidates, we will need to enter into additional agreements with BCM with respect to (i) a strategic alliance to advance pre-clinical research, early stage clinical trials, and Phase 2 clinical trials with respect to our product candidates, as well as continued access to our clinical data, and (ii) product manufacturing and support, including personnel and space at the institution for the foreseeable future. Any delays in entering into new strategic agreements with BCM related to our product candidates could delay the development, manufacture, and clinical trials of our product candidates.

The multiple roles of certain of Dr. Vera, our Chief Development and Scientific Officer, and John Wilson, our director, could limit their time and availability to us, and create, or appear to create, conflicts of interest.

Dr. Vera is a co-founder and member of Allovir Inc., or Allovir. Allovir has technology which is being developed under a license agreement with BCM by the same research group at BCM. Allovir is a clinical-stage biopharmaceutical company that is investigating and developing virus-specific T cell therapy technology for the prevention and/or treatment of viral infections. Accordingly, Dr. Vera may have other commitments that would, at times, limit his availability to us. Other research being conducted by Dr. Vera may, at times, receive higher priority than research on our programs, which may, in turn, delay the development or commercialization of our product candidates.

In addition, John Wilson is a co-founder, member and director of Allovir and is a director of our company. Both of these individuals have certain fiduciary or other obligations to us and certain fiduciary or other obligations to Allovir and, in the case of Dr. Vera to BCM. Such multiple obligations may in the future result in a conflict of interest with respect to presenting other potential business opportunities to us or to Allovir. A conflict of interest also may arise concerning the timing and scope of the parties' planned and ongoing clinical trials, investigational new drug application filings and the parties' opportunities for marketing their respective product candidates, as well as our intellectual property rights with those of Allovir. In addition, they may be faced with decisions that could have different implications for us than for Allovir. Consequently, there is no assurance that these members of our board and management will always act in our best interests in all situations should a conflict arise.

We have not yet sold any products or received regulatory approval to sell any product candidates.

We have no approved products or product candidates pending approval. As a result, we have not derived any revenue from the sales of products and have not yet demonstrated ability to obtain regulatory approval, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. Without revenue, we can only finance our operations through debt and equity financings.

Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier pre-clinical and clinical trials may not be predictive of future clinical trial results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical testing and early clinical trials of our product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of patients in a single academic clinical site for a limited number of indications. We will have to conduct larger, well-controlled trials in our proposed indications at multiple sites to verify the results obtained to date and to support any regulatory submissions for further clinical development of our product candidates. Our assumptions related to our product candidates, such as with respect to lack of toxicity and manufacturing cost estimates, are based on early limited clinical trials and current manufacturing processes at BCM and may prove to be incorrect. In addition, the initial estimates of the clinical cost of development may prove to be inadequate, particularly if clinical trial timing or outcome is different than predicted or regulatory agencies require further testing before approval. For example, we anticipate that the COVID-19 pandemic will delay our planned timelines for our Phase 2 trial of MT-401 for the treatment of post-transplant AML, which may impact our cost estimates for this trial. Several companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to receive regulatory approval or market our product candidates.

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach may be different. The competition comes from both biotechnology firms and from major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than us. We also experience competition in the development of our immunotherapies from universities, other research institutions and others in acquiring technology from such universities and institutions.

In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

We are subject to numerous risks inherent in conducting clinical trials.

We outsource some of the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. If any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, agents. We cannot be certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay our clinical trials.

The COVID-19 pandemic is also likely to cause disruptions to our clinical programs. For example, we expect that we will be delayed in initiating our Phase 2 trial of MT-401 for post-transplant AML per previously communicated timelines. The COVID-19 pandemic may also result in difficulties in initiating clinical sites and enrolling patients, the diversion of healthcare resources away from clinical trials and other challenges related to travel or quarantine policies that may impede patient movement or interrupt healthcare services.

We, or our regulators, may suspend or terminate our clinical trials for a variety of reasons. For example, in the fourth quarter of 2019 the FDA placed a clinical hold on our IND of MT-401 for the treatment of patients with post-transplant AML and requested certain information regarding quality and technical specifications for two reagents supplied by third party vendors that are used in our manufacturing process but not present in the final product infused to patients. In February 2020, the FDA lifted the clinical hold, permitting us to initiate a Phase 2 clinical trial with a safety lead-in portion but placed a partial clinical hold on the trial for the use of MT-401 manufactured using one of the reagents supplied by our alternative supplier. Our alternate supplier has notified us that they will be delayed in providing the new reagent for MT-401, along with the final data and certificate of analysis required by the FDA to satisfy the requirements for lifting the partial hold, which will delay our ability to initiate the trial per previously communicated timelines. The FDA may not agree that our response addresses all of their concerns and the partial clinical hold may remain in place and further delay the initiation of the trial. In addition, our ability to successfully work with our reagent supplier may be limited or further delayed due to the effects of the COVID-19 pandemic.

We may voluntarily suspend or terminate our clinical trials at any time if we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. For example, in November 2019 we elected to suspend our Phase 2 clinical trial of TPIV200 for the treatment of platinum-sensitive advanced ovarian cancer based on an unblinded review of interim results conducted by an independent Data and Safety Monitoring Board, or DSMB. Although the DSMB did not express any safety concerns with respect to TPIV200, we elected to suspend the trial because it did not meet the threshold for probability of clinical benefit based upon our pre-specified criteria. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, and we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in us failing to obtain regulatory approval for our product candidates, which would materially harm our business, results of operations and prospects.

The successful development of immunotherapies is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and depends on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or BLA preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payors were not to provide adequate coverage and reimbursement levels for any of our products if approved, market acceptance and commercial success would be reduced.

In addition, if one of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices, or cGMPs, and current Good Clinical Practices or cGCPs for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates' post-market approval could have a material adverse effect on our business, financial condition and results of operations.

It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.

