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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from _____ to _____

Commission file number: 001-33277

MADRIGAL PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**04-3508648**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Four Tower Bridge **200 Barr Harbor Drive, Suite 200** **West Conshohocken, Pennsylvania**	
(Address of principal executive offices)	**19428** **(Zip Code)**

Registrant's telephone number, including area code: (267) 824-2827

Former name, former address and former fiscal year, if changed since last report:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 Par Value Per Share	**MDGL**	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Exchange Act: None.

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities 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 May 5, 2023, the registrant had 18,289,173 shares of common stock outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

MADRIGAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited; in thousands, except share and per share amounts)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 113,308	$ 331,549
Marketable securities	216,169	27,225
Prepaid expenses and other current assets	1,807	2,595
Total current assets	331,284	361,369
Property and equipment, net	512	601
Right-of-use asset	653	602
Total assets	$ 332,449	$ 362,572
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,128	$ 23,831
Accrued expenses	85,567	91,461
Lease liability	653	602
Total current liabilities	98,348	115,894
Long term liabilities:		
Loan payable, net of discount	83,965	49,289
Total long term liabilities	83,965	49,289
Total liabilities	182,313	165,183
Stockholders' equity:		
Preferred stock, par value $0.0001 per share authorized: 5,000,000 shares at March 31, 2023 and December 31, 2022; 2,369,797 and 2,369,797 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Common stock, par value $0.0001 per share authorized: 200,000,000 at March 31, 2023 and December 31, 2022; 18,283,074 and 18,102,523 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	2	2
Additional paid-in-capital	1,189,776	1,160,079
Accumulated other comprehensive loss	(86)	(32)
Accumulated deficit	(1,039,556)	(962,660)
Total stockholders' equity	150,136	197,389
Total liabilities and stockholders' equity	$ 332,449	$ 362,572

See accompanying notes to condensed consolidated financial statements.

MADRIGAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited; in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Total revenues	$ —	$ —
Operating expenses:		
Research and development	62,154	47,929
General and administrative	16,182	9,658
Total operating expenses	78,336	57,587
Loss from operations	(78,336)	(57,587)
Interest income	3,776	69
Interest expense	(2,336)	—
Net loss	$ (76,896)	$ (57,518)
Net loss per common share:		
Basic and diluted net loss per common share	$ (4.23)	$ (3.36)
Basic and diluted weighted average number of common shares outstanding	18,187,924	17,103,395

See accompanying notes to condensed consolidated financial statements.

MADRIGAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited; in thousands)

	Three Months Ended March 31,	
	2023	2022
Net Loss	$ (76,896)	$ (57,518)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities	(54)	(322)
Comprehensive loss	$ (76,950)	$ (57,840)

See accompanying notes to condensed consolidated financial statements.

MADRIGAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited; in thousands, except share and per share amounts)

	Preferred stock		Common stock		Additional paid-in Capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	2,369,797	$ —	18,102,523	$ 2	$1,160,079	$ (32)	$ (962,660)	$ 197,389
Sale of common shares to related parties and exercise of common stock options, net of transaction costs	—	—	180,551	—	17,903	—	—	17,903
Compensation expense related to stock options for services	—	—	—	—	11,250	—	—	11,250
Unrealized loss on marketable securities	—	—	—	—	—	(54)	—	(54)
Hercules warrant	—	—	—	—	544	—	—	544
Net loss	—	—	—	—	—	—	(76,896)	(76,896)
Balance at March 31, 2023	2,369,797	$ —	18,283,074	$ 2	$1,189,776	$ (86)	$(1,039,556)	$ 150,136
Balance at December 31, 2021	1,969,797	$ —	17,103,395	$ 2	$ 863,495	$ (80)	$ (667,310)	$ 196,107
Compensation expense related to stock options for services	—	—	—	—	7,477	—	—	7,477
Unrealized loss on marketable securities	—	—	—	—	—	(322)	—	(322)
Net loss	—	—	—	—	—	—	(57,518)	(57,518)
Balance at March 31, 2022	1,969,797	$ —	17,103,395	$ 2	$ 870,972	$ (402)	$ (724,828)	$ 145,744

See accompanying notes to condensed consolidated financial statements.

MADRIGAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited; in thousands)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (76,896)	$ (57,518)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	11,250	7,477
Depreciation and amortization expense	124	107
Amortization of debt issuance costs and discount	433	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	788	121
Accounts payable	(11,703)	1,400
Accrued expense	(5,894)	(1,606)
Accrued interest, net of interest received on maturity of investments	(2,169)	106
Net cash used in operating activities	(84,067)	(49,913)
Cash flows from investing activities:		
Purchases of marketable securities	(198,822)	(37,567)
Sales and maturities of marketable securities	11,993	93,545
Purchases of property and equipment, net of disposals	(35)	(52)
Net cash provided by (used in) investing activities	(186,864)	55,926
Cash flows from financing activities:		
Proceeds from the sale of related party stock and exercise of common stock options, net of transaction costs	17,903	—
Proceeds from issuance of loan payable	35,000	—
Payment of debt issuance costs	(213)	—
Net cash provided by financing activities	52,690	—
Net increase (decrease) in cash and cash equivalents	(218,241)	6,013
Cash and cash equivalents at beginning of period	331,549	36,269
Cash and cash equivalents at end of period	$ 113,308	$ 42,282

See accompanying notes to condensed consolidated financial statements.

MADRIGAL PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization, Business, and Basis of Presentation

Organization and Business

Madrigal Pharmaceuticals, Inc. (the "Company" or "Madrigal") is a clinical-stage pharmaceutical company developing novel, high-quality, small-molecule drugs addressing major unmet needs in cardiovascular, metabolic, and liver diseases. The Company's lead compound, resmetirom, is being advanced for non-alcoholic steatohepatitis ("NASH"), a liver disease that commonly affects people with metabolic diseases such as obesity and diabetes, and non-alcoholic fatty liver disease ("NAFLD"). The Company initiated two Phase 3 studies of resmetirom in NASH in 2019 that are ongoing. The Company announced certain topline results from the MAESTRO-NAFLD-1 safety study of resmetirom in January 2022 and the MAESTRO-NASH study in December 2022. In August 2022, Madrigal initiated a third study, MAESTRO-NASH-OUTCOMES.

