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, 2019

☐ 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 August 5, 2019, the Company had 45,670,597 shares of common stock issued and outstanding.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

MARKER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,444,906	$ 61,746,748
Prepaid expenses and deposits	491,467	141,717
Interest receivable	98,154	108,177
Total current assets	54,034,527	61,996,642
Non-current assets:		
Property, plant and equipment, net	413,239	147,668
Right-of-use assets, net	547,455	-
Total non-current assets	960,694	147,668
Total assets	**$ 54,995,221**	**$ 62,144,310**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,946,782	$ 2,754,572
Lease liability	194,482	-
Warrant liability	65,000	49,000
Total current liabilities	3,206,264	2,803,572
Non-current liabilities:		
Lease liability, net of current portion	385,169	-
Total non-current liabilities	385,169	-
Total liabilities	3,591,433	2,803,572
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, 2019 and December 31, 2018, respectively	-	-
Common stock, $0.001 par value, 150 million shares authorized, 45.5 million and 45.4 million shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	45,513	45,440
Additional paid-in capital	368,353,041	365,400,748
Accumulated deficit	(316,994,766)	(306,105,450)
Total stockholders' equity	51,403,788	59,340,738
Total liabilities and stockholders' equity	**$ 54,995,221**	**$ 62,144,310**

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,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Grant income	$ -	$ 205,994	$ -	$ 205,994
Total revenues	-	205,994	-	205,994
Operating expenses:				
Research and development	3,152,445	1,826,837	5,985,140	3,426,387
General and administrative	2,721,120	3,052,954	5,526,895	4,650,890
Total operating expenses	5,873,565	4,879,791	11,512,035	8,077,277
Loss from operations	(5,873,565)	(4,673,797)	(11,512,035)	(7,871,283)
Other income (expense):				
Change in fair value of warrant liabilities	(7,000)	(139,000)	(16,000)	(138,000)
Interest income	310,174	-	638,719	-
Net loss	**$ (5,570,391)**	**$ (4,812,797)**	**$ (10,889,316)**	**$ (8,009,283)**
Net loss per share, basic and diluted	$ (0.12)	$ (0.41)	$ (0.24)	$ (0.71)
Weighted average number of common shares outstanding	45,501,078	11,838,371	45,483,513	11,233,755

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, 2019				
	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Par value	Paid-in Capital	Deficit	Equity
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 at June 30, 2019	**45,513,523**	**$ 45,513**	**$ 368,353,041**	**$ (316,994,766)**	**$ 51,403,788**

	For the Three Months Ended June 30, 2018				
	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Par value	Paid-in Capital	Deficit	Equity
Balance at April 1, 2018	**10,636,182**	**$ 10,636**	**$ 161,221,836**	**$ (160,616,513)**	**$ 615,959**
Issuance of common stock in private placement	1,300,000	1,300	3,118,700	-	3,120,000
Stock warrants exercised for cash	1,446,881	1,447	4,259,638	-	4,261,085
Stock warrants cashless exercised	118,425	118	(118)	-	-
Stock-based compensation	122,783	123	960,156	-	960,279
Fair value of repriced warrants as inducement	-	-	727,513	(727,513)	-
Net loss	-	-	-	(4,812,797)	(4,812,797)
Balance at June 30, 2018	**13,624,271**	**$ 13,624**	**$ 170,287,725**	**$ (166,156,823)**	**$ 4,144,526**

	For the Six Months Ended June 30, 2019				
	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Par value	Paid-in Capital	Deficit	Equity
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 at June 30, 2019	**45,513,523**	**$ 45,513**	**$ 368,353,041**	**$ (316,994,766)**	**$ 51,403,788**

	For the Six Months Ended June 30, 2018				
	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Par value	Paid-in Capital	Deficit	Equity
Balance at January 1, 2018	**10,615,724**	**10,616**	**161,067,538**	**(157,420,027)**	**3,658,127**
Issuance of common stock in private placement	1,300,000	1,300	3,118,700	-	3,120,000
Stock options exercised for cash	10,416	10	18,115	-	18,125
Stock warrants exercised for cash	1,446,881	1,447	4,259,638	-	4,261,085
Stock warrants cashless exercised	118,425	118	(118)	-	-
Stock-based compensation	132,825	133	1,096,339	-	1,096,472
Fair value of repriced warrants as inducement	-	-	727,513	(727,513)	-
Net loss	-	-	-	(8,009,283)	(8,009,283)
Balance at June 30, 2018	**13,624,271**	**$ 13,624**	**$ 170,287,725**	**$ (166,156,823)**	**$ 4,144,526**

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,	
	2019	**2018**
Cash Flows from Operating Activities:		
Net loss	$ (10,889,316)	$ (8,009,283)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	39,811	-
Changes in fair value of warrant liabilities	16,000	138,000
Stock-based compensation	2,889,243	1,096,472
Amortization on right-of-use assets	89,178	-
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(349,750)	(57,566)
Interest receivable	10,023	-
Accounts payable and accrued expenses	225,135	2,086,840
Lease liability	(89,907)	-
Net cash used in operating activities	(8,059,583)	(4,745,537)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(305,382)	-
Net cash used in investing activities	(305,382)	-
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock and warrants in private placement, net of offering costs	-	3,120,000
Proceeds from exercise of stock options	57,744	18,125
Proceeds from exercise of warrants	5,379	4,261,085
Net cash provided by financing activities	63,123	7,399,210
Net (decrease) increase in cash	(8,301,842)	2,653,673
Cash and cash equivalents at beginning of period	61,746,748	5,129,289
Cash and cash equivalents at end of period	$ 53,444,906	$ 7,782,962

	For the Six Months Ended June 30,	
	2019	**2018**
Supplemental schedule of non-cash financing activities:		
Fair value of repriced warrants as inducement	$ -	$ 727,513
Stock warrants cashless exercised	$ -	$ 118

See accompanying notes to these unaudited condensed consolidated financial statements.

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, 2019 or for any future interim period. The condensed consolidated balance sheet at June 30, 2019 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, 2018 and notes thereto included in the Company's annual report on Form 10-K filed on March 15, 2019.

