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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, 2023

☐ 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.)
9350 Kirby Drive, Suite 300 **Houston, Texas**	**77054**
(Address of principal executive offices)	(Zip Code)

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

4551 Kennedy Commerce Drive, Houston, Texas, 77032
(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 7, 2023, the Company had 8,889,020 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, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,473,899	$ 11,782,172
Prepaid expenses and deposits	1,929,355	1,849,239
Other receivables	83,313	2,402,004
Current assets of discontinued operations	—	585,840
Total current assets	19,486,567	16,619,255
Non-current assets of discontinued operations	—	17,802,929
Total assets	**$ 19,486,567**	**$ 34,422,184**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,304,019	$ 2,521,193
Related party payable	367,915	—
Deferred revenue	107,530	—
Current liabilities of discontinued operations	—	5,260,616
Total current liabilities	2,779,464	7,781,809
Non-current liabilities of discontinued operations	—	7,039,338
Total liabilities	2,779,464	14,821,147
Stockholders' equity:		
Preferred stock, $0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value, 30 million shares authorized, 8.8 million and 8.4 million shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively (see Note 10)	8,888	8,406
Additional paid-in capital	450,181,012	447,641,680
Accumulated deficit	(433,482,797)	(428,049,049)
Total stockholders' equity	16,707,103	19,601,037
Total liabilities and stockholders' equity	**$ 19,486,567**	**$ 34,422,184**

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock and a corresponding reduction in the total number of authorized shares of its common stock from 300,000,000 to 30,000,000. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

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,	
	2023	2022	2023	2022
Revenues:				
Grant income	$ 257,606	$ 999,571	$ 2,254,601	$ 2,754,401
Total revenues	257,606	999,571	2,254,601	2,754,401
Operating expenses:				
Research and development	2,044,980	3,591,897	7,799,472	9,786,138
General and administrative	1,412,672	3,234,133	6,098,716	9,720,598
Total operating expenses	3,457,652	6,826,030	13,898,188	19,506,736
Loss from operations	(3,200,046)	(5,826,459)	(11,643,587)	(16,752,335)
Other income (expenses):				
Arbitration settlement	—	—	—	(118,880)
Interest income	218,085	99,750	337,819	138,653
Loss from continuing operations	(2,981,961)	(5,726,709)	(11,305,768)	(16,732,562)
Discontinued operations:				
Loss from discontinued operations, net of tax	—	(1,192,874)	(2,922,406)	(9,341,717)
Gain on disposal of discontinued operations	—	—	8,794,426	—
Income (loss) from discontinued operations	—	(1,192,874)	5,872,020	(9,341,717)
Net loss	**$ (2,981,961)**	**$ (6,919,583)**	**$ (5,433,748)**	**$ (26,074,279)**
Net earnings (loss) per share:				
Loss from continuing operations, basic and diluted	$ (0.34)	$ (0.69)	$ (1.29)	$ (2.01)
Income (loss) from discontinued operations, basic	$ —	$ (0.14)	$ 0.67	$ (1.12)
Income (loss) from discontinued operations, diluted	$ —	$ (0.14)	$ 0.66	$ (1.12)
Net loss per share	$ (0.34)	$ (0.83)	$ (0.62)	$ (3.13)
Weighted average number of common shares outstanding:				
Basic	8,825,881	8,359,920	8,782,340	8,343,477
Diluted	8,825,881	8,359,920	8,834,512	8,343,477

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

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, 2023				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at July 1, 2023	**8,799,173**	**$ 8,799**	**$ 449,526,789**	**$ (430,500,836)**	**$ 19,034,752**
Issuance of common stock from exercise of stock options	24,774	24	84,580	—	84,604
Shares purchased pursuant to ATM agreeement	65,073	65	394,602	—	394,667
Stock-based compensation	—	—	175,041	—	175,041
Net loss	—	—	—	(2,981,961)	(2,981,961)
Balance at September 30, 2023	**8,889,020**	**8,888**	**450,181,012**	**(433,482,797)**	**16,707,103**

	For the Nine Months Ended September 30, 2023				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par value			
Balance at January 1, 2023	**8,405,771**	**$ 8,406**	**$ 447,641,680**	**$ (428,049,049)**	**$ 19,601,037**
Shares purchased pursuant to ATM and Lincoln Park agreeements	277,834	277	1,014,363	—	1,014,640
Issuance of common stock as commitment fee for future financing	180,410	180	(180)	—	—
Issuance of common stock from exercise of stock options	25,118	25	85,317	—	85,342
Stock-based compensation	—	—	1,439,832	—	1,439,832
Net loss	—	—	—	(5,433,748)	(5,433,748)
Fractional shares adjustment due to reverse split	(113)	—	—	—	—
Balance at September 30, 2023	**8,889,020**	**8,888**	**450,181,012**	**(433,482,797)**	**16,707,103**

	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	**8,359,919**	**$ 8,360**	**$ 445,290,964**	**$ (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	**8,359,919**	**$ 8,360**	**$ 446,785,996**	**$ (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	**8,307,868**	**$ 8,308**	**$ 442,095,642**	**$ (398,118,355)**	**$ 43,985,595**
Issuance common shares for cash, net	14,800	15	63,558	—	63,573
Stock-based compensation	37,251	37	4,626,796	—	4,626,833
Net loss	—	—	—	(26,074,279)	(26,074,279)
Balance at September 30, 2022	**8,359,919**	**$ 8,360**	**$ 446,785,996**	**$ (424,192,634)**	**$ 22,601,722**

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

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,	
	2023	**2022**
Cash Flows from Operating Activities:		
Net loss	$ (5,433,748)	$ (26,074,279)
Less: gain (loss) from discontinued operations, net of tax	5,872,020	(9,341,717)
Net loss from continuing operations	(11,305,768)	(16,732,562)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	714,899	2,921,765
Gain on lease termination	—	(278,681)
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(80,116)	(204,222)
Other receivables	2,318,691	(1,680,782)
Accounts payable and accrued expenses	208,348	(289,148)
Deferred revenue	107,530	(1,146,186)
Net cash used in operating activities - continuing operations	(8,036,416)	(17,409,816)
Net cash used in operating activities - discontinued operations	(6,035,961)	(3,256,915)
Net cash used in operating activities	(14,072,377)	(20,666,731)
Cash Flows from Investing Activities:		
Net cash provided by (used in) investing activities - discontinued operations	18,664,122	(4,817,794)
Net cash provided by (used in) investing activities	18,664,122	(4,817,794)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	1,014,640	63,573
Proceeds from stock options exercise	85,342	—
Net cash provided by financing activities	1,099,982	63,573
Net increase (decrease) in cash, cash equivalents and restricted cash	5,691,727	(25,420,952)
Cash, cash equivalents and restricted cash at beginning of the period	11,782,172	43,497,331
Cash, cash equivalents and restricted cash at end of the period	$ 17,473,899	$ 18,076,379

See accompanying notes to these unaudited condensed consolidated financial statements.