For budgeting and planning purposes, we have projected the dates for the commencement, continuation, and completion of our various clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, and competition for such eligible patents from other clinical trials, may cause significant delays. We may not commence or complete clinical trials involving any of our product candidates as projected or may not conduct them successfully.

We expect that we will be delayed in initiating our planned Phase 2 trial of MT-401 for post-transplant AML due to the COVID-19 pandemic. As previously announced, the FDA placed a partial clinical hold for the use of MT-401 manufactured using one of the reagents supplied by our alternative supplier. Our alternate supplier has notified us that they will be delayed in providing the new reagent for MT-401, along with the final data and certificate of analysis required by the FDA to satisfy the requirements for lifting the partial hold. We cannot guarantee when, or if, we will be successful in these efforts. Further, as a result of the COVID-19 pandemic, we will be delayed in our ability to enroll the first three patients in the safety lead-in portion of the trial required by the FDA. The pandemic may also impact our other clinical programs.

We may experience difficulties in patient enrollment in our future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Accordingly, we cannot guarantee that our clinical trials will progress as planned or as scheduled. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We rely on medical institutions, academic institutions, and clinical research organizations to conduct, supervise, or monitor some or all aspects of clinical trials involving our product candidates. We may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experiences delays in, any of our planned clinical trials, we may experience delays in our clinical development and/or commercialization plans.

In particular, while BCM will continue to support our trials with production of MultiTAA-specific T cells under contract, we anticipate that we will have to rely on internal facilities yet to be developed for the commercial manufacture of our multi-antigen specific T cell therapy product candidates for clinical trials and eventual licensure. If they fail to complete, or experience delays in, manufacturing our multi-antigen specific T cell therapy product candidates, our planned clinical trials with respect to such product candidates will be delayed, and we may experience delays in our clinical development and/or commercialization plans

Clinical trials are expensive, time-consuming, and difficult to design and implement, and our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies and manufactured on a patient-by-patient basis for our MultiTAA-specific T cell product candidates we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from, Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and we may be required by those trial sites to pay such costs. Accordingly, our clinical trial costs may be significantly higher per patient than those of more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex manufacturing and processing steps, the costs of which will be borne by us. Depending on the number of patients we ultimately enroll in our trials, and the number of trials we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments. Further, delays and interruptions to ongoing trials related to the COVID-19 pandemic may also increase the duration and costs of such trials.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of any approved products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. 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 trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. In addition, we expect that there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our MultiTAA-specific T cell product candidates, than for “off-the-shelf” products, like many other drugs. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable toxicities arise in the development of our product candidates, we or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from personalized cell therapy, as with our MultiTAA-specific T cell therapy products, are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our business, financial condition and prospects significantly.

We will be unable to seek regulatory approval of or commercialize our products if our trials are not successful.

Our research and development programs are at an early stage. We must demonstrate our products' safety and efficacy in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of our products, including but not limited to the following:

- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials;
- after reviewing trial results, we or our collaborators may abandon product candidates that we might previously have believed to be promising;
- we, our collaborators or regulators, may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks; and
- the effects our potential product candidates have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Further, we expect that the COVID-19 pandemic will delay our ability to initiate our planned Phase 2 trial of MT-401 for post-transplant AML and may impact our other clinical programs due to delays and difficulties in clinical site initiation and patient enrollment and potential diversion of healthcare resources and other interruptions in clinical trial activities.

Clinical testing is very expensive, can take many years, and the outcome is uncertain. For example, it can take as much as 12 months or more before we learn the results from any clinical trial using our MultiTAA-specific T cell therapy. The data collected from our clinical trials may not be sufficient to support approval by the FDA of our MultiTAA-specific T cell therapy-based product candidates for the treatment of hematological malignancies. The clinical trials for our product candidates under development may not be completed on schedule and the FDA may not ultimately approve any of our product candidates for commercial sale. If we fail to adequately demonstrate the safety and efficacy of any product candidate under development, we may not receive regulatory approval for those product candidates, which would prevent us from generating revenues or achieving profitability.

We may not be able to expand our manufacturing processes to other third-party manufacturing facilities or successfully create our own manufacturing infrastructure for supply of our requirements of product candidates for use in clinical trials and for commercial sale.

We currently do not operate our own facility that may be used as our clinical-scale manufacturing and processing facility. We currently rely on third-party Contract Manufacturing Organizations, or CMOs, for manufacture of our vaccine product candidates. For 2020, we anticipate that we will initially rely solely on the cGMP manufacturing facility within BCM for the manufacturing of our MultiTAA-specific T cell therapy-based product candidates. BCM has currently restricted access to its facilities due to the COVID-19 pandemic, and we are currently unable to conduct any manufacturing activities for MT-401. If the cGMP manufacturing facility of BCM, which does manufacture for itself and other parties, experiences capacity constraints, other disruptions, or delays in manufacturing our MultiTAA-specific T cell therapy-based product candidates, our planned clinical trials and necessary manufacturing capabilities will be disrupted or delayed, which will adversely affect our ability to conduct and further develop our business as currently planned. Further, the cGMP manufacturing facility is most likely too small to conduct the pivotal clinical studies being planned by us, so we will need to develop our own cGMP manufacturing capacity that will be adequate for such clinical trials with respect to our MultiTAA-specific T cell therapy-based product candidates.

We have begun to develop additional cGMP manufacturing capacity of our own that would be capable of supporting our manufacturing needs with respect to our clinical trials, particularly with respect to pivotal studies. We intend to begin a process technology transfer to develop in-house manufacturing capabilities in 2021. Establishment of our own manufacturing facility is subject to many risks. For example, the establishment of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals. Creating an internal manufacturing infrastructure will rely upon building out a complex facility and finding personnel with an appropriate background and training to staff and operate the facility. Should we be unable to find these individuals, we may need to rely on external contractors or train additional personnel to fill needed roles. There are a small number of individuals with experience in cell therapy, and the competition for these individuals is high.

We expect that the development of our own manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we do not have extensive experience in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures, transportation difficulties and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our clinical development and/or commercialization plans.