NOTE 3: LIQUIDITY AND FINANCIAL CONDITION

As of June 30, 2019, the Company had cash and cash equivalents of approximately $53.4 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 clinical and research and development plans and its timing expectations related to the progress of its programs, the Company expects that its cash and cash equivalents as of June 30, 2019 will enable the Company to fund its operating expenses and capital expenditure requirements through at least the third quarter of 2020. 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.

NOTE 4: SIGNIFICANT ACCOUNTING POLICIES

Leases

Effective January 1, 2019, the Company accounts for its leases under ASC Topic 842, Leases. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheet as both a right of use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right of use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right of use asset result in straight-line rent expense over the lease term. For finance leases, interest on the lease liability and the amortization of the right of use asset results in front-loaded expense over the lease term. Variable lease expenses are recorded when incurred.

In calculating the right of use asset and lease liability, the Company elects to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

The Company continues to account for leases in the prior period financial statements under ASC Topic 840.

Other than above, there have been no material changes in the Company's significant accounting policies to those previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 15, 2019.

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 Adopted in the Year

Leases

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. Based on the analysis, on January 1, 2019, the Company recorded right of use assets of approximately $637,000, lease liability of approximately $670,000 and eliminated deferred rent of approximately $33,000.

SEC Disclosure Update and Simplification

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule was effective on November 5, 2018. The first presentation of the changes in stockholders' equity in accordance with the new guidance was included in the Company's Form 10-Q for the quarter ended March 31, 2019 filed on May 10, 2019.

Improvements to Non-Employee Share-Based Payment Accounting

In June 2018, the FASB issued ASU 2018-07 "Improvements to Non-employee Share-Based Payment Accounting", which simplifies the accounting for share-based payments granted to non-employees for goods and services. Under the ASU, most of the guidance on such payments to non-employees would be aligned with the requirements for share-based payments granted to employees. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The Company has early adopted the new standard effective January 1, 2019 and the adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Numerator:				
Net loss	$ (5,570,391)	$ (4,812,797)	$ (10,889,316)	$ (8,009,283)
Denominator:				
Weighted average common shares outstanding	45,501,078	11,838,371	45,483,513	11,233,755
Net loss per share data:				
Basic and diluted	$ (0.12)	$ (0.41)	$ (0.24)	$ (0.71)

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,	
	2019	**2018**
Common stock options	4,568,000	439,000
Common stock purchase warrants	22,979,000	4,871,000
Common stock warrants - liability treatment	27,000	-
Potentially dilutive securities	27,574,000	5,310,000

NOTE 6: PROPERTY AND EQUIPMENT

Property and equipment consist of the following as of June 30, 2019 and December 31, 2018, respectively:

	Estimated Useful Lives	June 30, 2019	December 31, 2018
Lab equipment	5 Years	$ 64,000	$ -
Computers, equipment and software	3-5 Years	189,000	66,000
Office furniture	5 Years	177,000	82,000
Leasehold improvements	Lesser of lease term or estimated useful life	23,000	-
Total		453,000	148,000
Less: accumulated depreciation		(40,000)	-
Property and equipment, net		$ 413,000	$ 148,000

Depreciation expense for the three and six months ended June 30, 2019 was approximately $29,000 and $40,000, respectively. Furniture and computer equipment were placed in use on January 1, 2019, therefore no depreciation expense was recorded during the year ended December 31, 2018.

NOTE 7: LEASES

The Company leases office space under agreements classified as operating leases that expire on various dates through 2022. All of the Company's lease liabilities result from the lease of its corporate headquarters in Houston, Texas, which expires in 2021, and 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, 2019, the Company had operating lease liabilities of approximately $580,000 and right of use assets of approximately $547,000, which were included in the condensed consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases:

	For the Three Months Ended June 30, 2019	For the Six Months Ended June 30, 2019
Operating lease expense summary:		
Operating lease expense	$ 55,000	$ 110,000
Short-term lease expense	24,000	46,000
Variable lease expense	23,000	38,000
Total	$ 102,000	$ 194,000

Other information:

Operating cash flows from operating leases for the six months ended June 30, 2019	$ 111,000
Right of use assets exchanged for new operating lease liabilities as of adoption date	$ 670,000
Weighted-average remaining lease term as of June 30, 2019 – operating leases	1.8
Weighted-average discount rate as of adoption date – operating leases	6.8%

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

Six months ended December 31, 2019	$	114,000
Year ended December 31, 2020		231,000
Year ended December 31, 2021		226,000
Year ended December 31, 2022		68,000
Total	$	639,000
Less present value discount		(59,000)
Operating lease liabilities included in the Condensed Consolidated Balance Sheet at June 30, 2019	$	580,000

NOTE 8: ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following as of June 30, 2019 and December 31, 2018, respectively:

	June 30, 2019	December 31, 2018
Accounts payable	$ 1,436,000	$ 1,619,000
Compensation and benefits	781,000	416,000
Professional fees	388,000	236,000
Technology license fees	50,000	80,000
Investor relations fees	176,000	297,000
Other	116,000	106,000
Total accounts payable and accrued liabilities	$ 2,947,000	$ 2,754,000

NOTE 9: WARRANT LIABILITY AND FAIR VALUE MEASUREMENTS

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, 2019 and 2018 is as follows:

	For the Six Months Ended June 30,	
	2019	2018
Exercise price	$ 9.72	$ 8.67
Contractual term (years)	0.58	1.32
Volatility (annual)	78%	83%
Risk-free rate	2%	1%
Dividend yield (per share)	0%	0%

The foregoing assumptions are reviewed quarterly and are subject to change based primarily on management's assessment of the probability of the events described occurring. Accordingly, changes to these assessments could materially affect the valuations.

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, 2019			
	Quoted prices in active markets (Level 1)	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Fair value at June 30, 2019**
Warrant liability	$ -	$ -	$ 65,000	$ 65,000

	Fair value measured at December 31, 2018			
	Quoted prices in active markets (Level 1)	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Fair value at December 31, 2018**
Warrant liability	$ -	$ -	$ 49,000	$ 49,000

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, 2019.

