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

FORM 10-Q

☒ Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 30, 2022

☐ 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.)
4551 Kennedy Commerce Drive Houston, Texas	**77032**
(Address of principal executive offices)	(Zip Code)

(713) 400-6400
(Issuer's telephone number)

3200 Southwest Freeway, Suite 2500, Houston, Texas, 77027
(Former name, former address and former fiscal year, if changed since last report)

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 November 1, 2022, the Company had 83,599,187 shares of common stock issued and outstanding.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,076,379	$ 42,351,145
Restricted cash	—	1,146,186
Prepaid expenses and deposits	2,665,668	2,484,634
Other receivables	1,681,019	237
Total current assets	22,423,066	45,982,202
Non-current assets:		
Property, plant and equipment, net	13,059,816	10,096,861
Construction in progress	—	2,225,610
Right-of-use assets, net	5,631,683	9,830,461
Total non-current assets	18,691,499	22,152,932
Total assets	**$ 41,114,565**	**$ 68,135,134**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 5,746,404	$ 11,134,913
Related party deferred revenue	5,050,000	—
Lease liability	490,449	620,490
Deferred revenue	—	1,146,186
Total current liabilities	11,286,853	12,901,589
Non-current liabilities:		
Lease liability, net of current portion	7,225,990	11,247,950
Total non-current liabilities	7,225,990	11,247,950
Total liabilities	18,512,843	24,149,539
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at September 30, 2022 and December 31,2021, respectively	—	—
Common stock, $0.001 par value, 300 million and 150 million shares authorized, 83.6 million and 83.1 million shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	83,599	83,079
Additional paid-in capital	446,710,757	442,020,871
Accumulated deficit	(424,192,634)	(398,118,355)
Total stockholders' equity	22,601,722	43,985,595
Total liabilities and stockholders' equity	**$ 41,114,565**	**$ 68,135,134**

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Grant income	$ 999,571	$ —	$ 2,754,401	$ —
Related partry service revenue	2,950,000	—	2,950,000	—
Total revenues	3,949,571	—	5,704,401	—
Operating expenses:				
Research and development	7,290,899	6,784,390	20,872,264	19,777,454
General and administrative	3,678,005	3,239,148	10,926,189	9,936,256
Total operating expenses	10,968,904	10,023,538	31,798,453	29,713,710
Loss from operations	(7,019,333)	(10,023,538)	(26,094,052)	(29,713,710)
Other income (expenses):				
Arbitration settlement	—	(2,406,576)	(118,880)	(2,406,576)
Interest income	99,750	791	138,653	4,731
Net loss	**$ (6,919,583)**	**$ (12,429,323)**	**$ (26,074,279)**	**$ (32,115,555)**
Net loss per share, basic and diluted	$ (0.08)	$ (0.15)	$ (0.31)	$ (0.43)
Weighted average number of common shares outstanding, basic and diluted	83,599,187	83,078,675	83,434,760	74,290,598

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 September 30, 2022				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at July 1, 2022	**83,599,187**	**$ 83,599**	**$ 445,215,725**	**$ (417,273,051)**	**$ 28,026,273**
Stock-based compensation	—	—	1,495,032	—	1,495,032
Net loss	—	—	—	(6,919,583)	(6,919,583)
Balance at September 30, 2022	**83,599,187**	**$ 83,599**	**$ 446,710,757**	**$ (424,192,634)**	**$ 22,601,722**

	For the Nine Months Ended September 30, 2022				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2022	**83,078,675**	**$ 83,079**	**$ 442,020,871**	**$ (398,118,355)**	**$ 43,985,595**
Issuance common shares for cash, net	148,000	148	63,425	—	63,573
Stock-based compensation	372,512	372	4,626,461	—	4,626,833
Net loss	—	—	—	(26,074,279)	(26,074,279)
Balance at September 30, 2022	**83,599,187**	**$ 83,599**	**$ 446,710,757**	**$ (424,192,634)**	**$ 22,601,722**

	For the Three Months Ended September 30, 2021				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at July 1, 2021	**83,078,675**	**$ 83,079**	**$ 439,085,948**	**$ (375,925,716)**	**$ 63,243,311**
Stock-based compensation	—	—	1,468,020	—	1,468,020
Net loss	—	—	—	(12,429,323)	(12,429,323)
Balance at September 30, 2021	**83,078,675**	**$ 83,079**	**$ 440,553,968**	**$ (388,355,039)**	**$ 52,282,008**

	For the Nine Months Ended September 30, 2021				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2021	**50,731,072**	**$ 50,731**	**$ 383,533,326**	**$ (356,239,484)**	**$ 27,344,573**
Issuance of common stock for cash (net of offering costs of $3.9 million)	32,282,857	32,283	52,520,475	—	52,552,758
Stock options exercised for cash	1,456	2	3,085	—	3,087
Stock-based compensation	63,290	63	4,497,082	—	4,497,145
Net loss	—	—	—	(32,115,555)	(32,115,555)
Balance at September 30, 2021	**83,078,675**	**$ 83,079**	**$ 440,553,968**	**$ (388,355,039)**	**$ 52,282,008**

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	For the Nine Months Ended September 30,	
	2022	2021
Cash Flows from Operating Activities:		
Net loss	$ (26,074,279)	$ (32,115,555)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	1,975,996	1,584,495
Stock-based compensation	4,626,833	4,497,145
Amortization on right-of-use assets	739,446	757,958
Loss on disposal of assets	25,995	—
Gain on lease termination	(278,681)	—
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(181,034)	(643,403)
Other receivables	(1,680,782)	1,000,316
Accounts payable and accrued expenses	(3,310,051)	2,742,154
Related party deferred revenue	5,050,000	—
Deferred revenue	(1,146,186)	—
Lease liability	(413,988)	(244,752)
Net cash used in operating activities	(20,666,731)	(22,421,642)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(1,328,664)	(1,262,092)
Purchase of construction in progress	(3,489,130)	(1,519,196)
Net cash used in investing activities	(4,817,794)	(2,781,288)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	63,573	52,552,758
Proceeds from exercise of stock options	—	3,087
Net cash provided by financing activities	63,573	52,555,845
Net (decrease) increase in cash, cash equivalents and restricted cash	(25,420,952)	27,352,915
Cash, cash equivalents and restricted cash at beginning of the period	43,497,331	21,352,382
Cash, cash equivalents and restricted cash at end of the period	$ 18,076,379	$ 48,705,297

	For the Nine Months Ended September 30,	
	2022	2021
Supplemental schedule of non-cash financing and investing activities:		
Reclassifications between construction in progress and fixed assets	$ 4,089,135	$ 6,789,098
Capital expenditures included in accounts payable	$ 82,298	$ 70,399
Changes to right-of-use assets and lease liability due to close out of operating leases	$ 3,459,332	$ —

See accompanying notes to these unaudited condensed consolidated financial statements.

MARKER THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2022
(Unaudited)

NOTE 1: NATURE OF OPERATIONS

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

NOTE 2: BASIS OF PRESENTATION

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

The results for the condensed consolidated statement of operations are not necessarily indicative of results to be expected for the year ending December 31, 2022 or for any future interim period. The condensed consolidated balance sheet at September 30, 2022 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, 2021 and notes thereto included in the Company's annual report on Form 10-K filed on March 17, 2022.