Basis of Presentation

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ("GAAP") have been condensed or omitted. Accordingly, the unaudited condensed consolidated financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. However, we believe that the disclosures included in these financial statements are adequate to make the information presented not misleading. The unaudited condensed consolidated financial statements, in the opinion of management, reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of such interim results. The interim results are not necessarily indicative of the results that we will have for the full year ending December 31, 2023 or any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes to those statements for the year ended December 31, 2022.

2. Summary of Significant Accounting Policies

Principle of Consolidation

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. All significant intercompany balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities, and the reported amounts of revenues and expenses during the reporting periods. The Company bases its estimates on historical experience and various other assumptions that management believes to be reasonable under the circumstances. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. The Company maintains its cash in bank accounts, the balance of which, at times, exceeds Federal Deposit Insurance Corporation insured limits.

The primary objective of the Company's investment activities is to preserve its capital for the purpose of funding operations and the Company does not enter into investments for trading or speculative purposes. The Company's cash is deposited in highly rated financial institutions in the United States. The Company invests in money market funds and high-grade, commercial paper and corporate bonds, which management believes are subject to minimal credit and market risk.

Marketable Securities

Marketable securities consist of investments in high-grade corporate obligations and government and government agency obligations that are classified as available-for-sale. Since these securities are available to fund current operations, they are classified as current assets on the consolidated balance sheets.

The Company adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. The Company includes such amortization and accretion as a component of interest income, net. Realized gains and losses and declines in value, if any, that the Company judges to be the result of impairment or as a result of recognizing an allowance for credit losses on available-for-sale securities are reported as a component of interest income. To determine whether an impairment exists, the Company considers whether it intends to sell the debt security and, if the Company does not intend to sell the debt security, it considers available evidence to assess whether it is more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. During the three months ended March 31, 2023 and 2022, the Company determined it did not have any securities that were other-than-temporarily impaired.

Marketable securities are stated at fair value, including accrued interest, with their unrealized gains and losses included as a component of accumulated other comprehensive income or loss, which is a separate component of stockholders' equity. The fair value of these securities is based on quoted prices and observable inputs on a recurring basis. Realized gains and losses are determined on the specific identification method. During the three months ended March 31, 2023 and 2022, the Company did not have any realized gains or losses on marketable securities.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash equivalents and marketable securities, approximate their fair values. The fair value of the Company's financial instruments reflects the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy has the following three levels:

Level 1—quoted prices in active markets for identical assets and liabilities.

Level 2—observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3—unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

Financial assets and liabilities are classified in their entirety within the fair value hierarchy based on the lowest level of input that is significant to the fair value measurement. The Company measures the fair value of its marketable securities by taking into consideration valuations obtained from third- party pricing sources. The pricing services utilize industry standard valuation models, including both income and market based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker-dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities and other observable inputs.

As of March 31, 2023, the Company's financial assets valued based on Level 1 inputs consisted of cash and cash equivalents in a money market fund, its financial assets valued based on Level 2 inputs consisted of high-grade corporate and government agency bonds and commercial paper, and it had no financial assets valued based on Level 3 inputs. During the three months ended March 31, 2023 and 2022, the Company did not have any transfers of financial assets between Levels 1 and 2. As of March 31, 2023 and December 31, 2022, the Company did not have any financial liabilities that were recorded at fair value on a recurring basis on the balance sheet.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs are comprised of costs incurred in performing research and development activities, including internal costs (including stock-based compensation), costs for consultants, milestone payments under licensing agreements, and other costs associated with the Company's preclinical and clinical programs. In particular, the Company has conducted safety studies in animals, optimized and implemented the manufacturing of our drug, and conducted clinical trials, all of which are considered research and development expenditures. Management uses significant judgment in estimating the amount of research and development costs recognized in each reporting period. Management analyzes and estimates the progress of its clinical trials, completion of milestone events per underlying agreements, invoices received and contracted costs when estimating the research and development costs to accrue in each reporting period. Actual results could differ from the Company's estimates.

Patents

Costs to secure and defend patents are expensed as incurred and are classified as general and administrative expense in the Company's consolidated statements of operations.

Stock-Based Compensation

The Company recognizes stock-based compensation expense based on the grant date fair value of stock options and restricted stock units granted to employees, officers, and directors. Awards that vest as the recipient provides service are expensed on a straight-line basis over the requisite service period. The Company uses the Black-Scholes option pricing model to determine the grant date fair value of stock options as management believes it is the most appropriate valuation method for its option grants. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility and expected lives of the options. The expected lives for options granted represent the period of time that options granted are expected to be outstanding. The Company uses the simplified method for determining the expected lives of options. Expected volatility is based upon an industry estimate or blended rate including the Company's historical trading activity. The risk-free rate for periods within the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. The Company estimates the forfeiture rate based on historical data. This analysis is re-evaluated at least annually and the forfeiture rate is adjusted as necessary.

Income Taxes

The Company uses the asset and liability method to account for income taxes. Deferred tax assets and liabilities are determined based on the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. The Company currently maintains a 100% valuation allowance on its deferred tax assets.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Changes in unrealized gains and losses on marketable securities represent the only difference between the Company's net loss and comprehensive loss.

Basic and Diluted Loss Per Common Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed using the weighted average number of common shares outstanding and the weighted average dilutive potential common shares outstanding using the treasury stock method. However, for the three months ended March 31, 2023 and 2022, diluted net loss per share is the same as basic net loss per share because the inclusion of weighted average shares of common stock issuable upon the exercise of stock options and warrants or vesting of restricted stock units, and common stock issuable upon the conversion of preferred stock would be anti-dilutive. The following table summarizes outstanding securities not included in the computation of diluted net loss per common share, as their inclusion would be anti-dilutive:

	Three Months Ended March 31,	
	2023	2022
Common stock options	2,676,598	2,878,399
Restricted stock units	199,125	—
Preferred stock	2,369,797	1,969,797
Warrants	17,352	—

Recent Accounting Pronouncements

None

3. Liquidity and Uncertainties

The Company is subject to risks common to development stage companies in the biopharmaceutical industry including, but not limited to, uncertainty of product development and commercialization, dependence on key personnel, uncertainty of market acceptance of products and product reimbursement, product liability, uncertain protection of proprietary technology, potential inability to raise additional financing necessary for development and commercialization, and compliance with the U.S. Food and Drug Administration (FDA) and other government regulations.