The following table presents changes in Level 3 liabilities measured at fair value for the six months ended June 30, 2019:

	Warrant Liability
Balance - January 1, 2019	$ 49,000
Change in fair value of warrant liability	16,000
Balance – June 30, 2019	$ 65,000

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.

NOTE 11: STOCKHOLDERS' EQUITY

Common Stock Transactions

Exercise of Stock Warrants

During the six months ended June 30, 2019, certain outstanding warrants were exercised for 1,799 shares of common stock providing aggregate proceeds to the Company of approximately $5,400.

Exercise of Stock Options

In January 2019, 11,980 shares of common stock were issued pursuant to stock option exercises at an exercise price equal to $4.82 per share, providing aggregate proceeds to the Company of approximately $58,000.

Consulting Arrangements

During the six months ended June 30, 2019, the Company issued 30,000 shares of common stock in connection with consulting agreements. The fair value of the common stock of approximately $176,000 was recognized as stock-based compensation expense in general and administrative expenses.

Board Compensation

During the six months ended June 30, 2019, the Company issued an aggregate of 29,040 shares of common stock to its non-employee directors. The fair value of the common stock of approximately $174,000 was recognized as stock-based compensation expense in general and administrative expenses.

Share Purchase Warrants

A summary of the Company's share purchase warrants as of June 30, 2019 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, 2019	**23,016,000**	**$ 4.78**	**4.29**	**$ 26,066,000**
Exercised for cash	(2,000)	2.99	-	-
Expired or cancelled	(8,000)	12.72	-	-
Balance - June 30, 2019	**23,006,000**	**$ 4.78**	**3.82**	**$ 77,194,000**

NOTE 12: STOCK-BASED COMPENSATION

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,	
	2019	2018	2019	2018
Stock Compensation expenses:				
Research and development	$ 593,000	$ 316,000	$ 1,280,000	$ 386,000
General and administrative	770,000	644,000	1,609,000	710,000
Total stock compensation expenses	$ 1,363,000	$ 960,000	$ 2,889,000	$ 1,096,000

At June 30, 2019, the total stock-based compensation cost related to unvested awards not yet recognized was $14.7 million. The expected weighted average period compensation costs to be recognized was 1.77 years. Future option grants will impact the compensation expense recognized.

On October 19, 2018 the board of directors granted Mr. Peter Hoang, the Company's Chief Executive Officer, an option award of 1,359,855 shares of common stock at an exercise price of $9.18. These option awards had a term of ten years and were fully vested upon grant and as such, all stock-based compensation expenses were recorded during the fiscal year ended December 31, 2018.

After engagement of a compensation consultant, and further review and consideration of Mr. Hoang's overall compensation, in March 2019 Mr. Hoang's option award for 1,359,855 shares was amended to change the vesting from being fully vested to being subject to vesting on a monthly basis over four years. There was no incremental stock-based compensation expense recorded during the six months ended June 30, 2019 relating to this modification.

NOTE 13: RELATED PARTY TRANSACTIONS

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

During the six months ended June 30, 2019, the Company recorded approximately $92,000 of expenses under the SRA.

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.

During the six months ended June 30, 2019, the Company recorded $175,000 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. 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, 2019 included in this Quarterly Report, as well as our Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 15, 2019.

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 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 T cell program: our autologous T cells for the treatment of lymphoma, multiple myeloma, or MM, and selected solid tumors and our allogeneic T cells for the treatment of acute myeloid leukemia, or AML, and acute lymphoblastic leukemia, or ALL. Because we do not genetically engineer our MultiTAA therapies, we believe that our product candidates are easier and less expensive to manufacture, with reduced toxicities, than current engineered 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, as well as PolyStart, a proprietary nucleic acid-based antigen expression technology designed to improve the ability of the immune system to recognize and destroy diseased cells.

We are pursuing post-transplant AML as the lead indication for our MultiTAA program. Our MultiTAA therapy has been well tolerated in an ongoing Phase 1/2 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 our MultiTAA 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. 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 intend to submit an investigational new drug application to the United States Food and Drug Administration, or the FDA, in the third quarter of 2019 to initiate a Phase 2 clinical trial 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 expected to be the maximum tolerated dose from the Phase 1/2 trial. In the adjuvant setting, patients will be randomized to either MultiTAA therapy at approximately 90 days post-transplant versus standard of care observation, while the active disease patients will receive MultiTAA T cells as part of a single-arm group upon relapse.

We recently reported interim data for an ongoing Phase 1/2 clinical trial of our MultiTAA 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 in all arms of the trial 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 drug-related systemic or neurotoxicity in this trial.

We are also evaluating our MultiTAA therapy in a Phase 2 clinical trial for the treatment of breast cancer and in Phase 1/2 clinical trials for the treatment of ALL, lymphoma, MM and sarcoma, all of which are being conducted by BCM. As of July 2019, our MultiTAA therapy has 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 CD19 CAR-T therapies. Based on our observations in clinical trials in AML, pancreatic cancer, lymphoma, ALL and MM, we believe that our MultiTAA 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 in other indications in 2020 in addition to our planned Phase 2 trial in post-transplant AML patients.

In addition to our MultiTAA therapies, we are developing peptide-based immunotherapeutic vaccines that are designed to precisely target breast and ovarian cancer cells. We are currently evaluating TPIV100/110 for the treatment of breast cancers that overexpress human epidermal growth factor receptor 2, or HER2/neu, in Phase 1b clinical trials sponsored by the Mayo Clinic. We are also evaluating TPIV200 for the treatment of breast and ovarian cancers that overexpress folate receptor alpha, or FRa, in multiple Phase 2 clinical trials, including in platinum-sensitive ovarian cancer, for which we expect to report interim data in the fourth quarter of 2019, and triple negative breast cancer. Based on a preliminary analysis of 34 patients enrolled in the triple negative breast cancer trial to date, 31 patients showed meaningful immune response to vaccine treatment. These data are subject to final review by independent biostatistical analysis. As of June 30, 2019, 14 of the 80 patients treated in this trial have shown disease progression following treatment with TPIV200. We received Orphan Drug Designation from the FDA for TPIV200 for the treatment of ovarian cancer, and we received Fast Track Designation for TPIV200 as a maintenance therapy for patients with platinum-sensitive advanced ovarian cancer who achieved stable disease or partial response following completion of standard-of-care chemotherapy. We believe that our peptide vaccines and our PolyStart technology, which is currently in preclinical development, can be used as both standalone therapies and as complementary therapies that enhance the efficacy of other immunotherapy approaches.

