
**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 September 30, 2021

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
(State or other jurisdiction of
incorporation or organization)

04-3508648
(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:

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, \$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 November 2, 2021, the registrant had 17,097,090 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 49,174	\$ 54,004
Marketable securities	249,970	230,145
Prepaid expenses and other current assets	3,812	1,014
Total current assets	302,956	285,163
Property and equipment, net	844	1,047
Right-of-use asset	897	785
Total assets	<u>\$ 304,697</u>	<u>\$ 286,995</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 10,418	\$ 1,017
Accrued expenses	58,501	45,222
Lease liability	406	318
Total current liabilities	69,325	46,557
Long term liabilities:		
Lease liability	491	468
Total long term liabilities	491	468
Total liabilities	69,816	47,025
Stockholders' equity:		
Preferred stock, par value \$0.0001 per share authorized: 5,000,000 shares at September 30, 2021 and December 31, 2020; 1,969,797 shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, par value \$0.0001 per share authorized: 200,000,000 at September 30, 2021 and December 31, 2020; 16,860,211 and 15,508,146 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2	2
Additional paid-in-capital	837,636	665,385
Accumulated other comprehensive gain (loss)	4	47
Accumulated deficit	(602,761)	(425,464)
Total stockholders' equity	234,881	239,970
Total liabilities and stockholders' equity	<u>\$ 304,697</u>	<u>\$ 286,995</u>

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)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenues:				
Total revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	54,873	53,292	152,275	131,380
General and administrative	8,287	5,494	25,606	15,738
Total operating expenses	<u>63,160</u>	<u>58,786</u>	<u>177,881</u>	<u>147,118</u>
Loss from operations	(63,160)	(58,786)	(177,881)	(147,118)
Interest income	60	823	311	3,897
Other income	—	—	273	100
Net loss	<u>\$ (63,100)</u>	<u>\$ (57,963)</u>	<u>\$ (177,297)</u>	<u>\$ (143,121)</u>
Net loss per common share:				
Basic and diluted net loss per common share	\$ (3.79)	\$ (3.75)	\$ (10.84)	\$ (9.27)
Basic and diluted weighted average number of common shares outstanding	16,639,776	15,448,425	16,353,428	15,437,018

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net Loss	\$ (63,100)	\$ (57,963)	\$ (177,297)	\$ (143,121)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	(11)	(660)	(43)	205
Comprehensive loss	<u>\$ (63,111)</u>	<u>\$ (58,623)</u>	<u>\$ (177,340)</u>	<u>\$ (142,916)</u>

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, 2020	1,969,797	\$ —	15,508,146	\$ 2	\$665,385	\$ 47	\$ (425,464)	\$ 239,970
Issuance of common shares in equity offering, excluding to related parties, net of transaction costs	—	—	550,803	—	66,616	—	—	66,616
Exercise of common stock options	—	—	4,250	—	478	—	—	478
Compensation expense related to stock options for services	—	—	—	—	6,096	—	—	6,096
Unrealized loss on marketable securities	—	—	—	—	—	(61)	—	(61)
Net loss	—	—	—	—	—	—	(52,546)	(52,546)
Balance at March 31, 2021	1,969,797	\$ —	16,063,199	\$ 2	\$738,575	\$ (14)	\$ (478,010)	\$ 260,553
Issuance of common shares in equity offering, excluding to related parties, net of transaction costs	—	—	536,323	—	63,541	—	—	63,541
Compensation expense related to stock options for services	—	—	—	—	8,179	—	—	8,179
Unrealized loss on marketable securities	—	—	—	—	—	29	—	29
Net loss	—	—	—	—	—	—	(61,651)	(61,651)
Balance at June 30, 2021	1,969,797	\$ —	16,599,522	\$ 2	\$810,295	\$ 15	\$ (539,661)	\$ 270,651
Issuance of common shares in equity offering, excluding to related parties, net of transaction costs	—	—	260,164	—	21,092	—	—	21,092
Exercise of common stock options	—	—	525	—	8	—	—	8
Compensation expense related to stock options for services	—	—	—	—	6,241	—	—	6,241
Unrealized loss on marketable securities	—	—	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	—	—	(63,100)	(63,100)
Balance at September 30, 2021	1,969,797	\$ —	16,860,211	\$ 2	\$837,636	\$ 4	\$ (602,761)	\$ 234,881
Balance at December 31, 2019	1,969,797	\$ —	5,429,154	\$ 2	\$639,567	\$ 216	\$ (223,220)	\$ 416,565
Compensation expense related to stock options for services	—	—	—	—	4,846	—	—	4,846
Unrealized gain on marketable securities	—	—	—	—	—	199	—	199
Net loss	—	—	—	—	—	—	(36,135)	(36,135)
Balance at March 31, 2020	1,969,797	\$ —	15,429,154	\$ 2	\$644,413	\$ 415	\$ (259,355)	\$ 385,475
Exercise of common stock options	—	—	8,970	—	109	—	—	109
Compensation expense related to stock options for services	—	—	—	—	5,689	—	—	5,689
Unrealized gain on marketable securities	—	—	—	—	—	666	—	666
Net loss	—	—	—	—	—	—	(49,023)	(49,023)
Balance at June 30, 2020	1,969,797	\$ —	15,438,124	\$ 2	\$650,211	\$ 1,081	\$ (308,378)	\$ 342,916
Exercise of common stock options	—	—	28,327	—	350	—	—	350
Compensation expense related to stock options for services	—	—	—	—	5,061	—	—	5,061
Unrealized loss on marketable securities	—	—	—	—	—	(660)	—	(660)
Net loss	—	—	—	—	—	—	(57,963)	(57,963)
Balance at September 30, 2020	1,969,797	\$ —	15,466,451	\$ 2	\$655,622	\$ 421	\$ (366,341)	\$ 289,704