MARKER THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2023
(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 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.

The Company licensed the underlying technology for multiTAA-specific T cell therapy from Baylor College of Medicine ("BCM") in March 2018. BCM had utilized the therapy in seven exploratory clinical trials.

The Company is advancing three product candidates as part of its 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 ("AML"), and
3. off-the-shelf products in various indications

The current clinical development programs are:

- MT-401 for the treatment of post-transplant AML,
- MT-401-OTS for the treatment of AML,
- MT-601 for the treatment of lymphoma, and
- MT-601 for the treatment of pancreatic cancer [(1)].

The Company is currently undertaking a strategic review of its clinical development programs, including with respect to clinical trial initiation and readout guidance.

Purchase Agreement with Cell Ready

On June 26, 2023, the Company completed the previously announced transaction with Cell Ready, LLC ("Cell Ready") pursuant to a Purchase Agreement (the "Cell Ready Purchase Agreement), dated May 1, 2023, by and between the Company and Cell Ready. Mr. John Wilson is a member of the Company's board of directors and is serving as the CEO of Cell Ready, therefore Cell Ready is a related party. Pursuant to the Cell Ready Purchase Agreement, effective as of the Closing Date, the Company (i) assigned to Cell Ready the leases for the Company's two manufacturing facilities in Houston, Texas (the "Manufacturing Facilities"), (ii) sold to Cell Ready all of the equipment and leasehold improvements at the Manufacturing Facilities and (iii) assigned to Cell Ready its rights, title and interest in the Company's Master Services Agreement for Product Supply (the "MSA"), dated April 7, 2023, by and between the Company, Cell Ready and Indapta Therapeutics, Inc., as well as its rights, title and interest in any contracts related to the equipment and Manufacturing Facilities (collectively, the "Purchased Assets"). Cell Ready acquired the Purchased Assets for total consideration of $19.0 million. In connection with the purchase of the Manufacturing Facilities, Cell Ready also extended offers of employment to approximately 50 of the Company's former employees in its manufacturing, development, quality, and regulatory affairs functions.

(1) Clinical advancement will be pending additional financial support from non-dilutive grant activities.

The Purchased Assets constituted a significant disposition. Based upon the magnitude of the disposition and because the Company is exiting certain manufacturing operations, the disposition represents a significant strategic shift that will have a material effect on the Company's operations and financial results. Accordingly, the assets sold meet the definition of a discontinued operation, as defined by Accounting Standards Codification ("ASC") 205-20 – *Discontinued Operations*, and prior comparative periods have been retroactively adjusted to reflect the current presentation.

Reverse Stock Split

On January 26, 2023, the Company effected a one-for-ten (1-for-10) reverse stock split of its common stock (the "Reverse Stock Split") and a corresponding reduction in the total number of authorized shares of its common stock from 300,000,000 to 30,000,000. The Reverse Stock Split, which was approved by stockholders at an annual stockholder meeting on May 24, 2022, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on January 26, 2023. The Reverse Stock Split was effective on January 26, 2023. All references to common stock, warrants to purchase common stock, options to purchase common stock, share data, per share data and related information contained in the condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Organizational Changes

In May 2023 and June 2023, the Company implemented changes to its organizational structure as part of an operational cost reduction plan and reorganization plan due to the transaction with Cell Ready. In connection with these changes, the Company reduced headcount, including the separation of its former Chief Executive Officer, Peter Hoang, in May 2023 and its former Chief Accounting Officer, Michael Loiacono, in June 2023. During the second quarter of 2023, the Company recorded $0.9 million of severance and termination-related costs. The payments of these costs were completed in July of 2023.

Effective May 1, 2023, the Company's board of directors appointed Dr. Vera as the Company's Chief Executive Officer.

Effective June 30, 2023, the board of directors appointed Eliot M. Lurier as the Company's Interim Chief Financial Officer. Mr. Lurier provides consulting services to the Company pursuant to a consulting agreement between the Company and Danforth Advisors, LLC and receives no compensation directly from the Company.

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 (see Note 6 for information on discontinued operations).

The results for the unaudited condensed consolidated statement of operations are not necessarily indicative of results to be expected for the year ending December 31, 2023, or for any future interim period. The condensed consolidated balance sheet at December 31, 2022 has been derived from audited 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, 2022 and notes thereto included in the Company's annual report on Form 10-K filed on March 22, 2023.

NOTE 3: LIQUIDITY AND FINANCIAL CONDITION

As of September 30, 2023, the Company had cash and cash equivalents of approximately $17.5 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 financing.

In August 2021, the Company entered 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 9.87 million of shares of common stock over the 12 months ending March 22, 2024 pursuant to General Instruction I.B.6 of Form S-3, which limits the amounts that the Company may sell under the registration statement, and 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. During the nine months ended September 30, 2023, the Company sold 265,334 shares of its common stock under the ATM Agreement for proceeds of $1.0 million (see Note 10).

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 $6.9 million of funds from the CPRIT grant. The Company recorded $0.2 million and $2.0 million of grant income related to the CPRIT grant as revenue for the three and nine months ended September 30, 2023, respectively.

In September 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. The Company recorded $0.0 million and $0.2 million of grant income related to the FDA grant as revenue for the three and nine months ended September 30, 2023, respectively.

In December 2022, the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which provides that, upon the terms and subject to the conditions of the agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to $25,000,000 of shares of its common stock ("the Purchase Shares") from time to time over a 24-month term, at a variable price with certain market-based terms as defined in the Purchase Agreement. During the nine months ended September 30, 2023, The Company sold 12,500 shares of its common stock under the Lincoln Park agreement for proceeds of $33,000 (See Note 10).

As described in Note 1, on June 26, 2023, the Company completed the previously announced transaction with Cell Ready pursuant to the Cell Ready Purchase Agreement. Pursuant to the Cell Ready Purchase Agreement, effective as of the Closing Date, the Company (i) assigned to Cell Ready the leases for the Manufacturing Facilities, (ii) sold to Cell Ready all of the equipment and leasehold improvements at the Manufacturing Facilities and (iii) assigned to Cell Ready its rights, title and interest in the Company's MSA, dated April 7, 2023, by and between the Company, Cell Ready and Indapta Therapeutics, Inc., as well as its rights, title and interest in any contracts related to the equipment and Manufacturing Facilities (collectively, the "Purchased Assets"). Following the Closing Date, the Company and Cell Ready have agreed to enter a long-term contract pursuant to which Cell Ready will perform a wide variety of services for the Company, including research and development, manufacturing, and regulatory activity in support of the Company's clinical trials. The terms of the agreement were not yet finalized by September 30, 2023 and, therefore, the parties have not executed such an agreement. Cell Ready acquired the Purchased Assets for total consideration of $19.0 million. In connection with the purchase of the Manufacturing Facilities, Cell Ready also extended offers of employment to approximately 50 of the Company's former employees in its manufacturing, development, quality, and regulatory affairs functions.