We believe that our therapies present promising innovations in immuno-oncology. We developed our MultiTAA therapy in collaboration with the Cell and Gene Therapy Center at BCM, which was founded by Dr. Malcolm K. Brenner, M.D., Ph.D., a recognized pioneer in immuno-oncology. BCM remains an important strategic partner and conducts early-stage clinical trials of our MultiTAA therapies pursuant to a sponsored research agreement. Our cell therapy founders include Drs. Brenner, Ann Leen, Ph.D., Juan Vera, M.D., Helen Heslop, M.D., DSc (Hon) and Cliona Rooney, Ph.D., who all have significant experience in this field. Drs. Brenner, Heslop, Rooney, James P. Allison and Padmanee Sharma serve on our Scientific Advisory Board.

Pipeline

Our clinical-stage pipeline, including clinical trials being conducted by BCM, the Mayo Clinic and other partners, is set forth below.

MAPP: autologous
LAPP: allogeneic

Recent Developments

We recently reported interim data from our ongoing Phase 1/2 clinical trial of our MultiTAA therapy for the treatment of pancreatic adenocarcinoma being conducted by BCM. In this trial, BCM plans to enroll a total of 45 patients with advanced or borderline resectable pancreatic adenocarcinoma in three arms: Arm A, which includes patients with unresectable/metastatic disease who are responding to standard first-line chemotherapy; Arm B, which includes patients with progressive disease or therapy intolerance; and Arm C, which includes patients with surgically resectable disease. As of July 5, 2019, a total of 19 patients had been administered infusions of our MultiTAA therapy: 10 patients in Arm A, 6 patients in Arm B and 3 patients in Arm C.

Overall, we have observed a clinical benefit correlated with the detection of tumor-reactive T cells in patient peripheral blood (Arms A, B and C) and within tumor biopsy samples (Arm C) post-infusion. T cells exhibited activity against both targeted antigens as well as non-targeted TAAs, including MAGEA2B and AFP, indicating induction of antigen/epitope spreading. No cytokine release syndrome or neurotoxicity had been observed as of July 5, 2019, and patients continue to be evaluated and enrolled in the trial.

Arm A

Arm A is designed to evaluate the safety and potential efficacy of using MultiTAA therapy as part of first-line treatment for patients with pancreatic cancer. These patients in the chemo-responsive arm have completed or will complete at least three months of standard-of-care chemotherapy (gemcitabine/nab-paclitaxel or FOLFIRINOX), which is the period during which a response to chemotherapy would typically occur, before receiving up to six administrations of MultiTAA therapy in conjunction with chemotherapy. Of the nine evaluable patients in Arm A as of July 5, 2019 (one patient was too early to be evaluated):

- Three patients experienced objective responses after administration of MultiTAA therapy:
  - One patient experienced a complete response; and
  - Two patients experienced partial responses.
- Four patients experienced disease stabilization. Two patients within stable disease boundaries (+20%/-30%) saw reversal of tumor growth in which tumors previously growing after chemotherapy alone showed shrinkage after administration of MultiTAA therapy.
- One patient experienced a mixed response, in which some lesions increased in size and others decreased in size for a net zero change in the size of tumor lesions.
- One patient experienced disease progression.

In addition, overall tumor shrinkage volume was observed in six out of the eight patients with a measurable tumor after administration of MultiTAA therapy. One evaluable patient did not have tumor measurements for analysis.

In patients responding to therapy, significant expansion of the infused MultiTAA therapy was observed, along with broad-based epitope spreading, with significant expansion of endogenous T cells specific for other tumor specific antigens.

Arm B

Arm B is designed to evaluate the use of MultiTAA therapy as a second-line therapy for patients who have failed first-line chemotherapy. The patients in this chemo-refractory arm are either ineligible for chemotherapy or have progressed on chemotherapy and have received or are receiving up to six doses of MultiTAA therapy as a monotherapy. Of the six evaluable patients in Arm B as of July 5, 2019:

- Three patients experienced stable disease or clinical disease stabilization:
  - Two patients who previously had progressive disease experienced clinical disease stabilization for up to two months.
  - One patient has maintained stable disease for seven months (ongoing).
- Three patients experienced clinical decline.

Among the patients who saw clinical disease stabilization, significant expansion of the infused MultiTAA therapy was observed, along with broad-based epitope spreading, with significant expansion of endogenous T cells specific for other tumor specific antigens.

Arm C

Arm C is designed to assess T cell infiltration and expansion. These patients with borderline surgically resectable disease received or will receive a dose of MultiTAA therapy following chemotherapy, radiotherapy or combination and prior to surgical resection and up to five additional doses of T cells after surgery. In the patients evaluable in Arm C as of July 5, 2019, MultiTAA T cells were measurable in meaningful numbers as detected by correlative analysis of resected tumor, and significant expansion of the infused MultiTAA cells was observed, along with broad-based epitope spreading, with significant expansion of endogenous T cells specific for other tumor specific antigens.