The Company has incurred losses since inception, including approximately $76.9 million for the three months ended March 31, 2023, resulting in an accumulated deficit of approximately $1,040 million as of March 31, 2023. Management expects to incur losses for the foreseeable future. To date, the Company has funded its operations primarily through proceeds from sales of the Company's capital stock and debt financings. The Company believes that its cash, cash equivalents and marketable securities at March 31, 2023 will be sufficient to fund operations past one year from the issuance of these financial statements. To meet its future capital needs, the Company intends to raise additional capital through debt or equity financings, collaborations, partnerships or other strategic transactions. However, there can be no assurance that the Company will be able to complete any such transactions on acceptable terms or otherwise. The inability of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition. The Company has the ability to delay certain research activities and related clinical expenses if necessary due to liquidity concerns until a date when those concerns are relieved.

4. Cash, Cash Equivalents and Marketable Securities

A summary of cash, cash equivalents and available-for-sale marketable securities held by the Company as of March 31, 2023 and December 31, 2022 is as follows (in thousands):

	March 31, 2023			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash and cash equivalents:				
Cash	$ 10,094	$ —	$ —	$ 10,094
Money market funds (Level 1)	84,750	—	—	84,750
Corporate debt securities due within 3 months of date of purchase (Level 2)	18,464	—	—	18,464
Total cash and cash equivalents	113,308	—	—	113,308
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	207,138	7	(96)	207,049
U.S. government and government sponsored entities due within 1 year of date of purchase (Level 2)	9,117	3	—	9,120
Total cash, cash equivalents and marketable securities	$329,563	$ 10	$ (96)	$329,477

	December 31, 2022			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash and cash equivalents:				
Cash	$ 15,100	$ —	$ —	$ 15,100
Money market funds (Level 1)	316,449	—	—	316,449
Total cash and cash equivalents	331,549	—	—	331,549
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	27,257	7	(39)	27,225
Total cash, cash equivalents and marketable securities	$358,806	$ 7	$ (39)	$358,774

5. Accrued Liabilities

Accrued liabilities as of March 31, 2023 and December 31, 2022 consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Contract research organization costs	$ 57,984	$ 53,119
Other clinical study related costs	6,638	6,582
Manufacturing and drug supply	2,996	11,262
Compensation and benefits	11,208	14,864
Professional fees	4,741	4,867
Other	2,000	767
Total accrued liabilities	$ 85,567	$ 91,461

6. Long Term Debt

In May 2022 the Company and its wholly-owned subsidiary, Canticle Pharmaceuticals, Inc., entered into the $250.0 million Loan Facility with the several banks and other financial institutions or entities party thereto (each, a "Lender" and collectively referred to as the "Lenders"), and Hercules Capital, Inc. ("Hercules"), in its capacity as administrative agent and collateral agent for itself and the Lenders. Under the terms of the Loan Facility, the first $50.0 million tranche was drawn at closing. The Company also could draw up to an additional $125.0 million in two separate tranches upon achievement of certain resmetirom clinical and regulatory milestones. A fourth tranche of $75.0 million could be drawn by the Company, subject to the approval of Hercules. The Loan Facility had a minimum interest rate of 7.45% and adjusts with changes in the prime rate. The Company will pay interest-only monthly payments of accrued interest under the Loan Facility for a period of 30 months, which period may be extended to 36, 48, and 60 months upon the successive achievement of certain clinical and regulatory milestones and if the Company maintains compliance with applicable covenants. The Loan Facility matures in May 2026 and may be extended an additional year upon the achievement of certain clinical and regulatory milestones. The Loan Facility is secured by a security interest in substantially all of the Company's assets, other than intellectual property. It includes an end of term charge of 5.35% of the aggregate principal amount, which is accounted for in the loan discount. In connection with the first tranche drawn at closing, the Company issued Hercules a warrant to purchase 14,899 shares of Company common stock, which had a Black-Scholes value of $0.6 million.

On February 3, 2023, the Company entered into the First Amendment (the "Amendment") to the Loan Facility (as amended, the "Amended Loan Facility"). Under the Amended Loan Facility, an additional $35.0 million was drawn under a second, expanded, $65.0 million tranche ("Tranche 2") in February of 2023 following the Company's achievement of the Phase 3 clinical development milestone. The Company has the ability to draw an additional $15.0 million under Tranche 2 by June 19, 2023 and an additional $15.0 million under Tranche 2 by September 30, 2023 (for a total of $30.0 million in additional committed Tranche 2 capacity). The third tranche ("Tranche 3") of $75.0 million remains unchanged by the Amendment, and such borrowings are available subject to the Company obtaining a certain FDA approval for resmetirom. Coincident with the expansion of Tranche 2 borrowing capacity by $15 million, the Amendment reduced the fourth tranche under the Loan Facility ("Tranche 4") by $15.0 million to $60.0 million , which amount is available subject to Hercules' sole discretion. In connection with the $35.0 million drawn under the second tranche at the closing of the Amendment, the Company issued to Hercules and affiliates Tranche 2 Warrants to purchase 2,453 shares of common stock, which had a Black-Scholes value of $0.5 million. The Amendment reduced the interest rate under the Amended Loan Facility to the greater of (i) the prime rate as reported in The Wall Street Journal plus 2.45% and (ii) 8.25%. The Amendment and the Amended Loan Facility summary terms were disclosed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 9, 2023.

The Loan Facility includes affirmative and restrictive financial covenants commencing on January 1, 2023, including maintenance of a minimum cash, cash equivalents and liquid funds covenant of $35.0 million, which may decrease in certain circumstances if the Company achieves certain clinical milestones and a revenue milestone, and a revenue-based covenant that could apply commencing at or after the time that financial reporting is due for the quarter ending September 30, 2024. The Loan Facility contains event of default provisions for: the Company's failure to make required payments or maintain compliance with covenants under the Loan Facility; the Company's breach of certain representations or default under certain obligations outside the Loan Facility; insolvency, attachment or judgment events affecting the Company; and any circumstance which has occurred or could reasonably be expected to have a material adverse effect on the Company, provided that, any failure to achieve a clinical milestone or approval milestone under the Loan Facility shall not in and of itself constitute a material adverse effect. The Loan Facility also includes customary covenants associated with a secured loan facility, including covenants concerning financial reporting obligations, and certain limitations on indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, and deposit accounts.

As of March 31, 2023, the outstanding principal under the Loan Facility was $85.0 million. The interest rate as of March 31, 2023 was 10.45%. As of March 31, 2023, the Company was in compliance with all loan covenants and provisions.