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, will 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 the issuance 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, 2023, will enable the Company to fund its operating expenses and capital expenditure requirements into the second half of 2025. Prior to the Cell Ready transaction, there was substantial doubt regarding the Company's ability to continue as a going concern, which was alleviated by the proceeds from the transaction.

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 to meet operational needs and capital requirements for product development and commercialization. Because of the numerous risks and uncertainties associated with the development and commercialization of the Company's product candidates and the extent to which the Company may enter into additional collaborations with third parties to participate in their development and commercialization, the Company is unable to estimate the amounts of increased capital outlays and operating expenditures associated with its current and anticipated clinical trials. The Company's future funding requirements will depend on many factors, as it:

- initiates or continues clinical trials of its product candidates;
- continues the research and development of its product candidates and seeks to discover additional product candidates;
- seeks regulatory approvals for any product candidates that successfully complete clinical trials;
- maintains and enforces intellectual property rights;
- enters into contract manufacturing arrangements with Cell Ready or other contract manufacturing organizations for clinical manufacturing supply;
- establishes sales, marketing and distribution infrastructure and establishes third-party 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.

The Company does not have sufficient sources of revenue to provide incoming cash flows to sustain its future operations. As outlined above, its ability to pursue its long-term planned business activities is dependent upon its successful efforts to raise additional capital and grant income.

The COVID-19 pandemic, decades-high inflation, and concerns about an economic recession in the United States or other major markets has resulted in, among other things, volatility in the capital markets that may have the effect of reducing the Company's ability to access capital, which could, in the future, negatively affect the Company's liquidity. In addition, a recession or market correction due to these factors could materially affect the Company's business and the value of its common stock.

NOTE 4: SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

These consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Marker Cell Therapy, Inc. and GeneMax Pharmaceuticals Inc., a dormant subsidiary that wholly owns GeneMax Pharmaceuticals Canada, Inc. All significant intercompany balances and transactions are eliminated upon consolidation (see Note 6 for information on discontinued operations).

Use of Estimates and Assumptions

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results may differ from those estimates.

Management considers many factors in selecting appropriate financial accounting policies, controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: research and development expense, stock-based compensation expense, and income taxes.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with a maturity date of three months or less, when acquired, to be cash equivalents.

Cash Concentration Risk

The Federal Deposit Insurance Corporation (the "FDIC") insurance limits are $250,000 per depositor per insured bank. The Company had cash balances of $17.2 million and $11.5 million uninsured by the FDIC as of September 30, 2023 and December 31, 2022, respectively.

Discontinued Operations

The Purchased Assets sold to Cell Ready pursuant to the Cell Ready Purchase Agreement constituted a significant disposition and as such, the Company concluded that the disposition of its Purchased Assets represented a strategic shift that had a major effect on its operations and financial results. Therefore, the Purchased Assets, related party revenue, service revenue and related expenses are classified as discontinued operations for all periods presented herein. See Note 6 for further information.

New Accounting Standards

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

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the Annual Report on Form 10-K for the year ended December 31, 2022 filed on March 22, 2023.

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, 2023 and 2022, respectively:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Loss from continuing operations	$ (2,981,961)	$ (5,726,709)	$ (11,305,768)	$ (16,732,562)
Income (loss) from discontinued operations	$ —	$ (1,192,874)	$ 5,872,020	$ (9,341,717)
Net loss	$ (2,981,961)	$ (6,919,583)	$ (5,433,748)	$ (26,074,279)
Denominator:				
Weighted average common shares outstanding, basic	8,825,881	8,359,920	8,782,340	8,343,477
Weighted average common shares outstanding, diluted	8,825,881	8,359,920	8,834,512	8,343,477
Net earnings (loss) per share:				
Loss from continuing operations, basic and diluted	$ (0.34)	$ (0.69)	$ (1.29)	$ (2.01)
Income (loss) from discontinued operations, basic	$ —	$ (0.14)	$ 0.67	$ (1.12)
Income (loss) from discontinued operations, diluted	$ —	$ (0.14)	$ 0.66	$ (1.12)
Net loss per share	$ (0.34)	$ (0.83)	$ (0.62)	$ (3.13)

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 Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Common stock options	800,000	996,000	748,000	996,000
Common stock purchase warrants	1,848,000	1,848,000	1,848,000	1,848,000
Potentially dilutive securities	2,648,000	2,844,000	2,596,000	2,844,000

NOTE 6: DISCONTINUED OPERATIONS

As discussed in Note 1, on June 26, 2023, the Company completed the previously announced transaction with Cell Ready for cash consideration of $19.0 million, resulting in derecognition of the Purchased Assets and a gain on sale of approximately $8.8 million.

The assets and liabilities classified in discontinued operations as of September 30, 2023 and December 31, 2022 are as follows:

	September 30, 2023	December 31, 2022
Prepaid expenses and other current assets	$ —	$ 585,840
Total current assets of discontinued operations	—	585,840
Fixed Assets	—	12,323,143
Right of use assets	—	5,479,786
Total non-current assets of discontinued operations		17,802,929
Total assets of discontinued operations	**$ —**	**$ 18,388,769**
Accounts payable	$ —	$ 2,183,418
Related party deferred revenue	—	2,500,000
Short-term lease liabilities	—	577,198
Total current liabilities of discontinued operations	—	5,260,616
Long-term lease liabilities	—	7,039,338
Total non-current liabilities of discontinued operations	—	7,039,338
Total liabilities of discontinued operations	**$ —**	**$ 12,299,954**

The Company reclassified the following operations to discontinued operations for the three and nine months ended September 30, 2023 and 2022, respectively, excluding the gain on disposal:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Service revenue	$ —	$ —	$ 816,641	$ —
Related party service revenue	—	2,950,000	3,500,000	2,950,000
Total revenues	—	2,950,000	4,316,641	2,950,000
Operating expenses:				
Research and development	—	3,724,997	6,561,957	11,112,122
General and administrative	—	417,877	677,090	1,179,595
Total operating expenses	—	4,142,874	7,239,048	12,291,717
Loss from discontinued operations	$ —	$ (1,192,874)	$ (2,922,406)	$ (9,341,717)

Related Party Service Revenue

In April 2022, the Company entered into a binding services agreement ("Wilson Wolf Agreement") 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. 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 Wilson Wolf 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.