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (177,297)	\$ (143,121)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	20,517	15,596
Depreciation and amortization expense	299	355
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,799)	(513)
Accounts payable	9,401	5,099
Accrued expense	13,279	19,136
Accrued interest, net of interest received on maturity of investments	734	834
Net cash used in operating activities	<u>(135,866)</u>	<u>(102,614)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(339,371)	(213,186)
Sales and maturities of marketable securities	318,769	378,088
Purchases of property and equipment, net of disposals	(96)	(324)
Net cash provided by (used in) investing activities	<u>(20,698)</u>	<u>164,578</u>
Cash flows from financing activities:		
Proceeds from issuances of stock, excluding related parties, net of transaction costs	151,249	—
Proceeds from the exercise of common stock options	485	459
Net cash provided by financing activities	<u>151,734</u>	<u>459</u>
Net increase (decrease) in cash and cash equivalents	(4,830)	62,423
Cash and cash equivalents at beginning of period	54,004	46,697
Cash and cash equivalents at end of period	<u>\$ 49,174</u>	<u>\$ 109,120</u>
Supplemental disclosure of cash flow information:		
Obtaining a right-of-use asset in exchange for a lease liability	\$ 376	\$ 451

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, MGL-3196 (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 previously completed Phase 2 studies of resmetirom in NASH in May of 2018 and Heterozygous Familial Hypercholesterolemia (“HeFH”) in February of 2018.

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, 2021 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, 2020.

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. Realized gains and losses and declines in value, if any, that the Company judges to be other-than-temporary on available-for-sale securities are reported as a component of interest income. To determine whether an other-than-temporary 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 nine months ended September 30, 2021 and 2020, the Company determined it did not have any securities that were other-than-temporarily impaired.

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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 nine months ended September 30, 2021 and 2020, 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 September 30, 2021, 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 nine months ended September 30, 2021 and 2020, the Company did not have any transfers of financial assets between Levels 1 and 2. As of September 30, 2021 and December 31, 2020, 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 Phase 1-3 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 preclinical studies and 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 granted to employees, officers, and directors. The Company uses the Black-Scholes option pricing model to determine the grant date fair value 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.

Certain of the employee stock options granted by the Company are structured to qualify as incentive stock options ("ISOs"). Under current tax regulations, the Company does not receive a tax deduction for the issuance, exercise or disposition of ISOs if the employee meets certain holding requirements. If the employee does not meet the holding requirements, a disqualifying disposition occurs, at which time the Company may receive a tax deduction. The Company does not record tax benefits related to ISOs unless and until a disqualifying disposition is reported. In the event of a

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disqualifying disposition, the entire tax benefit is recorded as a reduction of income tax expense. The Company has not recognized any income tax benefit for its share-based compensation arrangements due to the fact that the Company does not believe it is more likely than not it will realize the related deferred tax assets.

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, excluding any restricted stock that has been issued but is not yet vested. 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 nine months ended September 30, 2021 and 2020, diluted net loss per share is the same as basic net loss per share because the inclusion of weighted average shares of unvested restricted common stock, common stock issuable upon the exercise of stock options, 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:

	Nine Months Ended September 30,	
	2021	2020
Common stock options	2,254,629	1,810,753
Preferred stock	1,969,797	1,969,797

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 and other government regulations.