Future minimum payments, including interest and principal, under the loans payable outstanding as of March 31, 2023 are as follows (in thousands):

Period Ending March 31, 2023:	Amount
2023	$ 6,772
2024	9,031
2025	58,537
Thereafter	39,356
	$113,696
Less amount representing interest	(24,149)
Less unamortized discount	(5,582)
Loans payable, net of discount	$ 83,965

7. Stockholders' Equity

Common Stock

Each common stockholder is entitled to one vote for each share of common stock held. The common stock will vote together with all other classes and series of stock of the Company as a single class on all actions to be taken by the Company's stockholders. Each share of common stock is entitled to receive dividends, as and when declared by the Company's board of directors. The Company has never declared cash dividends on its common stock and does not expect to do so in the foreseeable future.

Preferred Stock

The Series A and B Preferred Stock have a par value of $0.0001 per share and are convertible into shares of the common stock at a one-to-one ratio, subject to adjustment as provided in the Certificates of Designation of Preferences, Rights and Limitations of Series A Preferred Stock and Series B Preferred Stock that the Company filed with the Secretary of State of the State of Delaware on June 21, 2017 and December 22, 2022, respectively. The terms of the Series A and B Preferred Stock are set forth in such Certificates of Designation. Each share of the Series A and B Preferred Stock is convertible into shares of Common Stock following notice that may be given at the holder's option. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, after the satisfaction in full of the debts of the Company and the payment of any liquidation preference owed to the holders of shares of capital stock of the Company ranking prior to the Series A and B Preferred Stock upon liquidation, the holders of the Series A and B Preferred Stock shall participate pari passu with the holders of the Common Stock (on an as-if-converted-to-Common-Stock basis) in the net assets of the Company. Shares of the Series A and B Preferred Stock will generally have no voting rights, except as required by law. Shares of the Series A and B Preferred Stock will be entitled to receive dividends before shares of any other class or series of capital stock of the Company (other than dividends in the form of the Common Stock) equal to the dividend payable on each share of the Common Stock, on an as-converted basis.

December 2022 Registered Direct Offering

In December 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with a group of institutional accredited investors, who were existing, non-controlling stockholders of the Company, pursuant to which the Company sold securities to the Investors in an offering that was registered under the Company's existing shelf registration statement (the "2022 Registered Direct Offering"). Under the terms of the Purchase Agreement, the Company sold 44,444 shares of its common stock at a price of $225 per share, and 400,000 shares of its Series B Convertible Preferred Stock at a price of $225 per share. The 2022 Registered Direct Offering resulted in gross proceeds to the Company of approximately $100.0 million, and net proceeds to the Company of approximately $99.5 million. The 2022 Registered Direct Offering closed on December 23, 2022.

At-The-Market Issuance Sales Agreement

In June 2021, the Company entered into an at-the-market sales agreement (the "2021 Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company could, from time to time, issue and sell shares of its common stock. The 2021 Sales Agreement authorized an aggregate offering of up to $200 million in shares of our common stock, at the Company's option, through Cowen as its sales agent. Sales of common stock through Cowen could be made by any method that is deemed an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by the Company and Cowen. Subject to the terms and conditions of the 2021 Sales Agreement, Cowen would use commercially reasonable efforts consistent with its normal trading and sales practices to sell the common stock based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company imposed).

In December 2022, the Company sold 738,900 shares under the 2021 Sales Agreement for an aggregate of $159.1 million in gross proceeds, with net proceeds to the Company of $155.9 million after deducting commissions and other transaction costs.

In total, under the 2021 Sales Agreement the Company sold 1,235,943 shares for an aggregate of $199.9 million in gross proceeds, with net proceeds to the Company of approximately $195.8 million after deducting commissions and other transaction costs. Of those shares sold, 738,900 were sold in 2022, and 497,043 were sold in 2021. All shares were sold pursuant to the Company's effective shelf registration statement and the prospectus supplement relating thereto. As of March 31, 2023, no amounts remained reserved and available for sale under the 2021 Sales Agreement and the related prospectus supplement.

8. Stock-based Compensation

The Company's 2015 Stock Plan, as amended, is our primary equity incentive compensation plan through which equity based grants are awarded. The 2015 Stock Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock, restricted stock units and other stock-based compensation awards to employees, officers, directors, and consultants of the Company. The administration of the 2015 Stock Plan is under the general supervision of the Compensation Committee of the Board of Directors. The terms of stock options awarded under the 2015 Stock Plan, in general, are determined by the Compensation Committee, provided the exercise price per share generally shall not be set at less than the fair market value of a share of the common stock on the date of grant and the term shall not be greater than ten years from the date the option is granted. As of March 31, 2023, the Company had restricted stock units and options outstanding to purchase 2,875,723 shares of its common stock, which includes options outstanding under its prior incentive compensation plan, the 2006 Stock Plan. As of March 31, 2023, 690,809 shares were available for future issuance under the 2015 Stock Plan.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2023:

	Shares	Weighted average exercise price
Outstanding at January 1, 2023	2,857,054	$ 81.78
Options granted	5,205	283.08
Options exercised	(180,551)	99.16
Options cancelled	(5,110)	76.07
Outstanding at March 31, 2023	2,676,598	$ 81.02
Exercisable at March 31, 2023	1,637,134	$ 75.71

The total cash received by the Company as a result of stock option exercises was $17.9 million and $0 million, respectively, for the three months ended March 31, 2023 and 2022. The total intrinsic value of options exercised was $32.5 million and $0 million, respectively, for the three months ended March 31, 2023 and 2022. The weighted-average grant date fair values, based on the Black-Scholes option model, of options granted during the three months ended March 31, 2023 and 2022 were $219.02 and $59.63, respectively.

Restricted Stock Units

The Company's share-based compensation plan provides for awards of restricted stock units to employees, officers, directors and consultants to the Company. Restricted stock units vest over the service period, and are subject to forfeiture if employment or service terminates before vesting. As of March 31, 2023, the Company had 199,125 restricted stock units outstanding, with a weighted average grant date fair value of $297.18 per unit.,

Stock-Based Compensation Expense

Stock-based compensation expense during the three months ended March 31, 2023 and 2022 was as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Stock-based compensation expense by type of award:		
Stock options	$ 8,598	$ 7,477
Restricted stock units	2,652	—
Total stock-based compensation expense	$ 11,250	$ 7,477
Effect of stock-based compensation expense by line item:		
Research and development	$ 5,385	$ 3,187
General and administrative	5,865	4,290
Total stock-based compensation expense included in net loss	$ 11,250	$ 7,477

Unrecognized stock-based compensation expense on stock options as of March 31, 2023 was $52.3 million with a weighted average remaining period of 2.42 years.