In addition, the manufacturing process for any product candidates that we may develop is subject to the FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA, or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize any approved products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our clinical development and/or commercialization plans.

In order to transfer our MultiTAA-specific T cell manufacturing from or expand our manufacturing capabilities beyond BCM pursuant to our development plans, we will need access to the standard operating procedures and the specific batch production records that are used to manufacture the product candidates. If BCM does not support the transfer of our manufacturing processes or impedes our ability to transfer the manufacturing processes of its product candidates to us, our planned clinical trials and additional necessary manufacturing capabilities will be delayed, which will adversely affect our ability to conduct and further develop our business as currently planned.

Until our new manufacturing facility is operational, we will be dependent on third-party vendors to design, build, maintain and support our manufacturing and cell processing facilities.

Until our new manufacturing facility is operational, we will rely very heavily on BCM and other third-party manufacturers to perform the manufacturing of our product candidates for our clinical trials. We license our technology from others. We intend to rely on our contract manufacturers to produce large quantities of materials needed for clinical trials and potential product commercialization. Third-party manufacturers may not be able to meet our needs concerning timing, quantity, or quality. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval or the market introduction and subsequent sales of any approved products. Any such delay may lower our revenues and potential profitability. If any third party breaches or terminates its agreement with us or fails to conduct its activities in a timely manner, the commercialization of our product candidates could be slowed down or blocked completely. It is possible that third parties relied upon by us will change their strategic focus, pursue alternative technologies, or develop alternative product candidates, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by our collaborative programs, or for other reasons. The effectiveness of these third parties in marketing their own products may also affect our revenues and earnings.

We intend to continue to enter into additional third-party agreements in the future. However, we may not be able to negotiate any additional agreements successfully. Even if established, these relationships may not be scientifically or commercially successful.

Our manufacturing process is reliant upon the specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of this equipment and materials, we rely or may rely on sole-source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our product candidates.

We will depend on a limited number of vendors for supply of certain materials and equipment used in the manufacture of our MultiTAA-specific T cell therapy-based product candidates. For example, we will purchase equipment and reagents critical for the manufacture of our product candidates from Wilson Wolf (a company controlled by our director John Wilson), JPT Peptide Technologies and other suppliers. Some of our suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also may not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may not be able to obtain key materials and equipment to support clinical or commercial manufacturing. Further, the FDA may determine that our manufacturing process, or the materials required for the manufacture of our product candidates, are not acceptable, which would require us to find alternative suppliers or processes, which may not be available on favorable terms, if at all. For example, the FDA has requested additional data from us regarding the new reagent we intend to use to manufacture MT-401 before we can proceed with the remainder of our planned Phase 2 trial of MT-401 for the treatment of post-transplant AML.

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

As we continue to develop and scale our manufacturing process, we may need to obtain rights to and supplies of specific materials and equipment to be used as part of that process. For example, our MultiTAA-specific T cell manufacturing process is based, in part, upon the G-Rex® cell culture device manufactured by Wilson Wolf, which is used by many cell therapy developers, both in commercial and academic settings. Although we do hold the license to patents from BCM that could be used to prevent third parties from developing similar and competing processes, we do not own any exclusive rights to the G-Rex®. We may not be able to obtain rights to such materials and equipment on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we, or any of our third-party manufacturers encounter such difficulties, our ability to supply our product candidates for clinical trials, or our product candidates for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our product candidates are biologics, and the process of manufacturing our product candidates is complex, highly regulated and subject to multiple risks. For example, the manufacture of our MultiTAA-specific T cell therapy-based product candidates involves complex processes, including drawing blood from patients/donors, manufacturing the clinical product, and ultimately infusing the product into a patient. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing processes will be susceptible to product loss or failure due to any of the following: logistical issues associated with the collection of blood cells, or starting material, from the patient or a donor, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product; manufacturing issues associated with the variability in patients' or donor's starting cells; interruptions in the manufacturing process; contamination; equipment failure; improper installation or operation of equipment, vendor or operator error; inconsistency in cell growth; and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's or a donor's cells, or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome and/or the results of clinical trials. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Because our MultiTAA-specific T cell therapy-based product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to the patient's/donor's blood cells as it moves from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our product candidates from the market. Further, as product candidates are developed through preclinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Currently, our product candidates are manufactured using processes developed by BCM, our third-party research institution collaborator. Although we are working to develop our own commercially viable processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

No assurance can be given that we will be able to develop a new, FDA-compliant, more efficient, lower cost manufacturing process upon which our business plan to commercialize MultiTAA-based product candidates is dependent.

In cooperation with our current contract manufacturers, we intend to develop improved methods for generating and selecting T cells, and to develop methods for large-scale production of our current product candidates that are in accordance with current cGMP procedures. Developing a new, scaled-up, pharmaceutical manufacturing process that can more efficiently and cost effectively, and in a more automated manner produce, measure and control the physical and/or chemical attributes of our product candidates in a cGMP facility is subject to many uncertainties and difficulties. We have never manufactured our adoptive T cell therapy product candidate on a commercial scale. As a result, we cannot give any assurance that we will be able to establish a manufacturing process that can produce our product candidates at a cost or in quantities necessary to make them commercially viable. Moreover, we and our third-party manufacturers will have to continually adhere to current cGMP regulations enforced by the FDA through its facilities inspection program. If these facilities cannot pass a pre-approval plant inspection, the FDA premarket approval of our product candidates will not be granted. In complying with cGMP and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort in production, record-keeping and quality control to assure that our product candidates meet applicable specifications and other requirements. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action. No assurance can be given that we will be able to develop such manufacturing process, or that our partners will thereafter be able to establish and operate such a production facility.

The deviations in our proposed new MultiTAA-based product candidates from existing products may require us to perform additional testing, which will increase the cost, and extend the time for obtaining approval.