Results of Operations

In this discussion of the Company's 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, 2019 and June 30, 2018

The following table summarizes the results of our operations for the three months ended June 30, 2019 and 2018 (in thousands):

	For the Three Months Ended June 30,		Change	
	2019	**2018**		
Revenues:				
Grant income	$ -	$ 206,000	$ (206,000)	(100%)
Total revenues	-	206,000	(206,000)	(100%)
Operating expenses:				
Research and development	3,152,000	1,827,000	1,325,000	73%
General and administrative	2,721,000	3,053,000	(332,000)	(11%)
Total operating expenses	5,874,000	4,880,000	994,000	20%
Loss from operations	(5,874,000)	(4,674,000)	(1,200,000)	26%
Other income (expense):				
Change in fair value of warrant liabilities	(7,000)	(139,000)	132,000	(95%)
Interest income	310,000	-	310,000	-
Net loss	**$ (5,570,000)**	**$ (4,813,000)**	**$ (758,000)**	**16%**
Net loss per share, basic and diluted	$ (0.12)	$ (0.41)	$ 0.29	(72%)
Weighted average number of common shares outstanding	45,501,000	11,838,000	33,663,000	284%

Revenue

Grant Income

We did not receive any grant income during the three months ended June 30, 2019. During the three months ended June 30, 2018, we received $206,000 of a grant awarded to the Mayo Foundation by the United States Department of Defense to fund a Phase 2 clinical trial of TPIV200 for the treatment of triple-negative breast cancer. The portion of the grant we received compensated us for clinical supplies manufactured by us for the clinical trial.

Operating Expenses

Operating expenses incurred during the three months ended June 30, 2019 were $5.9 million compared to $4.9 million during the three months ended June 30, 2018. Significant changes in operating expenses included:

- Research and development costs during the three months ended June 30, 2019 were $3.2 million, compared to $1.8 million during the three months ended June 30, 2018. The increase of $1.4 million was due to increases in personnel-related expenses, including stock-based compensation expenses and consulting expenses, relating to the build-up of our internal infrastructure as we advance the clinical development of our MultiTAA T cell product candidates.

- General and administrative expenses were $2.7 million during the three months ended June 30, 2019 as compared to $3.1 million during the prior year period. This decrease was primarily due to:

    - $1.2 million of merger-related expenses incurred during the three months ended June 30, 2018, offset by increased expenses relating to:

    - $0.3 million of headcount-related expenses,

    - $0.4 million of non-merger-related legal and other professional expenses, and

    - $0.1 million of office-related and insurance expenses.

Other Income (Expense)

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities for the three months ended June 30, 2019 was $7,000 as compared to $139,000 for the three months ended June 30, 2018.

Interest Income

Interest income was $0.3 million for the three months ended June 30, 2019, attributable to interest income relating to a significant portion of the net proceeds received from our equity financing in October 2018 which are held in U.S. Treasury notes and U.S. government agency-backed securities with maturities of less than three months. We did not receive any interest income during the three months ended June 30, 2018.

Net Loss

We recorded 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, compared to a net loss of $4.8 million, or a net loss per share, basic and diluted of ($0.41), during the three months ended June 30, 2018. The increase in our net loss during the three months ended June 30, 2019 compared to during the three months ended June 30, 2018 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, 2019 and June 30, 2018

The following table summarizes the results of our operations for the six months ended June 30, 2019 and 2018 (in thousands):

	For the Six Months Ended June 30,			
	2019	**2018**	**Change**	
Revenues:				
Grant income	$ -	$ 206,000	$ (206,000)	(100%)
Total revenues	-	206,000	(206,000)	(100%)
Operating expenses:				
Research and development	5,985,000	3,426,000	2,559,000	75%
General and administrative	5,527,000	4,651,000	876,000	19%
Total operating expenses	11,512,000	8,077,000	3,435,000	43%
Loss from operations	(11,512,000)	(7,871,000)	(3,641,000)	46%
Other income (expense):				
Change in fair value of warrant liabilities	(16,000)	(138,000)	122,000	(88%)
Interest income	639,000	-	639,000	-
Net loss	**$ (10,889,000)**	**$ (8,009,000)**	**$ (2,880,000)**	**36%**
Net loss per share, basic and diluted	$ (0.24)	$ (0.71)	$ 0.47	(66%)
Weighted average number of common shares outstanding	45,484,000	11,234,000	34,250,000	305%

Revenue

Grant income

We did not receive any grant income during the six months ended June 30, 2019. During the six months ended June 30, 2018, we received $206,000 of a grant awarded to the Mayo Foundation from the US Department of Defense to fund the Phase 2 clinical trial of TPIV200 for the treatment of triple-negative breast cancer. The portion of the grant we received compensated us for clinical supplies manufactured by us for the clinical trial.

Operating Expenses

Operating expenses incurred during the six months ended June 30, 2019 were $11.5 million compared to $8.1 million during the six months ended June 30, 2018. Significant changes in operating expenses included:

- Research and development costs during the six months ended June 30, 2019 were $6.0 million, compared to $3.4 million during the six months ended June 30, 2018. The increase of $2.6 million was due to increases in personnel-related expenses, including stock-based compensation expenses and consulting expenses, relating to the build-up of our internal infrastructure as we advance the clinical development of our MultiTAA T cell product candidates.

- General and administrative expenses were $5.5 million during the six months ended June 30, 2019 as compared to $4.7 million during the six months ended June 30, 2018. The increase of $0.8 million was primarily due to increased expenses relating to:

    - $0.7 million of headcount-related expenses,

    - $0.5 million of stock-based compensation expenses,

    - $0.3 million of office-related and insurance expenses, and

    - $0.7 million of non-merger related legal and professional expenses, offset by

    - $1.4 million of merger-related expenses incurred during the six months ended June 30, 2018.

Other Income (Expense)

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities for the six months ended June 30, 2019 was $16,000 as compared to $138,000 for the six months ended June 30, 2018.

Interest Income

Interest income was approximately $0.6 million for the six months ended June 30, 2019, attributable to interest income relating to a significant portion of the net proceeds received from our equity financing in October 2018 which are held in U.S. Treasury notes and U.S. government agency-backed securities with maturities of less than three months. We did not receive any interest income during the six months ended June 30, 2018.