9. Commitments and Contingencies

The Company has a Research, Development and Commercialization Agreement with Hoffmann-La Roche ("Roche") which grants the Company a sole and exclusive license to develop, use, sell, offer for sale and import any Licensed Product as defined by the agreement.

The agreement requires future milestone payments to Roche. Remaining milestones under the agreement total $8 million and are payable upon Madrigal achieving specified objectives related to future regulatory approval in the United States and Europe of resmetirom or a product developed from resmetirom. Furthermore, a tiered single-digit royalty is payable on net sales of resmetirom or a product developed from resmetirom, subject to certain reductions. The Company has not achieved any additional product development or regulatory milestones and had no Licensed Product sales for the three months ended March 31, 2023 and 2022.

The Company has entered into customary contractual arrangements and letters of intent in preparation for and in support of the clinical trials.

10. Subsequent Event

In May 2023, the Company amended the 2021 Agreement (the "2023 Sales Agreement Amendment"), with Cowen, pursuant to which the Company may, from time to time, issue and sell shares of its common stock. The Company is not obligated to make any sales of its common stock under this arrangement. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 (the "Registration Statement") and a prospectus supplement filed pursuant to the Registration Statement. The Sales Agreement Amendment authorizes an additional aggregate offering of up to $200 million in shares of our common stock, from time to time, at the Company's option, through Cowen as its sales agent. Sales of common stock through Cowen may be made by any method that is deemed an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, and as described in the prospectus supplement.

********** END OF FINANCIAL STATEMENTS **********

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that are based on our beliefs and assumptions and on information currently available to us, but are subject to factors beyond our control Forward-looking statements: reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events; include all statements that are not historical facts; and can be identified by terms such as "accelerate," "achieve," "allow," "anticipates," "appear," "be," "believes," "can," "continue," "confidence," "could," "demonstrates," "design," "estimates," "expectation," "expects," "forecasts," "future," "goal," "help," "hopeful," "inform," "informed," "intends," "may," "might," "on track," "planned," "planning," "plans," "positions," "potential," "powers," "predicts," "predictive," "projects," "seeks," "should," "will," "will achieve," "will be," "would" or similar expressions and the negatives of those terms. In particular, forward-looking statements contained in or incorporated by reference to this Quarterly Report relate to, among other things,

- Anticipated or estimated future results, including the risks and uncertainties associated with our future operating performance and financial position;
- Our possible or assumed future results of operations and expenses, business strategies and plans (including ex-U.S. launch/partnering plans), capital needs and financing plans, including incurrence of indebtedness and compliance with debt covenants under the Loan and Security Agreement with Hercules Capital, Inc., as agent and lender, market trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things;
- Our ability to delay certain research activities and related clinical expenses as necessary;
- Our projected resources and sufficiency of capital to fund our operating expenses through the projected commercial launch of resmetirom, assuming Food and Drug Administration ("FDA") approval is obtained;
- Our clinical trials, including the anticipated timing of disclosure, presentations of data from, or outcomes from our trials,
- Research and development activities, and the timing and results associated with the future development of our lead product candidate, resmetirom (formerly known as MGL-3196), including projected market size, sector leadership, and patient treatment estimates for non-alcoholic steatohepatitis ("NASH") and nonalcoholic fatty liver disease ("NAFLD") patients,
- The timing and completion of projected future clinical milestone events, including enrollment, additional studies, top-line data and open label projections,
- Resmetirom's potential to be a cost-effective specialty therapy for NASH patients with significant liver fibrosis,
- Plans, objectives and timing for making a Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) submission to the FDA,
- Projections or objectives for obtaining accelerated or full approval for resmetirom for NASH patients with significant fibrosis (or non-cirrhotic NASH patients) and NASH patients with compensated cirrhosis,
- Our primary and key secondary study endpoints for resmetirom, and the potential for achieving such endpoints and projections, including NASH resolution, safety, fibrosis treatment, cardiovascular effects and lipid treatment with resmetirom,
- Optimal dosing levels for resmetirom and projections regarding potential NASH or NAFLD and potential patient benefits with resmetirom, including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment and/or biomarker effects with resmetirom,
- Our ability to address the unmet needs of patients suffering from NASH with significant fibrosis,
- The potential efficacy and safety of resmetirom for non-cirrhotic NASH patients and cirrhotic NASH patients,
- The potential for resmetirom to become the best-in-class and/or first-to-market treatment option for patients with NASH and liver fibrosis;
- Anticipated or estimated future results of operations and expenses as we expand our resmetirom clinical development program and our commercial development program;
- Ex-U.S. launch/partnering plans,
- The ability to develop clinical evidence demonstrating the utility of non-invasive tools and techniques to screen and diagnose NASH and/or NAFLD patients,

- The predictive power of liver fat reduction with resmetirom, as measured by non-invasive tests, on NASH resolution and/or fibrosis reduction or improvement, and potential NASH or NAFLD patient risk profile benefits with resmetirom,
- The predictive power of liver fat, liver volume changes or MAST scores for NASH and/or NAFLD patients,
- The predictive power of NASH resolution and/or liver fibrosis reduction with resmetirom or improvement using non-invasive tests, including the use of ELF, FibroScan, MRE and/or MRI-PDFF,
- The predictive power of non-invasive tests generally, including for purposes of diagnosing NASH, monitoring patient response to resmetirom, or recruiting and conducting a NASH clinical trial,
- Market demand for and acceptance of our products,
- Research, development and commercialization of new products,
- The potential for resmetirom to be an effective treatment for other disease indications,
- Obtaining and maintaining regulatory approvals, including, but not limited to, potential regulatory delays or rejections,
- Risks associated with meeting the objectives of our clinical studies, including, but not limited to our ability to achieve enrollment objectives concerning patient numbers (including an adequate safety database), outcomes objectives and/or timing objectives for our studies, any delays or failures in enrollment, the occurrence of adverse safety events, and the risks of successfully conducting trials that are substantially larger, and have patients with different disease states, than our past trials,
- our continued reliance on third-party contract manufacturers for the manufacture of our product candidates, including resmetirom,
- Risks related to the effects of resmetirom's mechanism of action and our ability to accomplish our business and business development objectives and realize the anticipated benefit of any such transactions, and
- Assumptions underlying any of the foregoing.

We caution you that the foregoing list may not include all of the forward-looking statements made in this Quarterly Report. Although management presently believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements.