Our MultiTAA-specific T cell therapy platform is based on the adoptive T cell therapy technology that we licensed from BCM and that is presently available as a physician-sponsored investigational therapy at BCM for the treatment of lymphoma, AML/MDS, multiple myeloma and select solid tumors in the United States. The current method of treatment is labor intensive and expensive. We are performing process optimization that we anticipate will enable more efficient manufacturing of our product candidates. We may have difficulty demonstrating that the product candidates produced from our new processes are identical to the existing products. The FDA may require additional clinical testing before permitting a larger clinical trial with the new processes, and such drug substance may not be as efficacious in the new clinical trials. Cellular products are not considered to be well characterized products because there are hundreds of markers present on T cells, and even small changes in manufacturing processes could alter the cell subtypes. It is unclear at this time which of those markers are critical for success of T cells to combat cancer, so our ability to predict the outcomes with newer manufacturing processes is limited. The changes that we may make to the existing manufacturing process may require additional testing, which may increase costs and timelines associated with these developments. In addition to developing a multi-antigen T cell-based therapy on existing adoptive T cell therapy technology, we are currently evaluating the desirability of conducting clinical trials of our product candidates in combination with other existing drugs. These combination therapies will require additional testing, and clinical trials will require additional FDA regulatory approval and will increase our future cost of development.

We may not be able to develop product candidates successfully or on a timely basis.

Our immunotherapy product candidates are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. We will need to complete significant additional clinical trials demonstrating that our product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, which involves substantial expenditures of resources, and depends upon a numerous factors, including the severity of the disease indication in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Our success depends on our ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may be unable to develop revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results.

Immunotherapies that we may develop are not likely to be commercially available for at least five years. Any delay in obtaining FDA and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U.S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. For example, the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of our clinical trials or study endpoints; or we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U.S. regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. 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. The proposed development schedules for our immunotherapy product candidates may be affected by a variety of other factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control.

Any delay in the development, approval, introduction or marketing of our product candidates could result either in such product candidates being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, we might not be able to successfully complete the development or marketing of any new product candidates, and as a result, our business, prospects, financial condition and results of operations could be materially and adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products and cease to operate.

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

Even if we obtain regulatory approval for our product candidates, they may not gain market acceptance among physicians, healthcare payors, patients or the medical community. Market acceptance of our product candidates, if we receive approval, depends on a number of factors, including the:

- efficacy and safety of our product candidates as demonstrated in clinical trials and post-marketing experience;
- clinical indications for which our product candidates may be approved;
- acceptance by physicians and patients of our product candidates as safe and effective;
- potential and perceived advantages of our product candidates over alternative treatments;

- safety of our product candidates seen in a broader patient group, including our use outside the approved indications should physicians choose to prescribe for such uses;
- prevalence and severity of any side effects;
- product labeling, or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of our product candidates as well as competitive products;
- cost in relation to alternative treatments;
- pricing and the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration; and
- effectiveness of any sales and marketing efforts.

Moreover, if our product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors and the medical community, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical research organizations and other third parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates, and to conduct clinical trials for some or all of our product candidates. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that it has generated, and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or with the USPTO.

If we, our licensing partners, or any potential future collaborator initiates legal proceedings against a third party to enforce a patent directed to one of our product candidates, the defendant could counterclaim that the patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, non-obviousness or enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they are no longer directed to our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid or could prevent a patent from issuing from one or more of our pending patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. 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. Such a loss of patent protection could have a material adverse impact on our business development.

If we are unable to protect our proprietary rights, we may not be able to compete effectively or operate profitably.

Our commercial success is dependent in part on our ability to obtain, maintain, and enforce the patents and other proprietary rights that we have licensed and may develop, and on our ability to avoid infringing the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims are directed to the technology. There can be no assurance that our patent applications or those of our licensor will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with relevant employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of the premises and physical and electronic security of the information technology systems. While we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, trade secrets may otherwise become known or be independently discovered by competitors. To the extent that the consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Although we have patents and patent applications in other countries, we cannot be certain that the claims in other pending U.S. or European patent applications, international patent applications, and patent applications in certain other foreign territories directed to methods of generating multi-antigen specific T cell product candidates, or our other product candidates, will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued European patent will not be found invalid or unenforceable if challenged.

Most of our intellectual property rights are currently licensed from BCM and the Mayo Foundation, so that the preparation and prosecution of these patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than us, and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties. We may also require the cooperation of one of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensor have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and it is uncertain how much protection, if any, will be given to the patents we have licensed from a licensor if either the licensor or we attempt to enforce the patents and/or if they are challenged in court or in other proceedings, such as oppositions, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third party may challenge our patents, if issued, or the patent rights that we license from others in the courts or patent offices in the United States and abroad. It is possible that a competitor may successfully challenge our patents or that a challenge will result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to

us. Moreover, it is possible that competitors may infringe our patents or successfully avoid them through design innovation. To stop these activities, we may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if we were successful in stopping the violation of our patent rights. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents were upheld, a court would refuse to stop the other party on the ground that its activities are not covered by, that is, do not infringe, our patents.

Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor(s) or by us in any future patent application, we may be required to participate in interference proceedings in the USPTO to determine priority of invention for those patents or patent applications that are subject to the first-to-invent law in the United States, or may be required to participate in derivation proceedings in the USPTO for those patents or patent applications that are subject to the "first-inventor-to-file" law in the United States. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding or derivation proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms or on any terms.

The use of our technologies could potentially conflict with the rights of others.

Our potential competitors or other entities may have or acquire patent or proprietary rights that they could enforce against our licensors. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, *inter partes* review proceedings and post-grant review, or PGR, proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. 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 manufacture of our product candidates. If they do so, then they could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position by requiring us to alter our product candidates, pay licensing fees or cease activities.