The Company has incurred losses since inception, including approximately \$177.3 million for the nine months ended September 30, 2021, resulting in an accumulated deficit of approximately \$602.8 million as of September 30, 2021. 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. The Company believes that its cash, cash equivalents and marketable securities at September 30, 2021 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.

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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 September 30, 2021 and December 31, 2020 is as follows (in thousands):

	September 30, 2021			Fair value
	Cost	Unrealized gains	Unrealized losses	
Cash and cash equivalents:				
Cash (Level 1)	\$ 2,116	\$ —	\$ —	\$ 2,116
Money market funds (Level 1)	47,058	—	—	47,058
Total cash and cash equivalents	49,174	—	—	49,174
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	233,697	21	(13)	233,705
U.S. government and government sponsored entities due within 1 year of date of purchase (Level 2)	12,000	1	—	12,001
Corporate debt securities due within 1 to 2 years of date of purchase (Level 2)	4,269	—	(5)	4,264
Total cash, cash equivalents and marketable securities	<u>\$299,140</u>	<u>\$ 22</u>	<u>\$ (18)</u>	<u>\$299,144</u>

	December 31, 2020			Fair value
	Cost	Unrealized gains	Unrealized losses	
Cash and cash equivalents:				
Cash (Level 1)	\$ 716	\$ —	\$ —	\$ 716
Money market funds (Level 1)	53,288	—	—	53,288
Total cash and cash equivalents	54,004	—	—	54,004
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	227,172	80	(36)	227,216
Corporate debt securities due within 1 to 2 years of date of purchase (Level 2)	2,926	4	(1)	2,929
Total cash, cash equivalents and marketable securities	<u>\$284,102</u>	<u>\$ 84</u>	<u>\$ (37)</u>	<u>\$284,149</u>

5. Accrued Liabilities

Accrued liabilities as of September 30, 2021 and December 31, 2020 consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Contract research organization costs	\$ 40,807	\$ 31,646
Other clinical study related costs	5,507	3,901
Compensation and benefits	4,970	4,686
Professional fees	1,711	830
Other	5,506	4,159
Total accrued liabilities	<u>\$ 58,501</u>	<u>\$ 45,222</u>

6. Stockholders' Equity

Common Stock

Each common stockholder generally is entitled to one vote for each share of common stock held, subject to limitations as may be established for certain other classes and series of stock of the Company from time to time. 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 Preferred Stock has a par value of \$0.0001 per share and is convertible into shares of the common stock at a one-to-one ratio, subject to adjustment as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, that the Company filed with the Secretary of State of the State of Delaware on June 21, 2017 (the “Series A Certificate”). The terms of the Series A Preferred Stock are set forth in the Series A Certificate. Each share of the Series A 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 Preferred Stock upon liquidation, the holders of the Series A 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 Preferred Stock will generally have no voting rights, except as required by law. Shares of the Series A 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.

At-The-Market Issuance Sales Agreement

In November 2020, the Company entered into an at-the-market sales agreement (the “2020 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 2020 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. The 2020 Sales Agreement was terminated in June 2021 when the Company filed a new shelf registration statement.

Under the 2020 Sales Agreement the Company sold 1,126,733 shares for an aggregate of approximately \$137.4 million in gross proceeds, with net proceeds to the Company of approximately \$134.8 million after deducting commissions and other transaction costs. Of those shares sold, 1,087,126 were sold in 2021, and 39,607 were sold in 2020.

In June 2021, the Company filed with the SEC and had declared effective a new shelf registration statement on Form S-3 and, in connection therewith, entered into a new at-the-market sales agreement (the “2021 Sales Agreement”) with Cowen. The terms of the 2021 Sales Agreement are substantially the same as the 2020 Sales Agreement. The 2021 Sales Agreement authorizes an 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. The 2021 Sales Agreement supersedes the 2020 Sales Agreement. Subject to the terms and conditions of the 2021 Sales Agreement, Cowen will 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 may impose).

As of September 30, 2021, 260,164 shares had been sold under the 2021 Sales Agreement for an aggregate of approximately \$21.5 million in gross proceeds, with net proceeds to the Company of approximately \$20.9 million after deducting commissions and other transaction costs. As of September 30, 2021, \$178.5 million remained reserved and available for sale under the 2021 Sales Agreement and the Company’s related prospectus supplement.

7. Stock-based Compensation

The 2015 Stock Plan, as amended, is our primary 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 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. Effective June 17, 2021, the 2015 Stock Plan was amended by stockholder vote to, among other things, increase the number of authorized shares by 1,200,000. As of September 30, 2021, the Company had options outstanding to purchase 2,254,629 shares of its common stock, which includes options outstanding under its 2006 Stock Plan. As of September 30, 2021, 1,714,543 shares were available for future issuance.