In March 2023, the Company recognized the final $2.5 million of revenue pursuant to this $8.0 million agreement and, at September 30, 2023, the Company had no related party deferred revenue on its condensed consolidated balance sheet.

Additionally, pursuant to the Wilson Wolf Agreement, Wilson Wolf agreed to pay the Company an additional $1.0 million because the Work Direction was completed within one year from the onset of the Wilson Wolf Agreement, achieving the agreed milestone. As such, the Company recorded an additional $1.0 million of service fee revenue during the three months ended March 31, 2023, which was received in May 2023 and recorded to discontinued operations.

Service Revenue

In April 2023, the Company signed the Indapta Master Services Agreement, pursuant to which the Company provided services to Indapta. Under an executed work order of that agreement, now complete, the Company recognized $0.8 million for the services rendered during the quarter ended June 2023. Effective as of the closing date of the Purchase Agreement with Cell Ready, the rights and obligations to the Indapta Agreement were transferred to Cell Ready, and as such the revenues were recorded to discontinued operations.

NOTE 7: PROPERTY AND EQUIPMENT

Substantially all the previously reported property and equipment was disposed of as part of the Cell Ready transaction (see Note 6).

NOTE 8: LEASES

Substantially all the previously reported leases were disposed of as a result of the Cell Ready transaction (see Note 6).

NOTE 9: ACCOUNTS PAYABLE, ACCRUED LIABILITIES AND RELATED PARTY PAYABLE

Accounts payable and accrued liabilities consist of the following as of September 30, 2023 and December 31, 2022, respectively:

	September 30, 2023	December 31, 2022
Accounts payable	$ 1,165,000	$ 1,101,000
Compensation and benefits	71,000	750,000
Professional fees	1,119,000	518,000
Arbitration settlement fees	—	114,000
Other	317,000	38,000
Total accounts payable, accrued liabilities and related party payable	$ 2,672,000	$ 2,521,000

$0.4 million of the total above reflects a related-party payable to Cell Ready.

NOTE 10: STOCKHOLDERS' EQUITY

Reverse Stock Split

On January 26, 2023, the Company effected the Reverse Stock Split and a corresponding reduction in the total number of authorized shares of its common stock from 300,000,000 to 30,000,000. The Reverse Stock Split, which was approved by stockholders at an annual stockholder meeting on May 24, 2022, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on January 26, 2023. The Reverse Stock Split was effective on January 26, 2023. All historical share and per share amounts reflected in this report have been adjusted to reflect the Reverse Stock Split.

Common Stock Transactions

Issuance of Stock Pursuant to ATM Agreement

During the nine months ended September 30, 2023, the Company sold 265,334 shares of its common stock under the ATM Agreement for proceeds of $1.0 million.

Stock Purchase Agreement

In December 2022, the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park which provides that, upon the terms and subject to the conditions of the agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to $25,000,000 of shares of its common stock (the "Purchase Shares") from time to time over a 24-month term, at a variable price with certain market-based terms as defined in the Purchase Agreement. The Purchase Agreement does not exhibit any of the characteristics for liability classification under ASC Topic 480, Distinguishing Liabilities from Equity. Instead, the purchase agreement is indexed to the Company's own stock under ASC Subtopic 815-40, *Contracts in Entity's Own Equity*, and classified as equity. In January 2023, Lincoln Park was issued 180,410 shares of stock as a commitment fee at a value of $0.5 million. During the nine months ended September 30, 2023, the Company sold 12,500 shares of its common stock under the Purchase Agreement for proceeds of approximately $33,000.

Exercise of Stock Options

During the nine months ended September 30, 2023, certain outstanding options were exercised for 25,118 shares of common stock, providing aggregate proceeds to the Company of approximately $0.1 million.

Share Purchase Warrants

A summary of the Company's share purchase warrants as of September 30, 2023 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, 2023	1,848,000	$ 44.51	0.79	$ —
Expired or cancelled	—	—	—	—
Balance - September 30, 2023	1,848,000	$ 44.51	0.04	$ —

All warrants outstanding at September 30, 2023 expired according to their terms on October 16, 2023.

NOTE 11: STOCK-BASED COMPENSATION

Stock Options

2022 Equity Incentive Awards

On February 27, 2023, pursuant to the Company's 2020 Equity Incentive Plan, the compensation committee of the Company's board of directors approved a total of 316,855 options to purchase the Company's common stock as equity-based incentive awards to the Company's executive officers and management team. Each option award was granted with an exercise price of $2.14 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 27, 2023, 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 27, 2023, the compensation committee of the Company's board of directors approved a total of 87,677 options to purchase the Company's common stock to non-executive employees and management team of the Company as equity-based incentive awards. Each option award was granted with an exercise price of $2.14 per share, the closing price of the Company's common stock on the Nasdaq Global Market on February 27, 2023, 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 7,000 stock option awards issued during the three months ended March 31, 2023 to new employees upon their commencement of employment with the Company. Each option award was granted with an exercise price of $2.769 per share, the closing price of the Company's common stock on the Nasdaq Global Market on January 3, 2023, 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.

On May 10, 2023, the Company's board of directors approved a one-time share option grant of 100,000 shares of common stock to Dr. Vera for his appointment as the Company's Chief Executive Officer. The option has a term of ten years and will vest in equal annual installments on May 10, 2024, May 10, 2025, May 10, 2026, and May 10, 2027, subject to Mr. Vera's continued service to the Company as of the applicable vesting date. Each option award was granted with an exercise price of $1.42 per share, the closing price of the Company's common stock on the Nasdaq Global Market on May 10, 2023.

On June 6, 2023, pursuant to the Company's Non-Employee Director Compensation Policy, which had previously been approved by the Company's board of directors, a total of 32,000 stock option awards were issued to independent members of the board of directors of the Company. Each option award was granted with an exercise price of $1.72 per share, the closing price of the Company's common stock on the Nasdaq Global Market on June 6, 2023. Each option award will vest in one year subject to the director's continuance of service through June 6, 2024.

A summary of the Company's stock option activity for the three months ended September 30, 2023 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, 2023	886,173	$ 42.90	$ —	7.3
Granted	544,532	1.99	—	9.5
Exercised	(25,118)	5.85	—	—
Canceled/Expired	(605,693)	32.67	—	—
Outstanding as of September 30, 2023	799,894	$ 24.01	$ 1,019,000	7.9
Options vested and exercisable	381,732	$ 45.72	$ 114,000	6.5

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, 2023 was as follows:

	For the Nine Months Ended September 30, 2023
Exercise price	$ 1.99
Expected term (years)	6.0
Expected stock price volatility	91 %
Risk-free rate of interest	4 %
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,	
	2023	2022	2023	2022
Stock Compensation expenses:				
Research and development	$ 106,000	$ 201,000	$ 299,000	$ 599,000
General and administrative	69,000	735,000	416,000	2,323,000
Stock compensation in continuing operations	175,000	936,000	715,000	2,922,000
Stock compensation in discontinued operations	—	560,000	725,000	1,705,000
Total stock compensation expenses	$ 175,000	$ 1,496,000	$ 1,440,000	$ 4,627,000

During the nine months ended September 30, 2023, the Company recorded incremental stock-based compensation expense of approximately $0.3 million pertaining to the modification of stock options in connection with the termination of certain employees that were hired by Cell Ready or transitioned to independent consultants. The modification provided for an acceleration of unvested options, resulting in a change in compensation expense that was immediately recognized. $0.2 million is reflected in loss from discontinued operations.