NOTE 3: LIQUIDITY, GOING CONCERN AND FINANCIAL CONDITION

As of September 30, 2022, the Company had cash and cash equivalents of approximately $18.1 million. The Company's activities since inception have consisted principally of acquiring product and technology rights, raising capital, and performing research and development. Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things, its ability to access potential markets; secure financing; successfully progress its product candidates through preclinical and clinical development; obtain regulatory approval of one or more of its product candidates; maintain and enforce intellectual property rights; develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances and collaborations. From inception, the Company has been funded by a combination of equity and debt financings.

In August 2021, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (the "ATM Agreement") with Cantor Fitzgerald & Co. and RBC Capital Markets, LLC (the "Sales Agents"), pursuant to which the Company can offer and sell, from time to time at its sole discretion through the Sales Agents, shares of its common stock having an aggregate offering price of up to $75.0 million. Any shares of its common stock sold will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-258687), which the SEC declared effective on August 19, 2021. The shelf registration statement on Form S-3 includes a prospectus supplement covering the offering up to $19.8 million of shares of common stock over the 12 months ending March 18, 2023 in accordance with the ATM agreement. The Sales Agents will be entitled to compensation under the Sales Agreement at a commission rate equal to 3.0% of the gross sales price per share sold under the ATM Agreement, and the Company has provided each of the Sales Agents with indemnification and contribution rights. From April 1, 2022 to the date of this filing, the Company sold 148,000 shares of its common stock under the ATM Agreement for net proceeds of $63,600.

In August 2021, the Company received notice of a Product Development Research award totaling approximately $13.1 million from the Cancer Prevention and Research Institute of Texas ("CPRIT") to support the Company's Phase 2 clinical trial of its lead MultiTAA-specific T cell product MT-401. The CPRIT award is intended to support the adjuvant arm of the Company's Phase 2 clinical trial evaluating MT-401 when given as an adjuvant therapy to patients with acute myeloid leukemia following a hematopoietic stem cell transplant. The primary objectives of the adjuvant arm of the trial are to evaluate relapse-free survival after MT-401 treatment when compared with a randomized control group. To date, the Company has received $2.4 million of funds from the CPRIT grant.

On April 21, 2022, the Company entered into a binding services agreement (the "Agreement"), effective April 12, 2022 (see Note 9), with Wilson Wolf Manufacturing Corporation ("Wilson Wolf"). Mr. John Wilson is a member of the Company's board of directors and is serving as the CEO of Wilson Wolf, therefore Wilson Wolf is a related party. Wilson Wolf is in the business of creating products and services intended to simplify and expedite the transition of cell therapies and gene-modified cell therapies to mainstream society (the "Wilson Wolf Mission"). Pursuant to the Agreement, Wilson Wolf made a cash payment to the Company in the amount of $8.0 million. For the three-month period ending September 30, 2022, the Company recognized $2.95 million of revenue pursuant to this agreement and at September 30, 2022, the Company recorded $5.05 million of related party deferred revenue on its condensed consolidated balance sheet.

On September 13, 2022, the Company received notice from the U.S. Food and Drug Administration (the "FDA") that it had awarded the Company a $2.0 million grant from the FDA's Orphan Products Grant program to support the Company's Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. To date, the Company has not received any funds from the FDA grant.

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 September 30, 2022 will enable the Company to fund its operating expenses and capital expenditure requirements through the second quarter of 2023. 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;
- continues development of its manufacturing capabilities and manufacturing facility;
- 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.

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

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

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term liquidity due to the COVID-19 pandemic. However, the Company will continue to assess the effect of the pandemic on its operations, including its clinical programs. The extent to which the COVID-19 pandemic will impact the Company's business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the geographic spread of the disease, the duration of the outbreak, the emergence of any new variant strains of COVID-19, the duration and effect of any future business disruptions in the United States and other countries to contain and treat the disease and the rate of public acceptance and efficacy of vaccines and other treatments. Further, disruption of global financial markets and a recession or market correction, including as a result of the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, and other global macroeconomic factors such as inflation, could reduce the Company's ability to access capital, which could in the future negatively affect the Company's liquidity and could materially affect the Company's business and the value of its common stock.

On February 16, 2022, the Company received a notice from The Nasdaq Stock Market that the Company was not in compliance with Nasdaq's Listing Rule 5450(a)(1), as the minimum bid price of its common stock had been below $1.00 per share for 30 consecutive business days. On August 16, 2022, Nasdaq approved the Company's application to transfer to The Nasdaq Capital Market, effective at the opening of business on August 18, 2022, and notified the Company that it had been granted an additional 180-calendar day compliance period, or until February 13, 2023, to regain compliance with the minimum bid price requirement. As part of the transfer, the Company provided notice to Nasdaq that it intended to cure the bid price deficiency by effecting a reverse stock split, if necessary, prior to the end of the compliance period. The Company's failure to regain compliance during this period could result in delisting, which the Company could appeal to a Nasdaq hearings panel. The Company intends to actively monitor the bid price of its common stock and will consider available options, including a reverse stock split, to regain compliance with the listing requirements. There can be no assurance that the Company will be able to regain compliance with Nasdaq's Listing Rule 5450 (a)(1) or will otherwise be in compliance with other Nasdaq listing criteria.

During the three months ended June 30, 2022, the Company's board of directors and stockholders approved a series of alternate amendments to the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock, where the board of directors will have the discretion to select the reverse stock split ratio from within a range between and including one-for-three and one-for-twelve. Such reverse stock split, and the reverse stock split ratio, will be at the sole discretion of the board of directors at any time prior to the Company's 2023 Annual Meeting of Stockholders.

NOTE 4: SIGNIFICANT ACCOUNTING POLICIES

Grant Income

The Company recognizes grant income in accordance with the terms stipulated under the grant awarded to the Company's collaborators at the Mayo Foundation from the U. S. Department of Defense. In various situations, the Company receives certain payments from the Mayo Foundation for reimbursement of clinical supplies. These payments are non-refundable and are not dependent on the Company's ongoing future performance. The Company has adopted a policy of recognizing these payments when received and as revenue in accordance with Accounting Standards Update No. 2014 09, "Revenue from Contracts with Customers (Topic 606)" issued by FASB.

In August 2021, the Company received notice of a Product Development Research award totaling approximately $13.1 million from CPRIT to support the Phase 2 clinical trial of MT-401.

In accordance with ASC 730-20-25-8, to the extent the financial risk associated with the research and development has been transferred to CPRIT, because repayment of the grant depends solely on the results of research and development having future economic benefit, the Company accounts for this obligation as a contract to perform research and development for others. The funds received from CPRIT will initially be recorded as a deferred credit in the Company's balance sheet.

Restricted cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. The Company recorded $2.8 million of grant income related to the CPRIT grant as revenue for the nine months ended September 30, 2022. At September 30, 2022, there were no restricted cash or deferred revenue amounts on the Company's condensed consolidated financial statements. At September 30, 2022, the Company recorded $1.6 million of grant income receivable, which represented grant income earned in advance of the next tranche of funds to be received from CPRIT.

New Accounting Standards

From time to time, new accounting pronouncements are issued by 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 consolidated financial position or results of operations upon adoption.