As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that later issue as patents that our product candidates may infringe. If our product candidates conflict with patent rights of others, third parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing and marketing of the affected product candidates. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected product candidates. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms or at all.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in post-grant proceedings including post grant review, derivation, reexamination, *inter-partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. In addition, recent U.S. Supreme Court rulings on several patent cases have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. While we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

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

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

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

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. We have received confidential and proprietary information from third parties. We employ individuals or engage consultants who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

If we fail to comply with any obligations under our existing license agreements or any future license agreements, or disputes arise with respect to those agreements, it could have a negative impact on our business and our intellectual property rights.

We are a party to license agreements with BCM and the Mayo Foundation that impose, and we may enter into additional licensing arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Our rights to use the licensed intellectual property are subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to us from a third party, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us, alone or with our licensors and collaborators;
- the scope and duration of our payment obligations;
- our rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

If disputes over intellectual property and other rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under current or future licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

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

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be subject to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide sufficient rights to exclude others from commercializing products similar or identical to our product candidates.

Certain of our technologies are in-licensed from third parties, and the protection of those technologies is not entirely within our control.

We have world-wide exclusive licenses from the Mayo Foundation on (i) a novel set of Class II HER2/neu peptide antigens, (ii) a novel Class I HER2/neu antigen, and (iii) a novel set of Class II Folate Receptor Alpha peptide antigens. We have a world-wide exclusive license from BCM of the rights in and to three patent families to develop and commercialize MultiTAA-specific T cell product candidates in the field of oncology. As a result of these in-licenses, we could lose the right to develop each of the technologies if:

- the owners of the patent rights underlying the technologies that we license do not properly maintain or enforce the patents and intellectual property underlying those properties,
- the Mayo Foundation or BCM seeks to terminate our license in contravention of the license agreements;
- we fail to make all payments due and owing under any of the licenses; or
- we fail to obtain on commercially reasonable terms, if at all, in-licenses from the Mayo Foundation or BCM or others for other rights that are necessary to develop the technology that we have already in-licensed.

If any of the above occurs, we could lose the right to use the in-licensed intellectual property, which would adversely affect our ability to commercialize our technologies, products or services. The loss of any current or future licenses from Mayo Foundation or BCM, or the exclusivity rights provided by such license agreements, could materially harm our financial condition and operating results.

We rely upon patents and licensed technologies to protect our technology. We may be unable to protect our intellectual property rights, and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively depends on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with whom we have entered into collaboration and licensing agreements. We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United States and abroad for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and sufficient funds might not be available. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will be issued from any pending or future patent applications owned by or licensed to us. Even if patents have been issued or will be issued, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including our patent positions, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without infringing our patents.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our intellectual property rights or those of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents which we own or in-license is not valid or is unenforceable, and/or is not infringed. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and/or pending patent applications will be due to the USPTO and foreign patent agencies in several stages over the lifetime of our patents and/or applications. 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. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business development.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. Should third parties file patent applications or be issued patents claiming technology also used or claimed by us, we may be required to participate in interference or derivation proceedings in the USPTO to determine priority of invention. We may be required to participate in interference or derivation proceedings involving our issued patents and pending applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially acceptable terms.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we are unable to obtain licenses needed for the development of our product candidates, or if we breach any of the agreements under which we license rights to patents or other intellectual property from third parties, we could lose license rights that are important to our business.

If we are unable to maintain and/or obtain licenses needed for the development of our product candidates in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned product candidates. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We might not meet these minimum license fees in the future, or these third parties might not grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, the patents underlying the licenses might not be valid and enforceable. To the extent any product candidates developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such product candidates uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business financial condition and our operations.

We may face legal claims; litigation is expensive and we may not be able to afford the costs.

We may face legal claims involving stockholders, consumers, competitors, entities from whom we license technology, entities with whom we collaborate, persons claiming that we are infringing on their intellectual property and others. The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may initiate or become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or we may become subject to proceedings initiated by our competitors or other third parties or the USPTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. In addition, litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others.

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial even if resolved in our favor. Some of our competitors or financial funding sources have far greater resources than we do and may be better able to afford the costs of complex legal procedures. Also, in a lawsuit for infringement or contractual breaches, even if frivolous, we will require considerable time commitments on the part of management, our attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect our financial results.

Our research and development programs are subject to uncertainty.

Factors affecting our research and development programs include, but are not limited to:

- limited financial resources from which to budget and allocate among our product candidates;
- competition from companies that are substantially and financially stronger than us;
- the need for acceptance of our immunotherapies;
- our ability to anticipate and adapt to a competitive market and rapid technological developments;
- the amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- the need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry;
- our dependence on BCM facilities to conduct research and development activities; and
- the dependence upon key personnel including key independent consultants and advisors.

Our research and development expenses may not be consistent from time to time. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

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 do not currently have an organization for the sale, marketing and distribution of any approved 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 approved by the FDA or 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. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an 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.

If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other immunotherapies. If we are unsuccessful in securing such strategic collaborations, we may be unable to commercialize any approved products as we have not yet licensed, marketed or sold any of our immunotherapies or entered into successful collaborations for these services in order to ultimately commercialize our immunotherapies. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, clinical, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our immunotherapies or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our research and development programs with the research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations at the early phases of drug development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our immunotherapies. Our corporate collaborators may not commit sufficient resources to their research and development programs or the commercialization, marketing or distribution of their immunotherapies. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestones or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

We may not be able to license newly developed MultiTAA-specific T cell technology from BCM and others.

An important element of our intellectual property portfolio is to license additional rights and technologies from BCM. Our inability to license the rights and technologies that we have identified, or newly developed MultiTAA-specific T cell technology that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. No assurance can be given that we will be successful in licensing any additional rights or technologies from BCM and others. Failure to obtain additional rights and licenses may detrimentally affect our planned development of additional product candidates and could increase the cost, and extend the timelines associated with our development of such other product candidates.