As of September 30, 2023, the total stock-based compensation cost related to unvested awards not yet recognized was $0.8 million. The expected weighted average period compensation costs to be recognized was approximately 1.8 years. Future option grants will impact the compensation expense recognized.

NOTE 12: GRANT INCOME

CPRIT

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.

If restricted cash is received from grants in advance of incurring qualifying costs, it is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. There was no restricted cash recorded as of September 30, 2023 and as of December 31, 2022. If qualifying grant income is earned in advance of cash received from grants, it is recognized as revenue and recorded as other receivable.

The Company recorded $0.2 million and $2.0 million of grant income related to the CPRIT grant as revenue for the three and nine months ended September 30, 2023, respectively. In July 2023, the Company received $2.1 million from CPRIT.

FDA

In September 2022, the Company 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 post-transplant AML. The Company recorded $0.0 million and $0.2 million of grant income related to the FDA grant as revenue for the three and nine months ended September 30, 2023, respectively.

National Institutes of Health Small Business Innovation Research

In May 2023, we announced that we had received a $2.0 million grant from the National Institutes of Health Small Business Innovation Research program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with hypomethylating agents. The Company has not received any funds associated with this 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. The Company is not currently a party to any material legal proceedings, and the Company is not aware of any pending or threatened legal proceeding against it that it believes could have an adverse effect on its business, operating results, or financial condition.

NOTE 14: RELATED PARTY EXPENSES

The following table sets forth related party transaction expenses recorded for the three and nine months ended September 30, 2023 and 2022, respectively.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Baylor College of Medicine	$ —	$ 1,000	$ 13,000	$ 1,142,000
Bio-Techne Corporation	—	—	—	101,000
Cell Ready	368,000	—	368,000	—
Wilson Wolf Manufacturing Corporation	—	71,000	277,000	172,000
Total Research and development	$ 368,000	$ 72,000	$ 658,000	$ 1,415,000

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 into 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 and is a part of continuing operations.

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

The Company is currently utilizing Wilson Wolf 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.

Purchases from Cell Ready, LLC

The Company is currently utilizing Cell Ready, LLC for its clinical manufacturing supply. Mr. John Wilson is a member of the Company's board of directors and is serving as the CEO of Cell Ready, LLC.

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 Baylor College of Medicine ("BCM") in March 2018. BCM had utilized the therapy in seven exploratory clinical trials. In these studies, BCM treated over 200 patients suffering from a variety of cancers including lymphoma, multiple myeloma, acute myeloid leukemia, acute lymphoblastic leukemia and pancreatic cancer. 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 ("AML"), and
3. off-the-shelf products in various indications

Our current clinical development programs are:

- MT-401 for the treatment of post-transplant AML,
- MT-401-OTS for the treatment of AML,
- MT-601 for the treatment of lymphoma, and
- MT-601 for the treatment of pancreatic cancer[(1)].

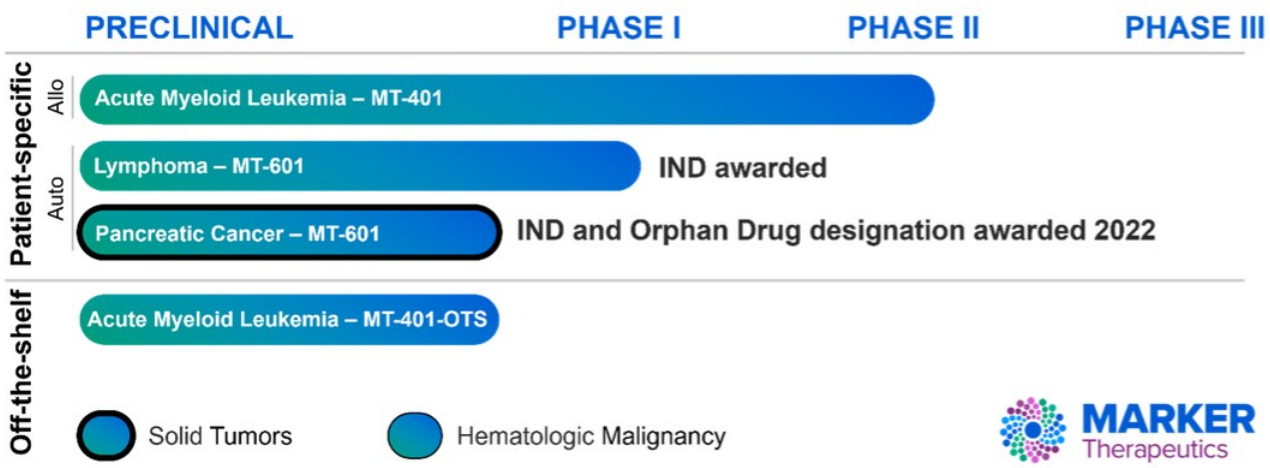
[(1)] Clinical advancement will be pending additional financial support from non-dilutive grant activities.

We are currently undertaking a strategic review of our clinical development programs, including with respect to clinical trial initiation and readout guidance.

We believe that the simplicity of our manufacturing process allows additional modifications to expand multiTAA-specific T cell recognition of cancer targets. In May 2023, we entered into a purchase agreement with Cell Ready, LLC with respect to our manufacturing facility and certain related assets. See “Recent Developments.”

Pipeline

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



Recent Developments

On June 26, 2023, we completed the previously announced transaction with Cell Ready, LLC, or Cell Ready, pursuant to a Purchase Agreement, or the Cell Ready Purchase Agreement, dated May 1, 2023, by and between us and Cell Ready. Mr. John Wilson is a member of our board of directors and is serving as the CEO of Cell Ready, therefore Cell Ready is a related party. Pursuant to the Cell Ready Purchase Agreement, effective as of the Closing Date, we (i) assigned to Cell Ready the leases for our two manufacturing facilities in Houston, Texas, or the Manufacturing Facilities, (ii) sold to Cell Ready all of the equipment and leasehold improvements at the Manufacturing Facilities and (iii) assigned to Cell Ready our rights, title and interest in our Master Services Agreement for Product Supply, or the MSA, dated April 7, 2023, by and between us, Cell Ready and Indapta Therapeutics, Inc. (“Indapta”) as well as our rights, title and interest in any contracts related to the equipment and Manufacturing Facilities (collectively referred to as the “Purchased Assets”). Following the Closing Date, we and Cell Ready have agreed to enter a long-term contract pursuant to which Cell Ready will perform a wide variety of services for us, including research and development, manufacturing, and regulatory activity in support of our clinical trials; however, the parties have not yet executed such agreement. Cell Ready acquired the Purchased Assets for total consideration of $19.0 million. In connection with the purchase of the Manufacturing Facilities, Cell Ready also extended offers of employment to approximately 50 of our former employees in our manufacturing, development, quality and regulatory affairs functions.