Net Loss

We recorded 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, compared to a net loss of $8.0 million, or a net loss per share, basic and diluted of ($0.71), during the six months ended June 30, 2018. The increase in our net losses during the six months ended June 30, 2019, compared to the six months ended June 30, 2018, 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, 2019 and December 31, 2018:

	June 30, 2019	**December 31, 2018**
Cash and cash equivalents	$ 53,445,000	$ 61,747,000
Working capital	$ 50,828,000	$ 59,193,000

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2019 and 2018:

	For the Six Months Ended June 30,	
	2019	**2018**
Net Cash provided by (used in):		
Operating activities	$ (8,060,000)	$ (4,746,000)
Investing activities	(305,000)	-
Financing activities	63,000	7,399,000
Net (decrease) increase in cash	$ (8,302,000)	$ 2,653,000

Operating Activities

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 a decrease in prepaid expenses and deposits of $350,000, an increase in accounts payable and accrued liabilities of $225,000, an increase in interest receivable of $10,000 and a decrease in lease liabilities of $90,000.

Net cash used in operating activities during the six months ended June 30, 2018 was $4.7 million. The use of cash primarily related to our net loss of $8.0 million, in addition to the effect of changes in asset and liability accounts, including a decrease in prepaid expenses and deposits of $58,000 and an increase in accounts payable and accrued liabilities of $2.1 million.

Investing Activities

Net cash used in investing activities was $0.3 million for the purchase of property and equipment during the six months ended June 30, 2019.

Financing Activities

Net cash provided by financing activities was $63,000 during the six months ended June 30, 2019, due primarily to the exercise of stock warrants and stock options. Net cash provided by financing activities was $7.4 million during the six months ended June 30, 2018, due to an equity financing, resulting in gross proceeds to us of $3.1 million; the exercise and repricing of stock warrants, resulting in aggregate proceeds to us of $4.3 million and 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, 2019, we had working capital of $50.8 million, compared to working capital of $59.2 million as of December 31, 2018. Based on our clinical and research and development plans and our timing expectations related to the progress of our programs, we expect that our cash and cash equivalents as of June 30, 2019 will enable us to fund our operating expenses and capital expenditure requirements through at least the third quarter of 2020. 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, 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.

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.

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, 2018.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer and Chief Financial Officer, we 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 June 30, 2019. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, because of a material weakness in our internal controls over financial reporting, our disclosure controls and procedures were not effective for the reasons described below. Notwithstanding the material weakness described below, the Company's management, including the Chief Executive Officer and Chief Financial Officer, has concluded that the consolidated financial statements included in the Quarterly Report and in this Form 10-Q are fairly stated, in all material respects, in accordance with generally accepted accounting principles in the United States for each of the periods presented herein.

During the first quarter of fiscal year 2019, we, together with our independent registered public accounting firm, identified a material weakness in our internal control over financial reporting, as described below. A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness in internal control over financial reporting resulted from ineffective controls related to the timing of recording non-cash stock-based compensation expenses on select stock option grants; grants which had vesting schedules that differed from the previously-standard vesting schedules. To remediate the material weakness, we are initiating controls and procedures in order to:

- Reinforce the importance of a strong control environment, to emphasize the technical requirements for controls that are designed, implemented and operating effectively and to set the appropriate expectations on internal controls through establishing the related policies and procedures;
- Review the categories that are underlying the calculations related to stock-based compensation, and revised procedures for the calculation and review of effects from granted, forfeited and expired options; and most importantly
- Transition the manual calculation of stock-based compensation expenses to a third-party automated software system.

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

We have made progress towards remediation of the material weaknesses identified above. Since the quarter ended March 31, 2019, we have:

- begun transitioning the manual calculation of stock-based compensation expenses to a third-party automated software system; and.
- implemented further procedures to review the manual calculation of stock-based compensation expenses.

There have been no additional changes in our internal controls over financial reporting during the six months ended June 30, 2019 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, 2019, 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

We are a development stage company with a history of operating losses.

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 products. 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 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.

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, 2019, we had an accumulated deficit of $317.0 million since inception. We expect to spend substantial additional sums on the continued administration and research and development of licensed and proprietary products 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 does 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.

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, Ann Leen, Ph.D., our Chief Scientific Officer, Juan Vera, M.D., our Chief Development Officer, and Mythili Koneru, M.D., Ph.D. our Senior Vice President, Clinical Development, 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 other products, 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 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, Marker Cell's founders include Ann Leen, Ph.D., Juan Vera, M.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. Leen and Dr. Vera are our Chief Scientific Officer and Chief Development Officer, respectively. In addition, Dr. Brenner, Dr. Heslop and Dr. Rooney have joined our newly-formed 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. Leen and Dr. Vera, who are also employed with the Center for Cell and Gene Therapy at BCM. If we lose Dr. Leen or Dr. Vera, or if either leaves their position at BCM, 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 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 II 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 our officers and directors could limit their time and availability to us, and create, or appear to create, conflicts of interest.

Dr. Leen and Dr. Vera are employees of BCM and are contractually obligated to spend a significant portion of their time with BCM. In addition, Dr. Leen and Dr. Vera are co-founders and members of AlloVir and perform services from time to time for AlloVir LLC ("AlloVir"). AlloVir is owned by the same principal stockholder group as Marker Cell prior to the Merger and 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, which is investigating and developing virus-specific T cell therapy technology for the prevention and/or treatment of viral infections. Accordingly, Dr. Leen and Dr. Vera may have other commitments that would, at times, limit their availability to us. Other research being conducted by Dr. Leen and 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 member, director and officer of AlloVir and is a director of the Company. Dr. Leen and Dr. Vera are also co-founders and members of AlloVir, and perform services for AlloVir from time to time, and Dr. Vera is a director of the Company. All 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. Leen and 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 of the parties' planned and ongoing clinical trials, investigational new drug application filings and the parties' opportunities for marketing their respective product candidates. 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 our products.

We have no approved products or products 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 pre-clinical 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 products, 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. A number of 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 II, Phase III, 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.

We, or our regulators, may suspend or terminate our clinical trials for a variety of reasons. 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. 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 Biologics License Application (“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 studies 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 once 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 ("cGMPs") and current Good Clinical Practices ("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 products as projected or may not conduct them successfully.