NOTE 5: NET LOSS PER SHARE

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

The following table sets forth the computation of net loss per share for the three and nine months ended September 30, 2022 and 2021, respectively:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (6,919,583)	$ (12,429,323)	$ (26,074,279)	$ (32,115,555)
Denominator:				
Weighted average common shares outstanding	83,599,187	83,078,675	83,434,760	74,290,598
Net loss per share:				
Basic and diluted	$ (0.08)	$ (0.15)	$ (0.31)	$ (0.43)

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 Nine Months Ended September 30,	
	2022	2021
Common stock options	9,962,000	7,544,000
Common stock purchase warrants	18,482,000	19,830,000
Potentially dilutive securities	28,444,000	27,374,000

NOTE 6: PROPERTY AND EQUIPMENT

Property and equipment consist of the following as of September 30, 2022 and December 31, 2021, respectively:

	Estimated Useful Lives	September 30, 2022	December 31, 2021
Lab and manufacturing equipment	5 Years	$ 11,857,000	$ 7,851,000
Computers, equipment and software	3-5 Years	1,051,000	1,020,000
Office furniture	5 Years	926,000	793,000
Leasehold improvements	Lesser of lease term or estimated useful life	3,897,000	3,173,000
Total		17,731,000	12,837,000
Less: accumulated depreciation		(4,671,000)	(2,740,000)
Construction in progress		—	2,226,000
Total fixed assets, net		$ 13,060,000	$ 12,323,000

In connection with the manufacturing facility, the Company has incurred costs pursuant to an agreement with a vendor to design, engineer, build and eventually install a second modular cleanrooms in a manufacturing facility. The completion of the facility's construction occurred during April 2022 and the Company received its certificate of occupancy in May 2022, and as such was placed into service in June 2022. During the three months ended June 30, 2022, $3.1 million of the costs previously recorded as construction in progress were recorded to lab and manufacturing equipment and $0.9 million were recorded to leasehold improvements.

Depreciation expense for the three months ended September 30, 2022 and 2021 was approximately $0.8 million and $0.6 million, respectively.

Depreciation expense for the nine months ended September 30, 2022 and 2021 was approximately $2.0 million and $1.6 million, respectively.

$82,300 of property and equipment transactions are included in accounts payable and accrued liabilities as of September 30, 2022.

NOTE 7: LEASES

The Company leases manufacturing, research and administrative facilities under operating leases. The Company evaluates its contracts to determine if an arrangement is a lease at inception and classify it as a finance or operating lease. Currently, all of the Company's leases are classified as operating leases. Leased assets and corresponding liabilities are recognized based on the present value of the lease payments over the lease term. The lease terms may include options to extend when it is reasonably certain that the Company will exercise that option.

Topic ASC 842 requires the Company to recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. Right-of-use assets are recorded in other assets on the Company's condensed consolidated balance sheets. Current and non-current lease liabilities are recorded in other accruals within current liabilities and other non-current liabilities, respectively, on its condensed consolidated balance sheets. Costs associated with operating leases are recognized on a straight-line basis within operating expenses over the term of the lease.

As of September 15, 2022, the Company and its landlord agreed to terminate the Company's office lease at 3200 Southwest Freeway, Suite 2500, Houston, Texas. As such the Company reduced its operating lease liabilities by $3.7 million and reduced its right-of-use assets by $3.5 million.

As of September 30, 2022, the Company had total operating lease liabilities of approximately $7.7 million and right-of-use assets of approximately $5.6 million, which were included in the condensed consolidated balance sheet.

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 following summarizes quantitative information about the Company's operating leases for the three and nine months ended September 30, 2022 and 2021, respectively:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating lease expense summary:				
Operating lease expense	$ 375,000	$ 425,000	$ 1,225,000	$ 1,275,000
Short-term lease expense	11,000	—	22,000	—
Variable lease expense	161,000	168,000	566,000	430,000
Total	$ 547,000	$ 593,000	$ 1,813,000	$ 1,705,000

	For the Nine Months Ended September 30,	
	2022	2021
Other information:		
Operating cash flows - operating leases	$ 900,000	$ 763,000

The weighted-average remaining lease term as of September 30, 2022 and December 31, 2021 was approximately 7.7 years and 8.4 years, respectively. The weighted-average discount rate used to determine the operating lease liability as of September 30, 2022 and December 31, 2021 was approximately 5.5% and 5.7%, respectively.

Maturities of our operating leases, excluding short-term leases, are as follows:

Three months ending December 31, 2022	$ 206,000
Year ended December 31, 2023	983,000
Year ended December 31, 2024	1,254,000
Year ended December 31, 2025	1,290,000
Year ended December 31, 2026	1,177,000
Thereafter	4,752,000
Total	9,662,000
Less present value discount	(1,946,000)
Operating lease liabilities included in the Condensed Consolidated Balance Sheet at September 30, 2022	$ 7,716,000

NOTE 8: ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following as of September 30, 2022 and December 31, 2021, respectively:

	September 30, 2022	December 31, 2021
Accounts payable	$ 2,021,000	$ 5,144,000
Compensation and benefits	2,306,000	2,055,000
Process development expenses	412,000	385,000
Professional fees	452,000	644,000
Technology license fees	250,000	250,000
Arbitration settlement fees	—	2,407,000
Other	305,000	250,000
Total accounts payable and accrued liabilities	$ 5,746,000	$ 11,135,000

In August 2022, the Company implemented changes to the Company's organizational structure as part of an operational cost reduction plan to conserve the Company's available capital. In connection with these changes, the Company reduced headcount in its general and

administrative function by approximately 23.5%, including the separation of the Company's Chief Financial Officer. At September 30, 2022, the Company recorded $0.5 million of accrued compensation and benefits for severance expenses related to the operational cost reduction plan.

NOTE 9: RELATED PARTY DEFERRED REVENUE

On April 21, 2022, the Company entered into a binding services agreement, effective April 12, 2022, with Wilson Wolf Manufacturing Corporation ("Wilson Wolf"). Wilson Wolf is in the business of creating products and services intended to simplify and expedite the transition of cell therapies and gene-modified cell therapies to mainstream society (the "Wilson Wolf Mission"). Pursuant to the agreement, Wilson Wolf made a cash payment to the Company in the amount of $8.0 million, as consideration for certain training and research services allocated as follows:

- $2.0 million for non-exclusive training of Wilson Wolf to make, use, and sell Marker's cell culture non-proprietary media formulation that has been cleared in an FDA investigational new drug application;
- $1.0 million for non-exclusive training of Wilson Wolf to replicate Marker's quality management system inclusive of all underlying documents related thereto, none of which shall include unique information specific to the manufacture of Marker's MultiTAA product candidates such as direct peptide stimulation;
- $2.0 million for non-exclusive training of Wilson Wolf to be able to replicate Marker's cGMP-compliant, linearly scalable, G-Rex based T-cell manufacturing process which Wilson Wolf shall use as it sees fit in pursuit of the Wilson Wolf Mission; and
- $3.0 million for Marker to train Wilson Wolf on its expertise in the optimization of T-cell therapy manufacturing processes using G-Rex and to conduct CAR T and TCR G-Rex Optimization Work under the direction of Wilson Wolf (the "Work Direction"), whereunder all intellectual property provided by Wilson Wolf or created or derived by Marker will be solely owned by Wilson Wolf, and whereby Marker will make good faith efforts to complete the conduct of such work as soon as practicable within 18 months from the date of the agreement. Wilson Wolf has agreed to pay Marker an additional $1.0 million if the Work Direction is completed within one year from the onset of the Agreement.