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 oncology therapies initially only for use in patients with relapsed or refractory metastatic disease. We expect to initially seek approval of our product candidates in this setting. Subsequently, for those product candidates 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. There is no guarantee, however, that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive second or third-line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our research and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of treatable 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 and may also be limited by the cost of our treatments and the reimbursement of those treatment costs by third-party payors. For instance, we expect our lead product candidate to initially target a small patient population that suffers from AML. 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 are required to pay substantial royalties and lump sum milestone payments under our license agreements with BCM and the Mayo Foundation, and we must meet certain milestones to maintain our license rights.

Under our license agreement with BCM for our MultiTAA-specific T cell therapy technologies, we are currently required to pay both substantial milestone payments and royalties to BCM based on our revenues from sales of any approved products utilizing the licensed technologies, and these payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. In order to maintain our license rights under the BCM license agreement, we will need to meet certain specified milestones, subject to certain cure provisions, in the development of our product candidates. Similarly, we are also required to pay both substantial milestone payments and royalties to the Mayo Foundation based on our revenues from sales of our products utilizing those licensed technologies. There is no assurance that we will be successful in meeting all of the milestones in our licenses in the future on a timely basis or at all.

In addition, upon a liquidity event (as defined in our BCM license agreement with BCM) of the licensee under the BCM license agreement (which, the licensee shall be the Company), BCM will receive a liquidity incentive payment of 0.5% of the liquidity event proceeds (as defined in the BCM license agreement) received by such licensee or its stockholders in the liquidity event, thereby diluting the amount of proceeds available to the licensee or its stockholders in a liquidity event.

Because our current product candidates represent, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of our product candidates.

There is no assurance that the approaches offered by our product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for proposed product candidates. Moreover, we do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent new approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend large amounts of money trying to obtain approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing our therapies. However, unless we are able to reduce those costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable.

Our MultiTAA-specific T cell therapy may be provided to patients in combination with other agents provided by third parties. The cost of such combination therapy may increase the overall cost of MultiTAA-specific T cell therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may adversely affect our ability to obtain reimbursement coverage for the combination therapy from third-party medical insurers.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent to the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;

- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any product candidate.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could inhibit or prevent the commercialization of products we develop, alone or with collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no insurance coverage. While we obtained clinical trial insurance for our Phase II clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.

Competition in the field of cancer therapy is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs that may render our product candidates obsolete even before they generate any revenue. There are products currently under development by others that could compete with the product candidates that we are developing. Many of our potential competitors have substantially greater research and development capabilities and manufacturing, marketing, financial and managerial resources than we have. Our competitors may:

- develop safer or more effective immunotherapies and other therapeutic products;
- reach the market more rapidly, reducing the potential sales of our products; or
- establish superior proprietary positions.

Potential competitors in the market for treating hematological malignancies are companies such as Juno Therapeutics/Celgene/Bristol-Myers Squibb, Roche/Genentech, Merck, Novartis, Kite Pharma/Gilead, Amgen, Pfizer, and GlaxoSmithKline, which already have products on the market or in development. Other companies, such as Cellectis, Bluebird Bio, and AdaptImmune, which are focused on genetically engineered T cell technologies to treat cancer, may also be competitors. Furthermore, companies such as Iovance, Immatics, WindMIL Therapeutics, Mana Therapeutics, Tessa Therapeutics and Torque Therapeutics (now Repetoire Immune Medicines) are developing non-genetically modified T cell therapies such as tumor infiltrating lymphocytes and marrow infiltrating lymphocytes therapies that may compete with our product candidates. All these companies, and most of our other current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally.

Universities and public and private research institutions in the U.S. and around the world are also potential competitors. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our technologies and product candidates.

Our lead product candidate is a therapy for the treatment of refractory AML. Currently, there are numerous companies that are developing various alternate treatments for AML. Accordingly, we face significant competition in the AML treatment space from multiple companies. Even if we obtain regulatory approval for our lead product candidate, the availability and price of competitors' products could limit the demand and the price we will be able to charge for our therapy. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product candidates for use in limited circumstances.

As a result of being a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This report by management is included in Part II, Item 9A of this Form 10-K. In addition, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting in this Form 10-K. We are also required to disclose significant changes made in our internal control procedures on a quarterly basis.

To comply with Section 404, we have engaged in the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. Our compliance with Section 404 requires that we incur substantial professional fees and expend significant management efforts, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our business and operations would suffer in the event of cybersecurity/information systems risk.

Despite the implementation of security measures, our internal computer systems, and those of our manufacturers and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, successful breaches, employee malfeasance, or human or technological error, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding our subjects. If a disruption 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 trial data from completed, ongoing or planned clinical trials 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 and the further development of our product candidates could be delayed.

We maintain cybersecurity insurance however an incident may exceed our coverage premiums.

We have cybersecurity insurance for a breach event covering expenses for notification, credit monitoring, investigation, crisis management, public relations and legal advice. We also maintain property and casualty insurance that may cover restoration of data, certain physical damage or third-party injuries caused by potential cybersecurity incidents. However, damage and claims arising from such incidents may not be covered or may exceed the amount of any insurance available.

We may incur costs of addressing a cybersecurity incident.

Cybersecurity incidents have increased in number and severity recently and it is expected that these trends will continue. Should we be affected by such an incident, we may incur substantial costs and suffer other negative consequences, which may include:

- investigation costs and costs to engage specialized consultants;
- remediation costs, such as liability for stolen assets or information, repairs of system damage, and incentives to customers or business partners in an effort to maintain relationships after an attack; and
- litigation and legal risks, including regulatory actions by state and federal regulators.

Our ability to use net operating losses and certain other tax attributes to offset future taxable income may be subject to limitation.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are permitted to be carried forward for only 20 years under applicable U.S. tax law. Our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2020 is subject to certain limitations. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, or, the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage over a rolling three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Changes in tax laws or regulations could materially adversely affect our company.

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, enacted many significant changes to the U.S. tax laws, including changes in corporate tax rates, the utilization of our NOLs and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. 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 could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or 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 newly enacted federal tax legislation. The impact of changes under the Tax Act, the CARES Act, or future reform legislation could increase our future U.S. tax expense and could have a material adverse impact on our business and financial condition.