During the second half of 2012, BCM began enrollment of the investigator-sponsored, Phase 1 clinical trial to establish the feasibility of one of our lead products, MAPP, and to assess its overall safety, inclusion of multiple antigens, and dosage tolerance in patients with lymphoma. During the second quarter of 2016, BCM began enrollment of the investigator-sponsored Phase 1 clinical trial to establish the feasibility of one of our lead products, LAPP, and to assess its overall safety, inclusion of multiple antigens, and dosage tolerance in patients with acute myeloid leukemia ("AML")/myelodysplastic syndromes ("MDS"). However, 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 products. 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 MAPP and LAPP T cells under contract, we anticipate that we will have to rely on third parties (contract manufacturing organizations or "CMOs") or internal facilities yet to be developed for the commercial manufacture of our multi-antigen specific T cell therapy products for clinical trials and eventual licensure. If they fail to commence or complete, or experience delays in, manufacturing our multi-antigen specific T cell therapy products, our planned clinical trials with respect to such products 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 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.

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 our 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 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 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.

Our MultiTAA T cell therapy research and development efforts are to a large extent dependent upon BCM's investigators.

It will take time to fully develop our research and development infrastructure. We currently depend upon and will continue to depend upon independent investigators and collaborators, such as BCM, and which in the future may include other universities, medical institutions, and strategic partners, to conduct our preclinical studies and clinical trials. If we need to enter into alternative arrangements, our product development activities would be delayed. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties.

We expect to use the results of BCM's research to support the filing with the FDA of IND applications to conduct more advanced clinical trials of our products. However, we have limited control over the nature or timing of BCM's clinical trials and limited visibility into their day-to-day activities. The research we are funding constitutes only a small portion of BCM's overall research. Other research being conducted by Dr. Ann Leen and Dr. Juan Vera may at times receive higher priority than research on our programs. These factors could adversely affect the timing of our IND filings and our ability to conduct future planned clinical trials.

We will be unable to 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 products 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 products 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.

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 T cell therapy. The data collected from our clinical trials may not be sufficient to support approval by the FDA of our MultiTAA T cell therapy-based product candidates for the treatment of hematological malignancies, or our Folate Receptor Alpha (TPIV200) product for breast and ovarian cancers, HER2/neu peptide antigen product (TPIV100/110) or possible future clinical trials utilizing our DNA expression PolyStart™ product. The clinical trials for our products 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 products, 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 do not own any 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 products. We anticipate we will initially rely solely on the Good Manufacturing Practices ("cGMP") manufacturing facility within BCM for the manufacturing of our MultiTAA T cell therapy-based product candidates. If the cGMP manufacturing facility of BCM, which does manufacture for itself and other parties, experiences capacity constraints, disruptions, or delays in manufacturing our MultiTAA T cell therapy-based product candidate products, 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 T cell therapy-based product candidates.

In 2019 or in 2020, we intend to begin developing 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. Our manufacturing strategy going forward will involve the use of one or more CMOs or we will establish our own capabilities and infrastructure, including a manufacturing facility. 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 development of our own manufacturing facility could 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 any 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 products 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 such 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.

Regardless of whether we engage additional CMOs to manufacture our products or establish our own manufacturing facility, in order to transfer our MultiTAA T cell manufacturing from or expand our manufacturing capabilities beyond BCM pursuant to our development plans, whether through additional third parties or by developing our own manufacturing capabilities, we will need access to the Standard Operating Procedures (“SOPs”) and the specific Batch Production Records that are used to manufacture the product candidates. If BCM fails to transfer our manufacturing processes or impedes our ability to transfer the manufacturing processes of its products to us or third-party manufacturers, 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.

We will be dependent on third-party vendors to design, build, maintain and support our manufacturing and cell processing facilities.

As a result of our strategy to outsource our manufacturing, we will rely very heavily on BCM and other third-party manufacturers to perform the manufacturing of our products 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 products for regulatory approval or the market introduction and subsequent sales of our 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 products under development 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 products, 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 products.

We will depend on a limited number of vendors for supply of certain materials and equipment used in the manufacture of our MultiTAA 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 John Wilson, who is a director of the Company), 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.

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 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. We do not own any exclusive rights to the G-Rex® that could be used to prevent third parties from developing similar and competing processes. 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 products 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 products is complex, highly regulated and subject to multiple risks. For example, the manufacture of our MultiTAA 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 differences 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 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 products 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 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 products is dependent.

In cooperation with our potential 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 products in a cGMP facility is subject to many uncertainties and difficulties. We have never manufactured our adoptive T cell therapy product candidate on any scale, commercially or otherwise. As a result, we cannot give any assurance that we will be able to establish a manufacturing process that can produce our products at a cost or in quantities necessary to make them commercially viable. Moreover, our third-party manufacturers will have to continually adhere to current cGMP regulations enforced by the FDA through its facilities inspection program. If the facilities of these manufacturers cannot pass a pre-approval plant inspection, the FDA premarket approval of our products 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 products 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 products from existing products may require us to perform additional testing, which will increase the cost, and extend the time for obtaining approval.

Our MultiTAA 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 U.S. 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 products. We may have difficulty demonstrating that the products 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 the product 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 products 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 enter into one or more transactions with entities controlled by one of our directors, which could pose a conflict of interest.

John Wilson, a director of the Company, is also CEO and co-founder of Wilson Wolf, which is the sole source vendor that provides us with the G-Rex® cell culture device for the large-scale production of T cells used in our manufacturing process. We do not currently have a supply contract with Wilson Wolf for the G-Rex®. We plan to negotiate a supply contract with Wilson Wolf for the purchase of G-Rex® devices. We have engaged Wilson Wolf in discussions to customize the G-Rex® further to optimally match our manufacturing requirements, as well as to develop a scalability plan to drive efficiencies for a commercial product. There may be conflicts of interest between us and Wilson Wolf. There can be no assurance that Wilson Wolf will agree to enter into any contract with us, or that the terms of any such agreements will be in the best interests of us or will have terms no less favorable to us than could have been obtained from unaffiliated third parties.