In May 2023, we announced that we had received a $2.0 million grant from the National Institutes of Health Small Business Innovation Research program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with hypomethylating agents. The Company has not received any funds associated with this grant.

In August 2023, we announced non-clinical data of its lead multiTAA-specific T cell product candidate, MT-401, in an Off-the-Shelf (OTS) setting and provided an update on clinical readiness for the OTS program. We anticipats that the first patient will be treated with MT-401 OTS in 2024.

In September 2023, we announced preliminary results of the first participant treated with MT-601 in our Phase 1 multicenter APOLLO clinical trial. After relapse following anti-CD19 CAR T cell therapy, the participant was treated with two doses of MT-601 at the 200 million cell dose level without prior lymphodepletion. MT-601 treatment was well tolerated with no reports of higher than Grade 1 treatment-related adverse events. The tolerability at this initial dose level is consistent with the favorable clinical safety profile and tolerability previously reported for other multiTAA-specific T cell products. Eight weeks after the 2nd infusion of MT-601, the participant demonstrated complete metabolic response based on PET-CT scans. We are treating and evaluating additional patients in the Phase 1 APOLLO trial and anticipate reporting additional data in the first quarter of 2024.

Organizational Changes

In May and June 2023, we implemented changes to our organizational structure as part of an operational cost reduction plan and reorganization plan due to the transaction with Cell Ready. In connection with these changes, we reduced headcount, including the separation of our former Chief Executive Officer, Peter Hoang, and our former Chief Accounting Officer, Michael Loiacono. During the second quarter of 2023, we recorded $0.9 million of severance and termination-related costs. The payment of these costs were completed in July of 2023.

Effective May 1, 2023, our board of directors appointed Dr. Vera as our Chief Executive Officer. Effective June 30, 2023, our board of directors appointed Eliot M. Lurier as our Interim Chief Financial Officer. Mr. Lurier provides consulting services to us pursuant to a consulting agreement between us and Danforth Advisors, LLC and receives no compensation directly from us.

Reverse Stock Split

On January 26, 2023, we effected the Reverse Stock Split and a corresponding reduction in the total number of authorized shares of its common stock from 300,000,000 to 30,000,000. The Reverse Stock Split, which was approved by stockholders at an annual stockholder meeting on May 24, 2022, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on January 26, 2023. The Reverse Stock Split was effective on January 26, 2023. All historical share and per share amounts reflected in this report have been adjusted to reflect the Reverse Stock Split.

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, 2023 and 2022

The following table summarizes the results of our continuing operations for the three months ended September 30, 2023 and 2022:

	For the Three Months Ended September 30,		Change	
	2023	2022		
Revenues:				
Grant income	$ 258,000	$ 1,000,000	$ (742,000)	(74)%
Total revenues	258,000	1,000,000	(742,000)	(74)%
Operating expenses:				
Research and development	2,045,000	3,592,000	(1,547,000)	(43)%
General and administrative	1,413,000	3,234,000	(1,821,000)	(56)%
Total operating expenses	3,458,000	6,826,000	(3,368,000)	(49)%
Loss from operations	(3,200,000)	(5,826,000)	2,626,000	(45)%
Other income (expenses):				
Arbitration settlement	—	—	—	0 %
Interest income	218,000	100,000	118,000	118 %
Loss from continuing operations before income taxes	(2,982,000)	(5,726,000)	2,744,000	(48)%
Loss from continuing operations	**$ (2,982,000)**	**$ (5,726,000)**	**$ 2,744,000**	**(48)%**

Revenue

We did not generate any revenue during the three months ended September 30, 2023 and 2022, 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 ("CPRIT") to support our Phase 2 clinical trial of MT-401. During the three months ended September 30, 2023, we recognized $0.2 million of revenue associated with the CPRIT grant.

In September 2022, we received notice from the FDA that it had awarded us a $2.0 million grant from the FDA's Orphan Products Grant program to support our Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. During the three months ended September 30, 2023, we recognized $16,000 of revenue associated with the FDA grant and $0 in the same period ended 2022.

Operating Expenses

Operating expenses incurred during the three months ended September 30, 2023 were $3.5 million compared to $6.8 million during the same period ended September 30, 2022.

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

Research and Development Expenses

Research and development expenses decreased by 43% to $2.0 million for the three months ended September 30, 2023, compared to $3.6 million for the three months ended September 30, 2022.

The decrease of $1.6 million in 2023 was primarily attributable to the following:

- decrease of $1.0 million in process development expenses,
- decrease of $0.5 million in clinical trial expenses,
- decrease of $0.4 million in headcount-related expenses,
- decrease of $0.1 million in other expenses, offset by
- increase of $0.4 million in Cell Ready production costs.

General and Administrative Expenses

General and administrative expenses decreased by 56% to $1.4 million for the three months ended September 30, 2023, compared to $3.2 million during the same period ended September 30, 2022.

The decrease of $1.8 million in 2023 was primarily attributable to the following:

- decrease of $0.7 million in stock-based compensation expenses,
- decrease of $1.0 million in headcount-related expenses, and
- decrease of $0.1 million in professional services expenses.

Other Income (Expense)

Interest Income

Interest income was $0.2 million and $0.1 million for the three months ended September 30, 2023 and 2022, 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.

Comparison of the Nine months Ended September 30, 2023 and 2022

The following table summarizes the results of our continuing operations for the nine months ended September 30, 2023 and 2022:

	For the Nine Months Ended September 30,		Change	
	2023	2022		
Revenues:				
Grant income	$ 2,255,000	$ 2,754,000	$ (499,000)	(18)%
Total revenues	2,255,000	2,754,000	(499,000)	(18)%
Operating expenses:				
Research and development	7,799,000	9,786,000	(1,987,000)	(20)%
General and administrative	6,099,000	9,721,000	(3,622,000)	(37)%
Total operating expenses	13,898,000	19,507,000	(5,609,000)	(29)%
Loss from operations	(11,643,000)	(16,753,000)	5,110,000	(31)%
Other income (expenses):				
Arbitration settlement	—	(119,000)	119,000	(100)%
Interest income	338,000	139,000	199,000	143 %
Loss from continuing operations before income taxes	(11,305,000)	(16,733,000)	5,428,000	(32)%
Loss from continuing operations	**$ (11,305,000)**	**$ (16,734,000)**	**$ 5,429,000**	**(32)%**

Revenue

We did not generate any revenue during the nine months ended September 30, 2023 and 2022, 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 to support our Phase 2 clinical trial of MT-401. During the nine months ended September 30, 2023, we recognized $2.1 million of revenue associated with the CPRIT grant.