Risks Related to Government Regulation

We are subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays; even if we obtain regulatory approval for some of our products, those product candidates may still face regulatory difficulties.

All of our current and future product candidates, cell processing and manufacturing activities, are subject to comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive and often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, regulatory agencies may lack experience with our technologies and product candidates, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

No adoptive T cell therapy using MultiTAA-specific T cells has been approved for marketing in the U.S. by the FDA. Consequently, there is no precedent for the successful commercialization of products based on our technologies. In addition, we have had only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely FDA approvals, if at all. We have not yet sought FDA approval for any adoptive T cell therapy product. We will not be able to commercialize any of our potential product candidates until we obtain FDA approval, and so any delay in obtaining, or inability to obtain, FDA approval would harm our proposed business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, forced to remove a product from the market and experience other adverse consequences including delay, which could materially harm our business development. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We may also be required to undertake post-marketing trials. Prescription drugs may be promoted only for the approved indications in accordance with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatment but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. In addition, if we or others identify side effects after any of our adoptive T cell therapy products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn, and reformulation of our products may be required.

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the CMC for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of cell therapies for cancer. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval by an independent IRB at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;

- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

Further, the performance of our CROs may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic. We could also encounter delays if physicians face unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRB for the institutions in which such trials are being conducted, the Data and Safety Monitoring Board or Committee for such trial, or by the FDA or other regulatory authorities due to a number of factors. Those factors could include failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of any approved product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing quality and regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency,

or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as current and future sales, marketing, patient co-payment assistance and education programs.

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, 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;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians, as defined by such law, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and

- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; state and local "drug takeback" laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. While our interactions with healthcare professionals have been structured to comply with these laws and related guidance, it is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

In addition, any sales of our product once commercialized outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Recently enacted and future legislation in the United States and other countries may affect the prices we may obtain for our product candidates and increase the difficulty and cost to commercialize our product candidates.

In the United States and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which has resulted in a number of changes to laws and regulations, and may result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any product candidates for which we have obtained marketing approval.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA was enacted in the United States in March 2010, with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare, and includes measures to change health care delivery, increase the number of individuals with insurance, ensure access to certain basic health care services, and contain the rising cost of care. Since January 2017, President Trump has signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Further, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 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. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. Congress may consider other legislation to repeal or replace elements of the ACA. These actions may result in increased health insurance premiums and reduce the number of people with health insurance in the United States and have other effects that could adversely affect U.S. health insurance markets and the ability of patients to have access to therapies that our product candidates can provide.

In addition, other federal health reform measures have been proposed and adopted in the United States. For example, as a result of the Budget Control Act of 2011 and subsequent legislative amendments thereto, providers are subject to Medicare payment reductions of 2% per fiscal year through 2030 unless additional Congressional action is taken. The 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. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and also introduced a quality payment program, or the Quality Payment Program,under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. This Quality Payment Program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. It is still unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for 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. On March 10, 2020, the Trump 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. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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. The Department of Health and Human Resources 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 of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Further, on July 24, 2020, President Trump signed four additional Executive Orders designed to reduce the cost of drugs. Although a number of these, and other measures may require additional authorization to become effective, Congress and the executive branch have each indicated that it will continue to seek new legislative and/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, designed to encourage importation from other countries and bulk purchasing.

The combination of healthcare cost containment measures, increased health insurance costs, reduction of the number of people with health insurance coverage, as well as future legislation and regulations focused on reducing healthcare costs by reducing the cost of, or reimbursement and access to, pharmaceutical products, may limit or delay our ability to commercialize our products, generate revenue or attain profitability. It is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that ACA qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

Efforts to ensure that our business arrangements comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or in asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to develop our business. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Generally, a product that has orphan drug designation and subsequently receives the first FDA approval for the disease for which it has such designation is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

The FDA has granted orphan drug designation for MT-401 for the treatment of AML after receiving an allogenic stem cell transplant. We may seek orphan drug designation for other indications or product candidates. Even if we were to obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA or European Medicines Agency (“EMA”) later 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. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

New regulatory pathways for biosimilar competition could reduce the duration of market exclusivity for our products.

Under the federal ACA enacted in 2010, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be “biosimilar” or “interchangeable” with an FDA-approved biological product. The ACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened. A number of jurisdictions outside of the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the European Union has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if one of our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

As described above, the ACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

The current U.S. administration and Congress could carry out significant changes in legislation, regulation, and government policy (including with respect to the possible repeal of all or portions of the ACA, possible changes in the existing treaty and trade relationships with other countries, and tax reform). While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our product candidates could adversely affect our business.

Risks Related to our Securities

The price of our stock may be volatile.

The trading price of our common stock may fluctuate substantially. The price of our common stock that will prevail in the market may be higher or lower than the price at which our shares of common stock, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume of fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- results of our preclinical studies and clinical trials or delays in anticipated timing;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners;
- announcements of acquisitions, mergers or business combinations;
- announcements of technological innovations, new commercial products, failures of products or product candidates, or progress toward commercialization by our competitors or peers;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotechnology sectors;
- major catastrophic events;

- sales of large blocks of our stock and sales by insiders and our institutional investors;
- departures of key personnel;
- changes in the regulatory status of our immunotherapies, including results of our clinical trials;
- events affecting BCM, Mayo Clinic, Mayo Foundation for Medical Education and Research or any future collaborators;
- announcements of new product candidates or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries, including changes in the structure of healthcare payment systems;
- failure of our common stock to maintain listing requirements on Nasdaq;
- the outcome of any litigation to which we are a party;
- changes in accounting principles; and
- discussion of the Company or our stock price by the financial and scientific press and in online investor communities.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

A limited public trading market may cause volatility in the price of our common stock.

The listing of our common stock on Nasdaq does not assure that a meaningful, consistent and liquid trading market currently exists or will exist in the future. In recent years, the stock market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our stockholders could suffer losses or be unable to liquidate their holdings. Our stock is thinly traded due to the limited number of shares available for trading thus causing large swings in price. There is no established trading market for our warrants.