We may not be able to develop products successfully or develop them 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 number of 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 products could result either in such products 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 products, 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;
- availability of coverage and adequate reimbursement and pricing 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 products, 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 products, 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 us 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 products 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 products. 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 products. 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 products.

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 products.

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 product candidates. 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 products. 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 products 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 products 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. We may also face litigation from third parties we have engaged in our capital raising or other activities that allege they are owed additional amounts.

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 law suit 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; 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 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 our 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 it 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 its research and development programs or the commercialization, marketing or distribution of its 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 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 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 products or to develop additional products. 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 products.

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 products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy. 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, LAPP, 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 agreement with BCM, and we must meet certain milestones to maintain our license rights.

Under our license agreement with BCM for our MultiTAA 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 our 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. There is no assurance that we will be successful in meeting all of the milestones 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, but shall not include the “Merger”) 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 products 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 products 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 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 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 products obsolete even before they generate any revenue. There are products currently under development by others that could compete with the products 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 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 and Torque Therapeutics are developing non-genetically modified T cell therapies such as Tumor Infiltrating Lymphocytes ("TIL") and Marrow Infiltrating Lymphocytes ("MIL") therapies that may compete with our products. All of 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 products.

Our lead product candidate, LAPP, is a therapy for the treatment of refractory AML. Currently, there are numerous companies that are developing various alternate treatments for AML. Accordingly, LAPP faces significant competition in the AML treatment space from multiple companies. Even if we obtain regulatory approval for LAPP, 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 products 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 products for use in limited circumstances.

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 only permitted to be carried forward for 20 years under applicable U.S. tax law. Under H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", informally titled the Tax Cuts and Jobs Act, or, the Tax Act, 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, 2017 is limited. 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," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. 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 shifts 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 will 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.

U.S. federal income tax reform could materially adversely affect our company.

On December 22, 2017, President Trump signed into law the Tax Act, which significantly revises the Code. The Tax Act, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, repeals the alternative minimum tax for corporations, limits the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limits the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income, eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, eliminates U.S. tax on foreign earnings (subject to certain important exceptions), allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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 products may still face regulatory difficulties.

All of our potential products, 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 products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

No adoptive T cell therapy using MultiTAA 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 products 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. 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.

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 receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our 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 certain types of individuals and entities, 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 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, 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 ("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 two 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, two 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, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. 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. While the Texas U.S. District Court Judge, as well as the Trump administration and the Centers for Medicare & Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, 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, providers are subject to Medicare payment reductions of 2% per fiscal year through 2027 unless additional Congressional action is taken. 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 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. Payment adjustments for the Medicare quality payment program will begin in 2019. At this time, it is 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. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics.

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 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Although a number of these, and other potential, proposals will 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.

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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, 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.

We have received Orphan Drug Designation from the FDA for TPIV200 in the treatment of ovarian cancer. The TPIV200 ovarian cancer clinical program is eligible to receive benefits including tax credits on clinical research and seven-year market exclusivity upon receiving marketing approval. Even though we were granted orphan drug designation, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U.S. regulations for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve a drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, if and when we request orphan drug designation in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or European Medicines Evaluation Agency (“EMEA”) 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.

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

Under the federal Patient Protection and Affordable Care Act (“PPACA”) 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 PPACA 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 PPACA 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 PPACA, 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

We identified a material weakness in our internal control over financial reporting.

During the first quarter of fiscal year 2019, we, together with our independent registered public accounting firm, identified a material weakness in our internal control over financial reporting resulting from ineffective controls related to the timing of recording non-cash stock-based compensation expenses on select stock option grants. As a result, our management concluded that we had a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. As described in Part I, Item 4 of this report, this material weakness has not yet been remediated and, as a result of this material weakness, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2019, our disclosure controls and procedures were not effective.

Maintaining effective disclosure controls and procedures and effective internal control over financial reporting are necessary for us to produce reliable financial statements. While we have designed a remediation plan to address the material weakness and enhance our internal control environment and are committed to remediating this as promptly as possible, if not remediated, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could have a material adverse effect on our financial condition and the trading price of our common stock. There can be no assurance as to when the material weakness will be remediated or that other material weaknesses will not arise in the future. Any failure to remediate the material weakness, or the development of new material weaknesses in our internal control over financial reporting, could result in material misstatements in our consolidated financial statements and cause us to fail to meet our reporting and financial obligations, which in turn could have a material adverse effect on our financial condition and the trading price of our common stock, and/or result in litigation against us. In addition, even if we are successful in strengthening our controls and procedures, those controls and procedures may not be adequate to prevent or identify irregularities or facilitate the fair presentation of our consolidated financial statements or our periodic reports filed with the SEC.

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 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 products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock to maintain listing requirements on the Nasdaq Capital Market;
- 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.

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 the Nasdaq Capital Market 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 conditions.

If we fail to remain current with our listing requirements, we could be removed from the Nasdaq Capital Market which would limit the ability of broker-dealers to sell its securities and the ability of stockholders to sell its securities in the secondary market.

Companies listed for trading on the Nasdaq Capital Market must be reporting issuers under Section 12 of the Exchange Act. If we fail to file such reports in a timely manner, or if we fail to meet any other listing requirements, the shares of our common stock would eventually cease to be listed on the Nasdaq Capital Market, and the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell its securities and the ability of stockholders to sell their securities in the secondary market.

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, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. 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 and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

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, 2019, we had 45.5 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, 2019, there were outstanding warrants to purchase up to approximately 23.0 million shares of our common stock at a weighted average exercise price of $4.78 per share, and options exercisable for an aggregate of approximately 4.6 million shares of common stock at a weighted average exercise price of $8.36 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, 2019, the fair value of the derivative liability-warrants was $65,000. 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

None.

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

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 9, 2019

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 9, 2019

/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 9, 2019

/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 the Quarterly Report on Form 10-Q for the period ending June 30, 2019, 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 9, 2019

/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 the Quarterly Report on Form 10-Q for the period ending June 30, 2019, 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 9, 2019

/s/ Anthony Kim

Anthony Kim
Chief Financial Officer and Principal Financial and Accounting Officer