Pursuant to the Agreement, in the event that Marker becomes insolvent, goes out of business, or an event other than force majeure occurs that cannot allow the Agreement to be fulfilled, Wilson Wolf will have right of first offer and right of first refusal for Marker's manufacturing facility provided it is able and willing to meet whatever financial obligations are required to do so and provided further that such clause will not apply in the event of a merger, reorganization or consolidation of Marker with a third party that results in the outstanding voting securities of Marker immediately prior thereto ceasing to represent, or being converted into or exchanged for voting securities that do not represent, at least fifty percent (50)% of the combined voting power of the voting securities of the surviving entity or the parent corporation of the surviving entity immediately after such merger, reorganization or consolidation, or the sale or other transfer of all or substantially all of Marker's business or assets. Marker agrees to assist as needed to the extent permitted under any applicable law (including bankruptcy or insolvency statutes). Further, prior to Marker undertaking any financing that would encumber any of Marker's assets necessary for Marker's performance under this Agreement, Wilson Wolf shall have the first right to provide such financing on equal terms to what Marker can obtain elsewhere.

The Company plans to recognize related party revenue over time in accordance with Accounting Standard Codification, or ASC, 606 Revenue from Contracts with Customers, as each of the training or and research services are provided to Wilson Wolf. Revenue will be recognized, using an output method based on progress toward satisfaction of the performance obligations. Additionally, in accordance the spirit of the standard expressed in ASC 606-50-1, the timing of the revenue recognition is expected to be approximately 12 months. For the three-month period ending September 30, 2022, the Company recognized $2.95 million of revenue pursuant to this agreement and at September 30, 2022, the Company recorded $5.05 million of related party deferred revenue on its condensed consolidated balance sheet.

NOTE 10: STOCKHOLDERS' EQUITY

Increase in Authorized Shares

During the three months ended June 30, 2022, the Company's board of directors and stockholders approved a Certificate of Amendment (the "Amendment") to the Company's Certificate of Incorporation to increase the authorized shares of common stock of the Company from 150,000,000 shares to 300,000,000 shares. The Company filed the Amendment with the Secretary of State of Delaware on May 25, 2022.

Approval of Reverse Stock Split to be Effected at the Discretion of the Board of Directors

During the three months ended June 30, 2022, the Company's board of directors and stockholders approved a series of alternate amendments to the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock, where the board of directors will have the discretion to select the reverse stock split ratio from within a range between and including one-for-three and one-for-twelve. Such reverse stock split, and the reverse stock split ratio, will be at the sole discretion of the board of directors at any time prior to the Company's 2023 Annual Meeting of Stockholders. As of the date of this filing, the Company's board of directors has not approved any reverse stock split.

Common Stock Transactions

Issuance of Restricted Stock Units to Executives

During the nine months ended September 30, 2022, upon the recommendation of the compensation committee and pursuant to the Company's 2020 Equity Incentive Plan, the Company's board of directors approved the issuance of a total of 372,512 shares of common stock, valued at a total of approximately $180,600, subject to restricted stock units, which were immediately vested upon grant, to certain executives as performance bonuses for 2021 performance.

Issuance of Stock Pursuant to ATM Agreement

During the nine months ended September 30, 2022, the Company sold 148,000 shares of its common stock under the ATM Agreement for net proceeds of $63,600.

Share Purchase Warrants

A summary of the Company's share purchase warrants as of September 30, 2022 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, 2022	**19,830,000**	**$ 4.42**	**1.70**	**$ —**
Warrants granted	—	—	—	—
Expired or cancelled	(1,348,000)	3.97	—	—
Balance - September 30, 2022	**18,482,000**	**$ 4.45**	**1.04**	**$ —**

NOTE 11: STOCK-BASED COMPENSATION

Stock Options

2022 Equity Incentive Awards

On February 17, 2022, pursuant to the Company's 2020 Equity Incentive Plan, the compensation committee of the Company's board of directors approved a total of 1,250,000 options to purchase the Company's common stock as equity-based incentive awards to the Company's executive officers. Each option award was granted with an exercise price of $0.46 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 17, 2022, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such executive officer's continued service on the applicable vesting date. Additionally, on February 17, 2022, the compensation committee of the Company's board of directors approved a total of 395,000 options to purchase the Company's common stock to non-executive employees of the Company as equity-based incentive awards. Each option award was granted with an exercise price of $0.46 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 17, 2022, with the option award vesting in 48 equal monthly installments over a four-year period, subject to such employee's continued service on the applicable vesting date.

The above awards were in addition to 175,000 stock option awards issued during the three months ended March 31, 2022 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $1.00

per share, the closing price of the Company's common stock on the Nasdaq Global Market on January 3, 2022, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

210,000 stock option awards were issued during the three months ended June 30, 2022 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $0.43 per share, the closing price of the Company's common stock on the Nasdaq Global Market on April 1, 2022, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

Additionally, 100,000 stock option awards were issued during the three months ended September 30, 2022 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $0.35 per share, the closing price of the Company's common stock on the Nasdaq Global Market on July 1, 2022, with 25% of the option award vesting in one year and the remaining 75% vesting in 36 equal monthly installments thereafter over a three-year period, subject to such employee's continued service on the applicable vesting date.

Also, pursuant to the Company's Non-Employee Director Compensation Policy, which had previously been approved by the Company's board of directors, 400,000 stock option awards were issued during the nine months ended September 30, 2022 to independent members of the board of directors of the Company. Each option award was granted on May 24, 2022 with an exercise price of $0.3377 per share, the closing price of the Company's common stock on the Nasdaq Global Market on May 24, 2022. Each option award will vest in one year subject to the director's continuance of service through May 24, 2023.

A summary of the Company's stock option activity for the nine months ended September 30, 2022 is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2022	7,686,233	$ 5.47	$ —	7.7
Granted	2,530,000	0.47	—	9.2
Canceled/Expired	(254,547)	2.60	—	—
Outstanding as of September 30, 2022	9,961,686	$ 4.27	$ 14,000	7.6
Options vested and exercisable	5,875,626	$ 6.10	$ —	6.7

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company's share-based compensation plans. The weighted average assumptions used in calculating the fair values of stock options that were granted during the nine months ended September 30, 2022 was as follows:

	For the Nine Months Ended September 30, 2022
Exercise price	$ 0.47
Expected term (years)	5.9
Expected stock price volatility	85 %
Risk-free rate of interest	2 %
Expected dividend rate	0 %

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock Compensation expenses:				
Research and development	$ 730,000	$ 727,000	$ 2,215,000	$ 2,132,000
General and administrative	765,000	741,000	2,412,000	2,365,000
Total stock compensation expenses	$ 1,495,000	$ 1,468,000	$ 4,627,000	$ 4,497,000

As of September 30, 2022, the total stock-based compensation cost related to unvested awards not yet recognized was $4.7 million. The expected weighted average period compensation costs to be recognized was approximately 1.9 years. Future option grants will impact the compensation expense recognized.

NOTE 12: GRANT INCOME

In August 2021, the Company received notice of a Product Development Research award totaling approximately $13.1 million from CPRIT to support the Company's Phase 2 clinical trial of MT-401. The CPRIT award is intended to support the adjuvant arm of the Company's Phase 2 clinical trial evaluating MT-401 when given as an adjuvant therapy to patients with acute myeloid leukemia following a hematopoietic stem cell transplant. The primary objectives of the adjuvant arm of the trial are to evaluate relapse-free survival after MT-401 treatment when compared with a randomized control group.During the fourth quarter of 2021, the Company received $2.4 million advancement of funds in relation to the CPRIT grant.

The Company recorded $2.8 million of grant income related to the CPRIT grant as revenue for the nine months ended September 30, 2022. At September 30, 2022, there were no restricted cash or deferred revenue amounts on the Company's condensed consolidated financial statements. At September 30, 2022, the Company recorded $1.6 million of grant income receivable, which represented grant income earned in advance of the next tranche of funds to be received from CPRIT.