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to: our clinical and commercial development of resmetirom; enrollment and trial outlook uncertainties, generally, based on blinded, locked or limited trial data and in relation to COVID-19-related measures and individual precautionary measures that may be implemented or continued for an uncertain period of time; our potential inability to raise sufficient capital to fund our ongoing operations as currently planned or to obtain financings on terms similar to those we have arranged in the past; our ability to service our indebtedness and otherwise comply with our debt covenants; outcomes or trends from competitive studies; future topline data timing or results; the risks of achieving potential benefits in studies that includes substantially more patients, and patients with different disease states, than our prior studies; limitations associated with early stage or non-placebo controlled study data; the timing and outcomes of clinical studies of resmetirom; and the uncertainties inherent in clinical testing. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Madrigal undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events. Please refer to Madrigal's submissions filed or furnished with the U.S. Securities and Exchange Commission for more detailed information regarding these risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied. We specifically discuss these risks and uncertainties in greater detail in the section appearing in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 23, 2023 (the "2022 Form 10-K"), as well as in our other filings with the SEC. You should read the 2022 Form 10-K, this Quarterly Report, and the other documents that we file or have filed with the SEC, with the understanding that our actual future results may be materially different from the results expressed or implied by these forward-looking statements.

Moreover, we operate in an evolving environment. New risks and uncertainties emerge from time to time and it is not possible for our management to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual future results to be materially different from those expressed or implied by any forward-looking statements.

Except as required by applicable law or the rules of the NASDAQ Stock Market, or NASDAQ, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. We qualify all of our forward-looking statements by these cautionary statements.

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

The consolidated financial statements, included elsewhere in this Quarterly Report on Form 10-Q, and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our audited financial statements and accompanying notes for year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are included in our Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As disclosed in this report under "Cautionary Note Regarding Forward-Looking Statements," our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" sections contained in our Annual Report on Form 10-K for the year ended December 31, 2022. Our operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period.

About Madrigal Pharmaceuticals, Inc.

Our Focus. We are a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis, or NASH. Our lead product candidate, resmetirom, is a proprietary, liver-directed, selective thyroid hormone receptor-ß, or THR-ß, agonist being developed as a once-daily oral pill for the treatment of NASH.

Our Patient Market Opportunity. NASH is a serious inflammatory form of nonalcoholic fatty liver disease, or NAFLD. NAFLD has become the most common liver disease in the United States and other developed countries and is characterized by an accumulation of fat in the liver with no other apparent causes. NASH can progress to cirrhosis or liver failure, require liver transplantation and can also result in liver cancer. Progression of NASH to end stage liver disease will soon surpass all other causes of liver failure requiring liver transplantation. Importantly, beyond these critical conditions, NASH and NAFLD patients additionally suffer heightened cardiovascular risk and, in fact, die more frequently from cardiovascular events than from liver disease. NASH and NAFLD have grown as a consequence of rising worldwide obesity-related disorders. In the United States, NAFLD is estimated to affect approximately 25% of the population, and approximately 25% of those will progress from NAFLD to NASH. Current estimates place NASH prevalence at approximately 22 million people in the United States by 2024, with similar prevalence in Europe and Asia. The prevalence of NASH is also increasing in developing regions due to the adoption of a more sedentary lifestyle and a diet consisting of processed foods with high fat and fructose content.

Our Completed Studies. For NASH, we enrolled 125 patients in a Phase 2 clinical trial with resmetirom. We achieved the 12-week primary endpoint for this Phase 2 clinical trial and reported the results in December 2017, and we reported positive topline 36-week results at the conclusion of the Phase 2 clinical trial in May 2018. We also completed a 36-week, open-label extension study in 31 participating NASH patients from our Phase 2 clinical trial, which included 14 patients who received placebo in the main study.

On December 18, 2019 the Company announced it had opened for enrollment MAESTRO-NAFLD-1, a 52-week, non-invasive, multi-center, double-blind, placebo-controlled Phase 3 clinical study of patients with biopsy-confirmed or presumed NASH recruited from sites in the U.S. Key endpoints are safety, including safety biomarkers. Secondary endpoints include LDL cholesterol, lipid biomarkers, MRI-PDFF, NASH and fibrosis biomarkers. Except for serial liver biopsies, the study protocol is similar to the MAESTRO-NASH study (discussed below under "—Our Ongoing and Planned Studies"), with resmetirom doses of 80 mg or 100 mg or placebo. Enrollment objectives for this study were exceeded, with approximately 1,300 patients enrolled overall. The MAESTRO-NAFLD-1 study will help support the adequacy of the safety database at the time of NDA submission for Subpart H approval for treatment of patients with NASH with fibrosis. In November of 2021, we reported data from the open label non-cirrhotic arm of MAESTRO-NAFLD-1, and in January 2022 we announced that we achieved primary and secondary endpoints for the double-blind portion of MAESTRO-NAFLD-1.

Our Ongoing and Planned Studies. On March 28, 2019, the Company announced that it had initiated MAESTRO-NASH, a Phase 3 trial in NASH with its once daily, oral thyroid hormone receptor beta selective agonist, resmetirom. This double-blind, placebo-controlled study is being conducted at more than 220 sites in the United States and the rest of the world. MAESTRO-NASH is a multicenter, randomized, double-blind, placebo-controlled Phase 3 study of resmetirom in patients with liver biopsy-confirmed NASH and was initiated in March 2019. The subpart H portion of the study enrolled more than 1,000 patients with biopsy-proven NASH (at least half with F3 (advanced) fibrosis, the remainder F2 or F1B (moderate fibrosis) with a few earlier F1 patients), randomized 1:1:1 to receive once-daily resmetirom 80 mg, resmetirom 100 mg, or placebo. After 52 weeks of treatment, a second liver biopsy is performed. The dual primary surrogate endpoints on biopsy are NASH resolution with ≥2-point reduction in NAS (NAFLD Activity Score), and with no worsening of fibrosis OR a 1-point decrease in fibrosis with no worsening of NAS. Achievement of either primary endpoint is considered a successful trial outcome. A key secondary endpoint is lowering of LDL-C. All patients enrolled in the

MAESTRO-NASH study (approximately 1,750) continue on therapy after the initial 52-week treatment period for up to 54 months to accrue and measure hepatic clinical outcome events including progression to cirrhosis on biopsy (52 weeks and 54 months) and hepatic decompensation events, as well as all-cause mortality. In December 2022, we reported topline results from the subpart H portion of the study: resmetirom achieved both primary endpoints with both daily oral doses, 80 mg and 100 mg, relative to placebo, as summarized in "- Key Developments" in our Annual Report on Form 10-K for the year ended December 31, 2022.