In September 2022, we received notice from the FDA that it had awarded us a $2.0 million grant from the FDA's Orphan Products Grant program to support our Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. During the nine months ended September 30, 2023, we recognized $0.2 million of revenue associated with the FDA grant and $0 in the same period ended 2022.

Operating Expenses

Operating expenses incurred during the nine months ended September 30, 2023 were $13.9 million compared to $19.5 million during the same period ended September 30, 2022.

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

Research and Development Expenses

Research and development expenses decreased by 20% to $7.8 million for the nine months ended September 30, 2023, compared to $9.8 million for the same period ended September 30, 2022.

The decrease of $2.0 million in 2023 was primarily attributable to the following:

- decrease of $1.4 million in process development expenses,
- decrease of $0.3 million in stock-based compensation expenses,
- decrease of $0.6 million in headcount-related expenses
- decrease of $0.5 million in sponsored research expenses from BCM agreements,

- decrease of $0.3 million in clinical trial expenses, offset by
- increase of $0.5 million in professional services expenses.
- increase of $0.4 million in Cell Ready production costs, and
- increase of $0.2 million in other expenses.

General and Administrative Expenses

General and administrative expenses decreased by 37% to $6.1 million for the nine months ended September 30, 2023, compared to $9.7 million for the same period ended September 30, 2022.

The decrease of $3.6 million in 2023 was primarily attributable to the following:

- decrease of $1.9 million in stock-based compensation expenses,
- decrease of $1.1 million in headcount-related expenses,
- decrease of $0.5 million in rent expenses, and
- decrease of $0.1 million in other expenses.

Other Income (Expense)

Interest Income

Interest income was $0.3 million and $0.1 million for the nine months ended September 30, 2023 and 2022, 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.

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 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 year ended December 31, 2021. During the nine months ended September 30, 2022, we recorded an additional $0.1 million of expense related to this matter.

Liquidity and Capital Resources

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

Cash and Working Capital

The following table sets forth our cash and cash equivalents and working capital as of September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 17,474,000	$ 11,782,000
Working capital	$ 16,707,000	$ 8,837,000

Cash Flows

The following table summarizes our cash flows for the three months ended September 30, 2023 and 2022:

	For the Nine Months Ended September 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	$ (14,072,000)	$ (20,667,000)
Investing activities	18,664,000	(4,819,000)
Financing activities	1,100,000	64,000
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 5,692,000	$ (25,422,000)

As of September 30, 2023 and December 31, 2021, the Company had $107,530 and $1,146,186 of restricted cash, respectively.

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2023 was ($14.1) million compared to ($20.7) million for the same period last year.

Net cash used in operating activities during the nine months ended September 30, 2023 was due to ($11.3) million of net losses from continuing operations partially offset by $0.7 million of stock-based compensation, and changes in operating assets and liabilities of $2.5 million, plus ($6.0) million of cash used in discontinued operations.

Net cash used in operating activities during the nine months ended September 30, 2022 was due to ($16.7) million of net losses from continuing operations combined with changes in operating assets and liabilities of ($3.3) million and gain on the termination of leases of ($0.3) million, partially offset by stock-based compensation of $2.9 million, plus ($3.3) million of cash used in discontinued operations.

Investing Activities

Net cash provided by investing activities was $18.7 million primarily from the sale of assets of discounted operations during the nine months ended September 30, 2023.

Net cash used in investing activities was ($4.8) million for the purchase of property and equipment and construction in progress related to our manufacturing facility during the nine months ended September 30, 2022.

Financing Activities

Net cash provided by financing activities was $1.1 million during the nine months ended September 30, 2023, due to sales of common stock under the ATM Agreement and the Lincoln Park Purchase Agreement (as defined below).

Net cash provided by financing activities was $0.1 million during the nine months ended September 30, 2022, due to sales of common stock.

Future Capital Requirements

To date, we have not generated any revenues from the commercial sale of approved drug products, and we do not expect to generate substantial revenue for at least the next several years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be compromised. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate significant revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of and seek marketing approval for our product candidates. In addition, if we obtain approval for any of our product candidates, we expect to incur

significant commercialization expenses related to sales, marketing, manufacturing, and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

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. 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, we have received $6.9 million of funds from the CPRIT grant.

In September 2022, we received notice from the U.S. Food and Drug Administration that it had awarded us a $2.0 million grant from the FDA's Orphan Products Grant program to support our Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. To date, we have received $0.2 million of funds from the FDA grant.

On June 26, 2023, we completed the previously announced transaction with Cell Ready. Pursuant to the Cell Ready Purchase Agreement, effective as of the Closing Date, we assigned and sold, as applicable, the Purchased Assets to Cell Ready. Following the Closing Date, we and Cell Ready have agreed to enter a long-term contract pursuant to which Cell Ready will perform a wide variety of services for us, including research and development, manufacturing, and regulatory activity in support of our clinical trials; however, the parties have not yet executed such agreement. Cell Ready acquired the Purchased Assets for total consideration of $19.0 million. In connection with the purchase of the Manufacturing Facilities, Cell Ready also extended offers of employment to approximately 50 of our former employees in our manufacturing, development, quality, and regulatory affairs functions.

As of September 30, 2023, we had working capital of $16.7 million, compared to working capital of $8.8 million as of December 31, 2022. Based on our clinical development plans and the disposition of the Purchased Assets pursuant to the Cell Ready Purchase Agreement and related organizational restructuring, we expect that our cash and cash equivalents as of September 30, 2023 will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025. 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 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 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;
- enter into contract manufacturing arrangements with Cell Ready or other contract manufacturing organizations for clinical manufacturing supply;
- 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 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 existing cash and future 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.

The COVID-19 pandemic, decades-high inflation, and concerns about an economic recession in the United States or other major markets has resulted in, among other things, volatility in the capital markets that may have the effect of reducing the Company's ability to access capital, which could in the future negatively affect the Company's liquidity. In addition, a recession or market correction due to these factors could materially affect the Company's business and the value of its common stock.