On September 13, 2022, the Company received notice from the U.S. Food and Drug Administration (the "FDA") that it had awarded the Company a $2.0 million grant from the FDA's Orphan Products Grant program to support the Company's Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. To date, the Company has not received any funds from the FDA grant.

NOTE 13: LEGAL PROCEEDINGS

From time to time, the Company may be party to ordinary, routine litigation incidental to their business. The Company knows of no material, active or pending legal proceedings against the Company, nor is the Company involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of the Company's directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to the Company's interest.

An arbitration proceeding was brought against the Company before the Financial Industry Regulatory Authority, Inc. ("FINRA") by a broker seeking to be paid compensation for two financing transactions that occurred in 2018, a warrant conversion and a private placement brokered by another broker. The broker's claims were based on a placement agent agreement for a private placement it brokered in 2017, under which it alleged it was entitled to compensation for the 2018 transactions. The FINRA panel found in favor of the broker and awarded the broker $2.4 million for compensation, interest and attorney fees. As of December 31, 2021, the Company recorded an accrual of $2.4 million in accrued liabilities on its consolidated balance sheet and a $2.4 million charge to other expenses. On September 17, 2021, the broker filed a petition to confirm the FINRA arbitration award in the Supreme Court of New York for the County of New York. The Company removed the case to the United States District Court for the Southern District of New York on September 27, 2021. On October 22, 2021, the Company filed a motion in federal court to vacate the award. On March 9, 2022, the Company was notified that its motion to vacate the award was denied and the broker was awarded an additional $0.1 million in interest. Post judgment interest accrued at 1.02% until the judgement was paid. The Company paid the $2.5 million judgement on March 24, 2022.

NOTE 14: RELATED PARTY TRANSACTIONS

The following table sets forth related party transaction expenses recorded for the three and nine months ended September 30, 2022 and 2021, respectively.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Baylor College of Medicine	$ —	$ 789,000	$ 1,142,000	$ 2,052,000
Bio-Techne Corporation	—	54,000	101,000	215,000
Wilson Wolf Manufacturing Corporation	71,000	70,000	172,000	110,000
Total Research and development	$ 71,000	$ 913,000	$ 1,415,000	$ 2,377,000

$16,000 of related party transactions are included in accounts payable and accrued liabilities as of September 30, 2022.

Agreements with The Baylor College of Medicine ("BCM").

In November 2018, January 2020 and February 2020, the Company entered in Sponsored Research Agreements with BCM, which provided for the conduct of research for the Company by credentialed personnel at BCM's Center for Cell and Gene Therapy.

In September 2019, May 2020 and July 2021, the Company entered into Clinical Supply Agreements with BCM, which provided for BCM to provide to the Company multi tumor antigen specific products.

In October 2019, the Company entered in a Workforce Grant Agreement with BCM, which provided for BCM to provide to the Company manpower costs of projects for manufacturing, quality control testing and validation run activities.

In August 2020, the Company entered in a Clinical Trial Agreement with BCM, which provided for BCM to provide to the Company investigator-initiated research studies.

The Company has also entered into a Clinical Site Agreement with BCM, which provided for BCM to conduct clinical trials for the Company.

Purchases from Bio-Techne Corporation.

The Company is currently utilizing Bio-Techne Corporation and two of its brands for the purchases of reagents, primarily cytokines. Mr. David Eansor is a member of the Company's board of directors and was serving as the President of the Protein Sciences Segment of Bio-Techne Corporation. Mr. Eansor resigned from Bio-Techne Corporation on March 1. 2022, and as such, two months of transactions in 2022 are included in the table above.

Purchases from Wilson Wolf Manufacturing Corporation.

The Company is currently utilizing Wilson Wolf Manufacturing Corporation for the purchases of cell culture devices called G-Rexes. Mr. John Wilson is a member of the Company's board of directors and is serving as the CEO of Wilson Wolf Manufacturing Corporation. Wilson Wolf Manufacturing became a related party during fiscal year 2021 due to the amounts of the Company's purchases and as such, $70,000 and $110,000 of transactions for the three and nine-month periods ended September 30, 2021, respectively, were included in the table above. Purchases from Wilson Wolf Manufacturing Corporation exclude amounts pertaining to the Related Party Deferred Revenue discussed in Note 9 above.

NOTE 15: SUBSEQUENT EVENTS

As part of the Company's review of its peptide-based immunotherapeutic vaccine programs to determine the future strategy of the programs and the proper allocation of the Company's resources to best maximize stockholder value, on October 16, 2022, the Company and Mayo Foundation for Medical Education and Research mutually agreed to terminate the (i) Patent and Know-How License Agreement dated March 25, 2012, the (ii) License and Assignment Agreement dated July 21, 2015, and the (iii) License and Assignment Agreement effective May 4, 2016 (collectively, the "License Agreements") in accordance with and subject to the terms of those agreements, pursuant to which Mayo granted the Company license grants to patent rights, know-how and materials in each of the License Agreements that were directed to the peptide-based immunotherapeutic vaccine programs. The termination of the License Agreements is effective as of October 16, 2022.

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

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

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

The following should be read in conjunction with our unaudited condensed consolidated interim financial statements and related notes included in this Quarterly Report on Form 10-Q.

Company Overview

We are a clinical-stage immuno-oncology company specializing in the development and commercialization of novel T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. We developed our lead product candidates from our MultiTAA-specific T cell technology, which is based on the manufacture of non-engineered, tumor-specific T cells that recognize multiple tumor-associated antigens, or TAAs. MultiTAA-specific T cells are able to recognize multiple tumor targets to produce broad spectrum anti-tumor activity. When infused into a cancer patient, the MultiTAA-specific T cells are designed to kill cancer cells expressing the TAA targets and potentially recruit the patient's immune system to participate in the cancer killing process.

We licensed the underlying technology for MultiTAA-specific T cell therapy from BCM in March 2018. BCM had utilized the therapy in seven exploratory clinical trials. In these studies, BCM treated over 170 patients suffering from a variety of cancers including lymphoma, multiple myeloma, acute myeloid leukemia, acute lymphoblastic leukemia, pancreatic cancer, breast cancer and various sarcomas. In those studies, BCM saw evidence of clinical benefit, expansion of infused cells, epitope spreading, and decreased toxicity compared to other cellular therapies.