On July 13, 2021 we announced first patient dosed in a planned 52-week open label active treatment extension study of MAESTRO-NAFLD-1, named MAESTRO-NAFLD-Open Label Extension (OLE). The OLE study allows patients who complete MAESTRO-NAFLD-1 to consent to 52 weeks of active treatment with resmetirom, making this treatment available to both patients who were assigned to placebo in MAESTRO-NAFLD-1 and patients who were on resmetirom in MAESTRO-NAFLD-1.

In August 2022, Madrigal initiated MAESTRO-NASH-OUTCOMES, a randomized double-blind placebo-controlled study in approximately 700 patients with early NASH cirrhosis to allow for noninvasive monitoring of progression to liver decompensation events. A positive outcome is expected to support the full approval of resmetirom for noncirrhotic NASH, potentially accelerating the timeline to full approval. In addition, this study has the potential to support an additional indication for resmetirom in patients with well-compensated NASH cirrhosis.

Key Developments

In April 2023, Madrigal announced that resmetirom has received Breakthrough Therapy designation from the FDA for the treatment of patients with NASH with liver fibrosis. Breakthrough Therapy designation is a process intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy, or over placebo if there is no available therapy. A drug that receives Breakthrough Therapy designation is eligible for more intensive guidance on an efficient drug development program and organizational commitment involving senior managers from FDA.

Also in April 2023, Madrigal announced that the outcomes portion of the Phase 3 MAESTRO-NASH biopsy trial has completed enrollment. Enrollment of the MAESTRO-NASH study was closed at approximately 1,750 patients based on the enrollment target of the 54-month long-term clinical outcome portion of the study.

Basis of Presentation

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our research activities, including the preclinical and clinical development of our product candidates. We expense our research and development expenses as incurred. We contract with clinical research organizations to manage our clinical trials under agreed upon budgets for each study, with oversight by our clinical program managers. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received. Manufacturing expense includes costs associated with drug formulation development and clinical drug production. We do not track employee and facility related research and development costs by project, as we typically use our employee and infrastructure resources across multiple research and development programs. We believe that the allocation of such costs would be arbitrary and not be meaningful.

Our research and development expenses consist primarily of:

- salaries and related expense, including stock-based compensation;
- external expenses paid to clinical trial sites, contract research organizations, laboratories, database software and consultants that conduct clinical trials;
- expenses related to development and the production of nonclinical and clinical trial supplies, including fees paid to contract manufacturers;
- expenses related to preclinical studies;
- expenses related to compliance with drug development regulatory requirements; and
- other allocated expenses, which include direct and allocated expenses for depreciation of equipment and other supplies.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we conduct our clinical studies programs, manufacturing and toxicology studies. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, additional drug manufacturing requirements, and later stage toxicology studies such as carcinogenicity studies. Our research and development expenses have increased period over period in each of 2023 and 2022 and we expect that our research and development expenses may increase in the future. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate is affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. Accordingly, we may never succeed in achieving marketing approval for any of our product candidates.

Completion dates and costs for our clinical development programs as well as our research program can vary significantly for each current and future product candidate and are difficult to predict. As a result, we cannot estimate with any degree of certainty the costs we will incur in connection with the development of our product candidates at this point in time. We expect that we will make determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the scientific success of research, results of ongoing and future clinical trials, potential collaborative agreements with respect to programs or potential product candidates, as well as ongoing assessments as to each current or future product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation expenses for employees, management costs, costs associated with obtaining and maintaining our patent portfolio, professional fees for accounting, auditing, consulting and legal services, and allocated overhead expenses.

We expect that our general and administrative expenses will increase in the future as we expand our operating activities, prepare for commercialization, maintain and expand our patent portfolio and incur additional costs associated with being a public company and maintaining compliance with exchange listing and SEC requirements. We expect these potential increases will likely include management costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and expenses associated with investor relations.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities as of the date of the financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses and stock-based compensation expense. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no material changes in our critical accounting policies and significant judgments and estimates during the three months ended March 31, 2023, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023.

Results of Operations

Three months Ended March 31, 2023 and 2022

The following table provides comparative unaudited results of operations for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		Increase / (Decrease)	
	2023	2022	$	%
Research and Development Expenses	$ 62,154	$ 47,929	14,225	30%
General and Administrative Expenses	16,182	9,658	6,524	68%
Interest (Income)	(3,776)	(69)	3,707	5372%
Interest Expense	2,336	—	2,336	100%
	$ 76,896	$ 57,518	19,378	34%

Revenue

We had no revenue for the three months ended March 31, 2023 and 2022.

Research and Development Expenses

Our research and development expenses were $62.2 million for the three months ended March 31, 2023, compared to $47.9 million in the corresponding period in 2022. Research and development expenses increased by $14.2 million in the 2023 period due primarily to the additional activities related to our Phase 3 clinical trials, including MAESTRO-NASH Outcomes for which no expenses were incurred in the prior year quarter, an increase in headcount, and an increase in stock compensation expense. We expect our research and development expenses to increase as we advance our clinical and preclinical development programs for resmetirom.

General and Administrative Expenses

Our general and administrative expenses were $16.2 million for the three months ended March 31, 2023, compared to $9.7 million in the corresponding period in 2022. General and administrative expenses increased by $6.5 million in the 2023 period due primarily to increases in commercial preparation activities, including a corresponding increase in headcount, and an increase in stock compensation expense. We believe our general and administrative expenses may increase over time as we advance our clinical and preclinical development programs for resmetirom, prepare for commercialization, and expand our operating activities, which will likely result in an increase in our headcount, consulting services, and related overhead needed to support those efforts.

Interest Income

Our net interest income was $3.8 million for the three months ended March 31, 2023, compared to $0.1 million in the corresponding period in 2022. The increase in interest income was due primarily to higher principal balances and interest rates in 2023.

Interest Expense

Our interest expense was $2.3 million for the three months ended March 31, 2023, compared to $0 million in the corresponding period in 2022. The increase in interest expense was as a result of the Loan Facility we entered into with Hercules during the second quarter of 2022.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and we have funded our operations primarily through the issuance of shares of our common stock and shares of our preferred stock, borrowings under the Loan Facility with Hercules, the issuance of convertible debt and the proceeds from the merger with Synta Pharmaceuticals Corp. Our most significant use of capital pertains to salaries and benefits for our employees, including clinical, scientific, operational, financial and management personnel, and external research and development expenses, such as clinical trials and preclinical activity related to our product candidates.