The market prices for our common stock may be adversely impacted by future events.

Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of shares upon the exercise of outstanding warrants or the issuance of preferred stock;
- changes in interest rates;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;

- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock and warrants;
- investor perceptions of us and the pharmaceutical and biotech industries generally; and
- general economic and other national and global conditions, including the ongoing COVID-19 pandemic and related global economic uncertainty.

Sales of additional equity securities may adversely affect the market price of our common stock and your rights may be reduced.

We expect to continue to incur drug development and sale, general and administrative costs. Until such time, if ever, as we can generate substantial product revenue, we expect to fund our cash requirements through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. We do not currently have a committed external source of funds. To the extent that we sell equity securities or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets may adversely affect the market price of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Because we have a significant number of additional authorized shares of common stock available for issuance and outstanding warrants to purchase our common stock, our stockholders may experience dilution in the future and it may adversely affect the market price of our securities.

We are currently authorized to issue 150 million shares of our common stock. As of June 30, 2020, we had 46.6 million shares of our common stock issued and outstanding. Those outstanding shares represent a minority of our authorized shares, meaning that the ownership position of the current stockholders could be diluted significantly were we to issue a large number of additional shares. In addition, as of June 30, 2020, there were outstanding warrants to purchase up to approximately 21.4 million shares of our common stock at a weighted average exercise price of $4.69 per share, and options exercisable for an aggregate of approximately 5.8 million shares of common stock at a weighted average exercise price of $6.34 per share. We have registered the resale of the shares issuable upon exercise of our outstanding warrants, and as a result the shares issued upon exercise will be tradable by the exercising party. Upon such registration, the holders may sell these shares in the public markets from time to time, without limitations on the timing, amount, or method of sale. If our stock price rises, the holders may exercise their warrants and options and sell a large number of shares. This could cause the market price of our common stock to decline and cause existing stockholders to experience significant further dilution.

The accounting treatment for certain of our warrants is complex and subject to judgments concerning the valuation of embedded derivative rights within the applicable securities. Fluctuations in the valuation of these rights could cause us to take charges to our statement of operations and make our financial results unpredictable.

Certain of our outstanding warrants contain or contained prior to being amended, or may be deemed to contain from time to time, embedded derivative rights in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). There is a risk that questions could arise from investors or regulatory authorities concerning the appropriate accounting treatment of these instruments, which could require us to restate previous financial statements, which in turn could adversely affect our reputation, as well as our results of operations. These derivative rights, or similar rights in securities we may issue in the future, need to be, or may need to be, separately valued as of the end of each accounting period in accordance with GAAP. We record these embedded derivatives as liabilities at issuance, valued using the Black Scholes Option Pricing Model and are subject to revaluation at each reporting date. Any change in fair value between reporting periods is reported on our statement of operations. At June 30, 2020, the fair value of the derivative liability-warrants was $0. Changes in the valuations of these rights, the valuation methodology or the assumptions on which the valuations are based could cause us to take charges to our earnings, which would adversely impact our results of operations. Moreover, the methodologies, assumptions and related interpretations of accounting or regulatory authorities associated with these embedded derivatives are complex and, in some cases uncertain, which could cause our accounting for these derivatives, and as a result, our financial results, to fluctuate.

We do not intend to pay cash dividends.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and depends on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

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

We did not record any issuances of unregistered securities during the six months ended June 30, 2020.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following exhibits are included with this Quarterly Report on Form 10-Q:

Exhibit number	Exhibit description	Incorporated by Reference			Filing date	Filed herewith
		Form	File no.	Exhibit		
3.1	Certificate of Incorporation (Delaware).	8-K	001-37939	3.4	10/17/18	
3.2	Bylaws of Marker Therapeutics, Inc.	8-K	001-37939	3.6	10/17/18	
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1933, as amended.					X
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1933, as amended.					X
32.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1933, as amended.					X
32.2*	Certification of Chief Financial Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

Exhibit 101

101.INS - XBRL Instance Document
101.SCH - XBRL Taxonomy Extension Schema Document
101.CAL - XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF - XBRL Taxonomy Extension Definition Linkbase Document
101.LAB - XBRL Taxonomy Extension Label Linkbase Document
101.PRE - XBRL Taxonomy Extension Presentation Linkbase Document
104 - Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 filed herewith).

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 10, 2020

MARKER THERAPEUTICS, INC.

/s/ Peter L. Hoang
Peter L. Hoang
President, Chief Executive Officer and Principal Executive Officer

/s/ Anthony Kim
Anthony Kim
Chief Financial Officer and Principal Financial and Accounting Officer

Exhibit 31.1

CERTIFICATION

I, Peter L. Hoang, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Marker Therapeutics, Inc.;

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

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

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 assurances regarding the reliability of financial reporting in 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(s) and I have disclosed, based on our most recent evaluation of the 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 10, 2020

/s/ Peter L. Hoang

By: **Peter L. Hoang**
Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Anthony Kim, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Marker Therapeutics, Inc.;

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

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

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 assurances regarding the reliability of financial reporting in 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(s) and I have disclosed, based on our most recent evaluation of the 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 10, 2020

/s/ Anthony Kim

By: **Anthony Kim**
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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

The undersigned, Peter L. Hoang, the Chief Executive Officer of Marker Therapeutics, Inc. (the "Company") hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, the Quarterly Report on Form 10-Q for the period ending June 30, 2020, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of the Company.

Date: August 10, 2020

/s/ Peter L. Hoang
Peter L. Hoang
Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

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

The undersigned, Anthony Kim, the Chief Financial Officer of Marker Therapeutics, Inc. (the "Company") hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, the Quarterly Report on Form 10-Q for the period ending June 30, 2020, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of the Company.

Date: August 10, 2020

/s/ Anthony Kim
Anthony Kim
Chief Financial Officer (Principal Financial and Accounting Officer)