We are advancing three product candidates as part of our MultiTAA-specific T cell program for:

1. autologous treatment of lymphoma, and selected solid tumors
2. allogeneic T cells for the treatment of acute myeloid leukemia, or AML
3. off-the-shelf products in various indications

Our current clinical development programs are:

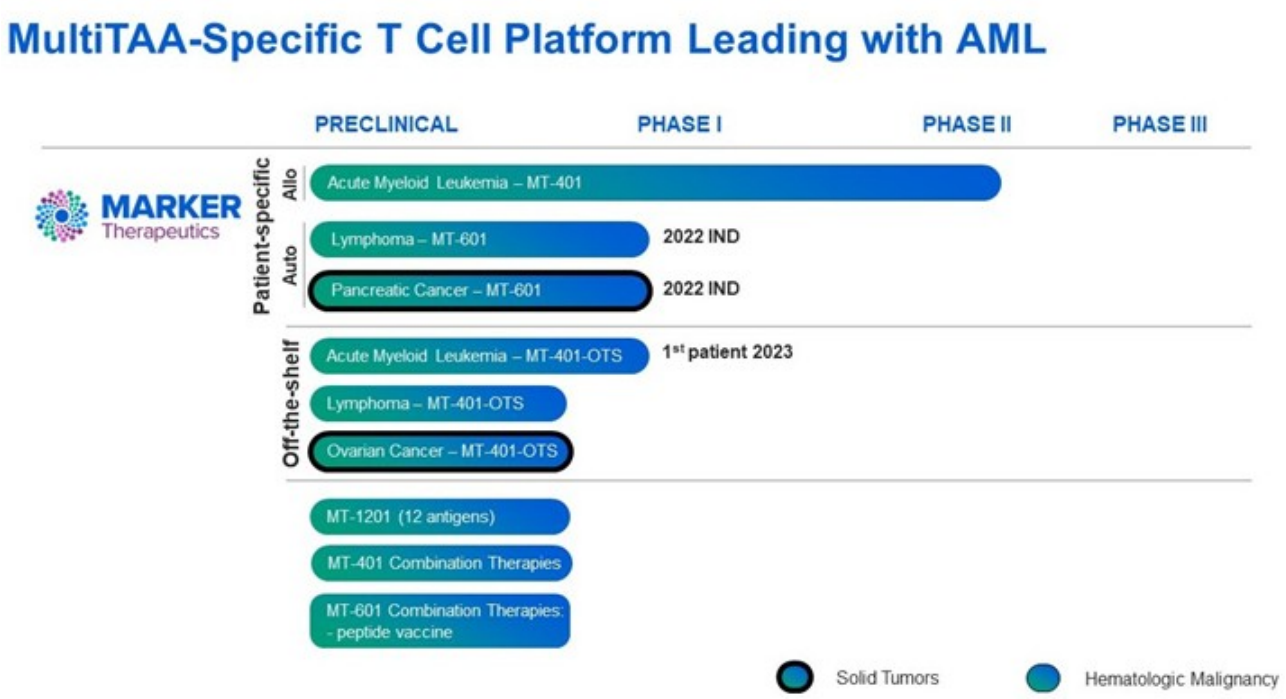
- MT-401 for the treatment of post-transplant AML, currently in a Phase 2 clinical trial
- MT-401-OTS for the treatment of AML, for which we expect to dose the first patient in a Phase 1 clinical trial in 2023
- MT-601 for the treatment of pancreatic cancer, for which we plan to submit an IND to the FDA in 2022 to initiate a Phase 1 trial in 2023, with the first patient expected to be enrolled in the first quarter of 2023
- MT-601 for the treatment of lymphoma, for which we have a cleared IND from the FDA to initiate a Phase 1 trial in 2023

We believe that the simplicity of our manufacturing process allows additional modifications to expand MultiTAA-specific T cell recognition of cancer targets. For example, we are currently analyzing the potential for a 12-antigen MultiTAA-specific T cell therapy and assessing the potential for combination therapies for our MultiTAA-specific T cell products.

We have positioned ourselves to be in full control of our research and development and clinical manufacturing needs by establishing a fully validated, FDA registered, manufacturing facility. We believe that this has key advantages that distinguish us from our competitors, particularly because we are less reliant on contract manufacturing organizations, which are expensive and often have long lead times, shortages of skilled labor and a backlog of customers.

Pipeline

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



Recent Developments

On September 13, 2022, we announced that we received notice from the FDA that it had awarded the Company a $2.0 million grant from the FDA's Orphan Products Grant program to support the Company's Phase 2 clinical trial of MT-401 for the treatment of minimal residual disease in post-transplant AML after allogeneic stem cell transplant. To date, the Company has not received any funds from the FDA grant. With respect to this trial, we have treated all six patients in Cohorts 4 and 5 using MT-401 manufactured with our new T cell manufacturing process. The new manufacturing process is designed to produce a more potent product with increased antigen specificity and diversity and a reduction in manufacturing time. To date, all six patients have completed dose-limiting toxicity, or DLT, periods with no DLTs reported. We expect to announce an efficacy analysis from the six patients in Cohorts 4 and 5 by year-end 2022.

Results of Operations

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

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes the results of our operations for the three months ended September 30, 2022 and 2021:

	For the Three Months Ended September 30,		Change	
	2022	2021		
Revenues:				
Grant income	$ 1,000,000	$ —	$ 1,000,000	100 %
Related partry service revenue	2,950,000	—	2,950,000	100 %
Total revenues	3,950,000	—	3,950,000	100 %
Operating expenses:				
Research and development	7,291,000	6,784,000	507,000	7 %
General and administrative	3,678,000	3,239,000	439,000	14 %
Total operating expenses	10,969,000	10,024,000	945,000	9 %
Loss from operations	(7,019,000)	(10,024,000)	3,005,000	(30)%
Other income (expense):				
Arbitration settlement	—	(2,407,000)	2,407,000	(100)%
Interest income	100,000	1,000	99,000	9,900 %
Net loss	**$ (6,920,000)**	**$ (12,429,000)**	**$ 5,511,000**	**(44)%**
Net loss per share, basic and diluted	$ (0.08)	$ (0.15)	$ 0.07	(47)%
Weighted average number of common shares outstanding	83,599,000	83,079,000	520,000	1 %

Revenue

We did not generate any revenue during the three months ended September 30, 2022 and 2021, respectively, from the sales or licensing of our product candidates.

In August 2021, we received notice of a Product Development Research award totaling approximately $13.1 million from the Cancer Prevention and Research Institute of Texas, or CPRIT, to support our Phase 2 clinical trial of MT-401. During the three months ended September 30, 2022, we recognized $1.0 million of revenue associated with the CPRIT grant.

In April 21 2022, we entered into a binding services agreement with Wilson Wolf Manufacturing Corporation. Wilson Wolf is in the business of creating products and services intended to simplify and expedite the transition of cell therapies and gene-modified cell therapies to mainstream society. Pursuant to the agreement, Wilson Wolf made a cash payment to the Company in the amount of $8.0 million, as consideration for certain training and research services. During the three months ended September 30, 2022, we recognized $2.95 million of revenue associated with the Wilson Wolf services agreement.

Operating Expenses

Operating expenses incurred during the three months ended September 30, 2022 were $11.0 million compared to $10.0 million during the three months ended September 30, 2021.

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

Research and Development Expenses

Research and development expenses increased by 7% to $7.3 million for the three months ended September 30, 2022, compared to $6.8 million for the three months ended September 30, 2021.

The increase of $0.5 million in 2022 was primarily attributable to the following:

- increase of $0.2 million in process development expenses,
- increase of $0.6 million in headcount-related expenses,
- increase of $0.3 million in depreciation expenses,
- increase of $0.1 million of other expenses, and
- increase of $0.1 million in clinical trial expenses, offset by
- decrease of $0.8 million in sponsored research expenses from BCM agreements,

General and Administrative Expenses

General and administrative expenses were $3.7 million and $3.2 million for the three months ended September 30, 2022 and 2021, respectively. The increase was mainly attributable to severance expenses recorded during the quarter related to the reduction of headcount as part of our cost reduction plan.

Other Income (Expense)

Arbitration settlement

An arbitration proceeding was brought against us before the FINRA by a broker seeking to be paid compensation for two financing transactions that occurred in 2018, a warrant conversion and a private placement brokered by another broker. The broker's claims were based on a placement agent agreement for a private placement it brokered in 2017, under which it alleged it was entitled to compensation for the 2018 transactions. The FINRA panel found in favor of the broker and awarded the broker $2.4 million for compensation, interest and attorney fees, which we recorded in the three months ended September 30, 2021.