As of March 31, 2023, we had cash, cash equivalents and marketable securities totaling $329.5 million compared to $358.8 million as of December 31, 2022, with this decrease attributable to funding of operations, partially offset by $35.0 million drawn from the Loan Facility with Hercules and proceeds from the exercise of stock options. Our cash and investment balances are held in a variety of interest-bearing instruments, including obligations of U.S. government agencies, U.S. Treasury debt securities, corporate debt securities and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy with a view toward capital preservation and liquidity.

We anticipate continuing to incur operating losses for the foreseeable future. While our rate of cash usage will likely increase in the future, in particular to support our product development and clinical trial efforts, as well as preparation for commercialization, we believe our available cash resources as of March 31, 2023 will be sufficient to fund our operations past one year from the issuance of the financial statements contained herein. Our future long-term liquidity requirements will be substantial and will depend on many factors. To meet future long-term liquidity requirements, as well as maintain compliance with certain of our Loan Facility covenants, we will need to raise additional capital to fund our operations through equity or debt financings, collaborations, partnerships or other strategic transactions. We regularly consider fundraising opportunities and may decide, from time to time, to raise capital based on various factors, including market conditions and our plans of operation. Additional capital may not be available on terms acceptable to us, or at all. We also have the ability to delay certain research activities and related clinical expenses, as well as commercial preparation investments, if necessary due to liquidity concerns until a date when those concerns are relieved. If adequate funds are not available, or if the terms of potential funding sources are unfavorable, our business and our ability to develop our product candidates would be harmed. Furthermore, any sales of additional equity securities may result in dilution to our stockholders, and any debt financing may include covenants that restrict our business.

Cash Flows

The following table provides a summary of our net cash flow activity (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash used in operating activities	$ (84,067)	$ (49,913)
Net cash (used in) provided by investing activities	(186,864)	55,926
Net cash provided by financing activities	52,690	—
Net increase (decrease) in cash and cash equivalents	$ (218,241)	$ 6,013

Net cash used in operating activities was $84.1 million for the three months ended March 31, 2023, compared to $49.9 million for the corresponding period in 2022. The use of cash in these periods resulted primarily from our losses from operations, as adjusted for non-cash charges for stock-based compensation, and changes in our working capital accounts.

Net cash used in investing activities was $186.9 million for the three months ended March 31, 2023, compared to $55.9 million provided by for the corresponding period in 2022. Net cash used in investing activities for the three months ended March 31, 2023 consisted of $198.8 million of purchases of marketable securities for our investment portfolio, partially offset by $12.0 million from sales and maturities of marketable securities. Net cash provided by for the corresponding period in 2022 consisted of $93.5 million from sales and maturities of marketable securities, partially offset by $37.6 million of purchases of marketable securities for our investment portfolio.

Net cash provided by financing activities was $52.7 million for the three months ended March 31, 2023, compared to $0 million for the corresponding period in 2022. Financing activities for the three months ended March 31, 2023 consisted of $35.0 million from issuance of the Loan Facility and $17.9 million from proceeds from the exercise of common stock options, partially offset by $0.2 million of loan issuance costs.

Contractual Obligations and Commitments

Except for the future minimum payments due on the Loan Facility with Hercules set forth in “Note 6 – Long Term Debt” to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, no significant changes to contractual obligations and commitments occurred during the three months ended March 31, 2023, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our exposure to market risk is confined to our cash, cash equivalents and marketable securities and Loan Facility. We regularly review our investments and monitor the financial markets. We invest in high-quality financial instruments, primarily money market funds, U.S. government and agency securities, government- sponsored bond obligations and certain other corporate debt securities, with the effective duration of the portfolio less than twelve months and no security with a duration in excess of twenty-four months, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term duration of our investment portfolio and the current risk profile of our investments, we believe that an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We do not believe that we have any material exposure to interest rate risk or changes in credit ratings arising from our investments.

In May 2022 we entered into a Loan Facility, which has an interest rate that is linked to the prime rate. We do not believe that we have any material exposure to interest rate risk given the current principal amount of the loan.

Capital Market Risk

We currently have no product revenues and depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price and the factors described in our “Cautionary Note Regarding Forward-Looking “Statements.” “Liquidity and Capital Resources” and “Risk Factors” disclosures included or referred to in this filing.

Effects of Inflation

Inflation generally affects us with increased cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Definition and Limitations of Disclosure Controls

Our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file under the Exchange Act, such as this Quarterly Report, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management evaluates these controls and procedures on an ongoing basis.

We carried out an evaluation, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Limitations on the Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

We are not party to any material pending legal proceedings. From time to time, we may be involved in legal proceedings arising in the ordinary course of business.

Item 1A. Risk Factors.

There have been no material changes to the risk factors included in detail in the "Risk Factors" sections appearing in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 23, 2023 (the "Annual Report").

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
4.1	Form of Tranche 2 Warrant Agreement, dated February 3, 2023, by and among Madrigal Pharmaceuticals, Inc. and Hercules Capital, Inc. and affiliates.	Form 8-K	001-33277	4.1	February 9, 2023	
10.1†	Loan and Security Agreement, dated May 9, 2022, as amended by the First Amendment to Loan and Security Agreement, dated February 3, 2023, by and among Madrigal Pharmaceuticals, Inc., Canticle Pharmaceuticals, Inc., the several banks and other financial institutions or entities from time to time party thereto and Hercules Capital, Inc.	Form 8-K	001-33277	10.1	February 9, 2023	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certifications of Principal Executive Officer and Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
104	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.					

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, shall not be deemed "filed" by the registrant for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any of the registrant's filings under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in any such filing.

† Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

MADRIGAL PHARMACEUTICALS, INC.

Date: May 9, 2023

By: /s/ Paul A. Friedman, M.D.
Paul A. Friedman, M.D.
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

Date: May 9, 2023

By: /s/ Alex G. Howarth
Alex G. Howarth
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul A. Friedman, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Madrigal Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Paul A. Friedman, M.D.

Paul A. Friedman, M.D.
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)
Date: May 9, 2023

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alex G. Howarth, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Madrigal Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Alex G. Howarth
Alex G. Howarth
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: May 9, 2023

Exhibit 32.1

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350)), each of the undersigned officers of Madrigal Pharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2023

/s/ Paul A. Friedman, M.D.
Paul A. Friedman, M.D.
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

Dated: May 9, 2023

/s/ Alex G. Howarth
Alex G. Howarth
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

These certifications accompany the Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.