ATM Agreement

In August 2021, we entered 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 we can offer and sell, from time to time at our sole discretion through the Sales Agents, shares of our common stock having an aggregate offering price of up to $75.0 million. Any shares of our common stock sold will be issued pursuant to our 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 a value of $9.87 million of shares of common stock over the 12 months ending March 22, 2024 pursuant to General Instruction I.B.6 of Form S-3, which limits the amounts that the Company may sell under the registration statement, and 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 we have provided each of the Sales Agents with indemnification and contribution rights. During the nine months ended September 30, 2023, the Company sold 265,334 shares of its common stock under the ATM Agreement for proceeds of $1.0 million.

Stock Purchase Agreement

In December 2022, we entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park up to $25,000,000 of shares of our common stock (the "Purchase Shares") from time to time over a 24-month term, at a variable price with certain market-based terms as defined in the Purchase Agreement. The Purchase Agreement does not exhibit any of the characteristics for liability classification under ASC Topic 480, Distinguishing Liabilities from Equity. Instead, the purchase agreement is indexed to the Company's own stock under ASC Subtopic 815-40, Contracts in Entity's Own Equity, and classified as equity. In January 2023, Lincoln Park was issued 180,410 shares of stock as a commitment fee at a value of $0.5 million. During the nine months ended September 30, 2023, we sold 12,500 shares of our common stock under the Purchase Agreement for proceeds of approximately $33,000.

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, 2022.

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

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

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

(b) Changes in Internal Control Over Financial Reporting

There have been no changes in our internal controls over financial reporting during the three and nine months ended September 30, 2023 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.

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, 2022, filed with the Securities and Exchange Commission on March 12, 2023. There have been no material changes to the risk factors described in that report, other than as described below.

We may not realize the expected benefits from the transaction with Cell Ready.

We may not be able to achieve the full strategic and financial benefits expected to result from the closing of the transaction with Cell Ready, or such benefits may be delayed or not occur at all. In particular, we have made the strategic decision to dispose of our manufacturing facilities and related assets in order to focus on clinical development of the multiTAA-specific T cell therapy-based product candidates in our pipeline. Following the closing of the transaction, we no longer operate our own cGMP manufacturing facility and must rely on third parties for the clinical and, if approved, commercial manufacture of our product candidates. Although we intend to enter into a long-term agreement with Cell Ready for manufacturing, among other services, we have not yet executed such agreement and may not realize the anticipated cost savings associated with contracting out our manufacturing, research and development and regulatory requirements. The assumptions we made related to the Cell Ready transaction may prove to be inaccurate, including as to the expected benefits of the transaction and anticipated cost savings. Further, the transition activities following closing may disrupt our operations and divert management's attention to our business, particularly because our Chief Executive Officer, Dr. Juan Vera, expects to perform consulting work for Cell Ready in addition to his duties for our company. An inability to realize the anticipated benefits of the Cell Ready transaction could have an adverse impact on our business, financial condition and results of operations.

Following the closing of the transaction with Cell Ready, we no longer operate our own cGMP manufacturing facility and instead will rely on third parties, including Cell Ready, for the clinical and, if approved, commercial manufacture of our product candidates. The third-party manufacturing facilities on which we rely may have limited capacity or fail to meet the applicable stringent regulatory requirements.

We do not have any cGMP manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the cGMP manufacture of our product candidates for clinical development and, if approved, commercial supply. We intend to enter into a long-term agreement with Cell Ready, pursuant to which Cell Ready will perform a wide variety of services for us, including research and development, manufacturing and regulatory activity in support of our clinical trials; however, we have not yet executed such agreement. There is no guarantee that we will or have properly estimated our required manufacturing capacities or that the third parties we rely on to provide required machinery and materials for the manufacturing process will be able to perform on our proposed timelines or meet our manufacturing demands, if at all. Also, if we must increase production capacity for any reason, we may need to make considerable investments that could lead to significant financing needs or require us to enter into subcontracting agreements in order to outsource part of the production.

If Cell Ready or any other third-party contract manufacturing organization on which we rely experiences capacity constraints, other disruptions, or delays in manufacturing our multiTAA-specific T cell therapy-based product candidates, our planned clinical trials and necessary manufacturing capabilities will be disrupted or delayed. Third-party manufacturers may not be able to meet our needs concerning timing, quantity, or quality. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval or the market introduction and subsequent sales of any approved products. Any such delay may lower our revenues and potential profitability. If any third party breaches or terminates its agreement with us or fails to conduct its activities in a timely manner, the commercialization of our product candidates could be slowed down or blocked completely. It is possible that third parties relied upon by us will change their strategic focus, pursue alternative technologies, or develop alternative product candidates, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by our collaborative programs, or for other reasons. The effectiveness of these third parties in marketing their own products may also affect our revenues and earnings. We intend to continue to enter into additional third-party agreements in the future. However, we may not be able to negotiate any additional agreements successfully. Even if established, these relationships may not be scientifically or commercially successful.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may be unable to obtain regulatory approval of our marketing applications. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supply of our products.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

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, 2023.

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	
3.1.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation	8-K	001-37939	3.1	1/26/2023	
3.2	Bylaws of Marker Therapeutics, Inc.	8-K	001-37939	3.6	10/17/18	
10.1	Separation Agreement between Marker Therapeutics, Inc. and Peter Hoang dated as of April 27, 2023.	10-Q	001-37939	10.1	5/15/2023	
10.2#	Purchase Agreement between Cell Ready, LLC and Marker Therapeutics, Inc., dated May 1, 2023	10-Q	001-37939	10.2	5/15/2023	
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1933, as amended.					X
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1933, as amended.					X
32.1*	Certification of Chief Executive Officer Pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Chief Financial Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

Exhibit 101

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

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* 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.

\# Certain schedules to this agreement have been omitted in accordance with Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished supplementally to the SEC upon request.

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 9, 2023

MARKER THERAPEUTICS, INC.

/s/ Juan Vera
Juan Vera
President, Chief Executive Officer and Principal Executive Officer

/s/ Eliot M. Lurier
Eliot M. Lurier
Interim Chief Financial Officer and Interim Principal Financial and Accounting Officer

Exhibit 31.1

CERTIFICATION

I, Juan Vera, 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 9, 2023

/s/ Juan Vera

By: **Juan Vera**

Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Eliot M. Lurier, 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 9, 2023

/s/ Eliot M. Lurier
By: **Eliot M. Lurier**
Title: Interim Chief Financial Officer (Interim Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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

The undersigned, Juan Vera, 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, 2023, 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 9, 2023

/s/ Juan Vera
Juan Vera
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, Eliot M. Lurier, the Interim Chief Financial Officer of Marker Therapeutics, Inc. (the "Company") hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, the Quarterly Report on Form 10-Q for the period ended September 30, 2023, 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 9, 2023

/s/ Eliot M. Lurier
Eliot M. Lurier
Interim Chief Financial Officer (Interim Principal Financial and Accounting Officer)