Interest Income

Interest income was $100,000 and $1,000 for the three months ended September 30, 2022 and 2021, respectively, and was attributable to interest income relating to funds that are held in U.S. Treasury notes and U.S. government agency-backed securities.

Net Loss

The decrease in our net loss during the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was due to the timing of process development expenses, lower costs associated with our BCM clinical supplies agreement and higher grant income, offset by the continued expansion of our research and development activities, increased expenses relating to 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 Nine Months Ended September 30, 2022 and 2021

The following table summarizes the results of our operations for the nine months ended September 30, 2022 and 2021:

	For the Nine Months Ended September 30,		Change	
	2022	2021		
Revenues:				
Grant income	$ 2,754,000	$ —	$ 2,754,000	100 %
Related partry service revenue	2,950,000	—	2,950,000	100 %
Total revenues	5,704,000	—	5,704,000	100 %
Operating expenses:				
Research and development	20,872,000	19,777,000	1,095,000	6 %
General and administrative	10,926,000	9,936,000	990,000	10 %
Total operating expenses	31,798,000	29,714,000	2,084,000	7 %
Loss from operations	(26,094,000)	(29,714,000)	3,620,000	(12)%
Other income (expense):				
Arbitration settlement	(119,000)	(2,407,000)	2,288,000	(95)%
Interest income	139,000	5,000	134,000	2,680 %
Net loss	**$ (26,074,000)**	**$ (32,116,000)**	**$ 6,042,000**	**(19)%**
Net loss per share, basic and diluted	$ (0.31)	$ (0.43)	$ 0.12	(28)%
Weighted average number of common shares outstanding	83,435,000	74,291,000	9,144,000	12 %

Revenue

We did not generate any revenue during the nine months ended September 30, 2022 and 2021, respectively, from the sales or licensing of our product candidates.

In August 2021, we received notice of a Product Development Research award totaling approximately $13.1 million from the Cancer Prevention and Research Institute of Texas, or CPRIT, to support our Phase 2 clinical trial of MT-401. During the nine months ended September 30, 2022, we recognized $2.8 million of revenue associated with the CPRIT grant.

In April 21 2022, we entered into a binding services agreement with Wilson Wolf Manufacturing Corporation. Pursuant to the agreement, Wilson Wolf made a cash payment to the Company in the amount of $8.0 million, as consideration for certain training and research services. During the nine months ended September 30, 2022, we recognized $2.95 million of revenue associated with the Wilson Wolf services agreement.

Operating Expenses

Operating expenses incurred during the nine months ended September 30, 2022 were $31.8 million compared to $29.7 million during the nine months ended September 30, 2021.

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

Research and Development Expenses

Research and development expenses increased by 6% to $20.9 million for the nine months ended September 30, 2022, compared to $19.8 million for the nine months ended September 30, 2021.

The increase of $1.1 million in 2022 was primarily attributable to the following:

- increase of $1.6 million in headcount-related expenses,
- increase of $0.8 million in expenses related to our AML clinical trial.
- increase of $0.4 million in depreciation expenses,
- increase of $0.4 million in maintenance and repairs at our manufacturing facility, and
- increase of $0.1 million of other expenses, offset by
- decrease of $0.6 million in process development expenses,
- decrease of $1.3 million in sponsored research expenses from BCM agreements, and
- decrease of $0.3 million in technology licensing fees.

General and Administrative Expenses

General and administrative expenses were $10.9 million and $9.9 million for the nine months ended September 30, 2022 and 2021, respectively.

The increase of $1.0 million in 2022 was primarily attributable to the following:

- increase of $0.4 million in headcount-related expenses,
- increase of $0.5 million in professional services, and
- increase of $0.6 million in severance-related expenses, offset by
- decrease of $0.4 million in legal fees, and
- decrease of $0.1 million in other expenses.

Other Income (Expense)

Arbitration settlement

An arbitration proceeding was brought against us before the Financial Industry Regulatory Authority, Inc., or FINRA by a broker seeking to be paid compensation for two financing transactions that occurred in 2018, a warrant conversion and a private placement, each brokered by another broker. The broker's claims were based on a placement agent agreement for a private placement it brokered in 2017, under which it alleged it was entitled to compensation for the 2018 transactions. The FINRA panel found in favor of the broker and awarded the broker $2.4 million for compensation, interest and attorney fees, which we recorded in the nine months ended September 30, 2021. We removed the case to the United States District Court for the Southern District of New York on September 27, 2021. On October 22, 2021, we filed a motion in federal court to vacate the award. On March 9, 2022, we were notified that our motion to vacate the award was denied and the broker was awarded an additional $0.1 million in interest. Post judgment interest accrued at 1.02% until the judgement was paid. During the nine months ended September 30, 2022, we recorded an additional $0.1 million of expense related to this matter. We paid the $2.5 million judgement on March 24, 2022.

Interest Income

Interest income was $139,000 and $5,000 for the nine months ended September 30, 2022 and 2021, respectively, and was attributable to interest income relating to funds that are held in U.S. Treasury notes and U.S. government agency-backed securities.

Net Loss

The decrease in our net loss during the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 was due to the timing of process development expenses, lower costs associated with our BCM clinical supplies agreement and higher grant income, offset by the continued expansion of our research and development activities, increased expenses relating to 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, cash equivalents and restricted cash and working capital as of September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021
Cash, cash equivalents and restricted cash	$ 18,076,000	$ 43,497,000
Working capital	$ 11,136,000	$ 33,081,000

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021:

	For the Nine Months Ended September 30,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ (20,667,000)	$ (22,422,000)
Investing activities	(4,818,000)	(2,781,000)
Financing activities	64,000	52,556,000
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (25,421,000)	$ 27,353,000

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2022 was $20.7 million compared to $22.4 million for the same period last year. The changes in cash flow from operating activities during the nine months ended September 30, 2022 were due to $26.1 million of net losses and a $1.6 million decrease from changes in operating assets and liabilities. This was in addition to $4.6 million of stock-based compensation, $2.0 million of depreciation expense, $0.7 million right-of-use asset amortization and lease liability accretion and $0.3 million gain on lease termination.

Net cash used in operating activities during the nine months ended September 30, 2021 was $22.4 million. The changes in cash flow used in operating activities during the nine months ended September 30, 2021 were due to $32.1 million of net losses and a $2.9 million increase from changes in operating assets and liabilities. This was in addition to $4.5 million of stock-based compensation, $1.6 million of depreciation expense and $0.8 million right-of-use asset amortization and lease liability accretion.

Investing Activities

Net cash used in investing activities was $4.8 million for the purchase of property and equipment and construction in progress related to the manufacturing facility during the nine months ended September 30, 2022. The increase mainly relates to purchases of equipment for the manufacturing and research facilities.

Net cash used in investing activities was $2.8 million for the purchase of property and equipment and construction in progress during the nine months ended September 30, 2021. The increase relates to purchases of laboratory equipment for the manufacturing facility.

Financing Activities

Net cash provided by financing activities was $0.1 million during the nine months ended September 30, 2022, due to sales of common stock under the ATM Agreement. Net cash provided by financing activities was $52.6 million during the nine months ended September 30, 2021, due to the net proceeds received from the underwritten public offering.

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, continue or initiate clinical trials 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.

In August 2021, we received notice of a Product Development Research award totaling approximately $13.1 million from CPRIT to support our Phase 2 clinical trial of MT-401. To date, we have received $2.4 million of funds from the CPRIT grant.

On September 13, 2022, the Company received notice from the U.S. Food and Drug Administration (the “FDA”) that is has awarded the Company a $2.0 million grant from the FDA’s Orphan Products Grant program to support the Company’s Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. To date, the Company has not received any funds from the FDA grant.

As of September 30, 2022, we had working capital of $11.1 million, compared to working capital of $33.1 million as of December 31, 2021. Based on our revised clinical and research and development plans and our revised timing expectations related to the progress of our programs, we expect that our cash and cash equivalents as of September 30, 2022 will enable us to fund our operating expenses and capital expenditure requirements through the second quarter of 2023. 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 plans may change, and we may need additional funds sooner than planned in order to meet operational needs and capital requirements for product development and commercialization. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, as we:

- initiate or continue clinical trials of our product candidates;
- continue the research and development of our product candidates and seek to discover additional product candidates;seek regulatory approvals for our product candidates if they successfully complete clinical trials;
- continue development of our manufacturing capabilities and our manufacturing facility;
- 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.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term liquidity due to the COVID-19 pandemic. However, the Company will continue to assess the effect of the pandemic on its operations, including its clinical programs. The extent to which the COVID-19 pandemic will impact the Company's business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the geographic spread of the disease, the duration of the outbreak, the emergence of any new variant strains of COVID-19, the duration and effect of any future business disruptions in the United States and other countries to contain and treat the disease and the rate of public acceptance and efficacy of vaccines and other treatments. Further, disruption of global financial markets and a recession or market correction, including as a result of the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, and other global macroeconomic factors such as inflation, could reduce the Company's ability to access capital, which could in the future negatively affect the Company's liquidity and could materially affect the Company's business and the value of its common stock.

On February 16, 2022, the Company received a notice from the Nasdaq Global Market that the Company was not in compliance with Nasdaq's Listing Rule 5450(a)(1), as the minimum bid price of its common stock had been below $1.00 per share for 30 consecutive business days. On August 16, 2022, Nasdaq approved the Company's application to transfer to The Nasdaq Capital Market, effective at the opening of business on August 18, 2022, and notified the Company that it had been granted an additional 180-calendar day compliance period, or until February 13, 2023, to regain compliance with the minimum bid price requirement. As part of the transfer, the Company provided notice to Nasdaq that it intended to cure the bid price deficiency by effecting a reverse stock split, if necessary, prior to the end of the compliance period. The Company's failure to regain compliance during this period could result in delisting, which the Company could appeal to a Nasdaq hearings panel. The Company intends to actively monitor the bid price of its common stock and will consider available options, including a reverse stock split, to regain compliance with the listing requirements. There can be no assurance that the Company will be able to regain compliance with Nasdaq's Listing Rule 5450(a)(1) or will otherwise be in compliance with other Nasdaq listing criteria.

During the three months ended June 30, 2022, the Company's board of directors and stockholders approved a series of alternate amendments to the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock, where the board of directors will have the discretion to select the reverse stock split ratio from within a range between and including one-for-three and one-for-twelve. Such reverse stock split, and the reverse stock split ratio, will be at the sole discretion of the board of directors at any time prior to the Company's 2023 Annual Meeting of Stockholders.

Aspire Common Stock Purchase Agreement

In February 2020, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $30.0 million of shares of our common stock over the 30-month term of the Purchase Agreement. As of December 31, 2021, Aspire Capital had purchased 4,113,440 shares under the Purchase Agreement, providing aggregate proceeds to the Company of approximately $6.2 million. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 345,357 shares of the Company's common stock.

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

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

ATM Agreement

In August 2021, the Company entered into a Controlled Equity OfferingSM Sales Agreement (the "ATM Agreement") with Cantor Fitzgerald & Co. and RBC Capital Markets, LLC (the "Sales Agents"), pursuant to which the Company can offer and sell, from time to time at its sole discretion through the Sales Agents, shares of its common stock having an aggregate offering price of up to $75.0 million. Any shares of its common stock sold will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-258687), which the SEC declared effective on August 19, 2021. The shelf registration statement on Form S-3 includes a prospectus supplement covering the offering up to $19.8 million of shares of common stock over the 12 months ending March 18, 2023 in accordance with the ATM agreement. The Sales Agents will be entitled to compensation under the Sales Agreement at a commission rate equal to 3.0% of the gross sales price per share sold under the ATM Agreement, and the Company has provided each of the Sales Agents with indemnification and contribution rights. From April 1, 2022 to the date of this filing, the Company sold 148,000 shares of its common stock under the ATM Agreement for net proceeds of $63,600.

Going Concern

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

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

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 condensed 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, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

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

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

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

(b) Changes in Internal Control Over Financial Reporting

There have been no changes in our internal controls over financial reporting during the nine months ended September 30, 2022 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

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

An arbitration proceeding was brought against us before the Financial Industry Regulatory Authority, Inc., or FINRA, by a broker seeking to be paid compensation for two financing transactions that occurred in 2018, a warrant conversion and a private placement brokered by another broker. The broker's claims were based on a placement agent agreement for a private placement it brokered in 2017, under which it alleged it was entitled to compensation for the 2018 transactions. The FINRA panel found in favor of the broker and awarded the broker $2.4 million for compensation, interest and attorney fees. On September 17, 2021, the broker filed a petition to confirm the FINRA arbitration award in the Supreme Court of New York for the County of New York. We removed the case to the United States District Court for the Southern District of New York on September 27, 2021. On October 22, 2021, we filed a motion in federal court to vacate the award. On March 9, 2022, the Company was notified that its motion to vacate the award was denied and the broker was awarded an additional $0.1 million in interest. Post judgment interest accrued at 1.02% until the judgement was paid. During the three months ended September 30, 2022, we recorded an additional $0.1 million of expense related to this matter. We paid the $2.5 million judgement on March 24, 2022.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. In addition to the other information set forth in this quarterly report on Form 10-Q, you should carefully consider the factors described in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission on March 17, 2022. There have been no material changes to the risk factors described in that report.

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

We did not record any issuances of unregistered securities during the nine months ended September 30, 2022.

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	
3.1.1	Certificate of Amendment to Certificate of Incorporation.	8-K	001-37939	3.1	5/27/2022	
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 Principal Financial And Accounting 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 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial And Accounting Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

Exhibit 101

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

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

SIGNATURES

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

Date: November 10, 2022

MARKER THERAPEUTICS, INC.

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

/s/ Michael J. Loiacono
Michael J. Loiacono
Chief Accounting 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 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 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: November 10, 2022

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

Exhibit 31.2

CERTIFICATION

I, Michael J. Loiacono, 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 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 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: November 10, 2022

/s/ Michael J. Loiacono

By: **Michael J. Loiacono**
Chief Accounting Officer (Principal Financial and
Title: Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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

The undersigned, Peter L. Hoang, the Chief Executive Officer of Marker Therapeutics, Inc. (the "Company") hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, the Quarterly Report on Form 10-Q for the period ended September 30, 2022, 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: November 10, 2022

/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, Michael J. Loiacono, the Chief Accounting Officer of Marker Therapeutics, Inc. (the "Company") hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, the Quarterly Report on Form 10-Q for the period ended September 30, 2022, 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: November 10, 2022

/s/ Michael J. Loiacono
Michael J. Loiacono
Chief Accounting Officer (Principal Financial and Accounting Officer)