The following table summarizes stock option activity during the nine months ended September 30, 2021:

	Shares	Weighted average exercise price
Outstanding at January 1, 2021	1,837,540	\$ 71.80
Options granted	602,059	113.04
Options exercised	(4,775)	101.79
Options cancelled	(180,195)	114.37
Outstanding at September 30, 2021	<u>2,254,629</u>	<u>\$ 79.34</u>
Exercisable at September 30, 2021	1,392,219	\$ 61.07

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The total cash received by the Company as a result of stock option exercises was \$0.5 million and \$0.5 million, respectively, for the nine months ended September 30, 2021 and 2020. The weighted-average grant date fair values, based on the Black-Scholes option model, of options granted during the nine months ended September 30, 2021 and 2020 were \$75.71 and \$65.65, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense during the nine months ended September 30, 2021 and 2020 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock-based compensation expense by type of award:				
Stock options	\$ 6,241	\$ 5,061	\$20,517	\$15,596
Total stock-based compensation expense	\$ 6,241	\$ 5,061	\$20,517	\$15,596
Effect of stock-based compensation expense by line item:				
Research and development	\$ 2,622	\$ 2,266	\$ 8,120	\$ 6,633
General and administrative	3,619	2,795	12,397	8,963
Total stock-based compensation expense included in net loss	\$ 6,241	\$ 5,061	\$20,517	\$15,596

Unrecognized stock-based compensation expense on stock options as of September 30, 2021 was \$52.6 million with a weighted average remaining period of 2.85 years.

8. 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 earned by achieving specified objectives related to future regulatory approval in the United States and Europe of a product developed from resmetirom. A single-digit royalty payment range is based on net sales of products 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 nine months ended September 30, 2021 and 2020.

The Company has entered into customary contractual arrangements and letters of intent in support of its Phase 3 clinical trials.

9. Subsequent Event

Since the end of the third quarter through November 2, 2021, the Company sold 236,879 shares under the 2021 Sales Agreement (described in Note 6) for an aggregate of approximately \$19.4 million in gross proceeds. Net proceeds to the Company were approximately \$19.0 million after deducting commissions and other transaction costs. After giving effect to such sales as of November 2, 2021, approximately \$159.2 million remained reserved and available for sale under the 2021 Sales Agreement and the Company’s related prospectus supplement.

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 “allow,” “anticipates,” “appear,” “be,” “believes,” “continue,” “could,” “demonstrates,” “design,” “estimates,” “expects,” “forecasts,” “future,” “help,” “hopeful,” “inform,” “goal,” “intends,” “may,” “might,” “plans,” “potential,” “predicts,” “predictive,” “projects,” “seeks,” “should,” “will,” “will achieve,” “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, market trends, competitive position, industry environment and potential growth opportunities,
- Our clinical trials, research and development activities, and the timing and results associated with the future development of our lead product candidate, MGL-3196 (resmetirom), including sector leadership,
- The timing and completion of projected 2021 and 2022 clinical milestone events, including enrollment, top-line data and open label projections,
- Our primary and secondary study endpoints for resmetirom, and the potential for achieving such endpoints and projections, including non-alcoholic steatohepatitis (“NASH”) resolution, safety, fibrosis treatment, cardiovascular effects and lipid treatment with resmetirom,
- Optimal dosing levels for resmetirom and projections regarding potential NASH or nonalcoholic fatty liver disease (“NAFLD”) patient benefits with resmetirom,
- The predictive power of resmetirom liver fat reduction on NASH resolution with fibrosis reduction or improvement, and potential NASH or NAFLD patient risk profile benefits with resmetirom,
- The predictive power of liver fibrosis reduction with resmetirom using non-invasive tests and the predictive power of non-invasive tests generally, including for purposes of recruiting and conducting a NASH clinical trial,
- Market demand for and acceptance of our products,
- Research, development and commercialization of new products,
- 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) and/or timing 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 than our past trials,
- Risks related to our ability to accomplish our 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 development of resmetirom; enrollment uncertainties, generally and in relation to COVID-19 shelter-in-place and social distancing measures and individual precautionary measures that may be implemented or continued for an uncertain period of time; 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 than our prior studies; 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, 2020, filed with the SEC on February 25, 2021, as well as in our other filings with the SEC. You should read the 2020 Annual Report on Form 10-K, this Quarterly Report, and the other documents that we file or have

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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, 2020 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, 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 “Cautionary Note Regarding Forward-Looking Statements” in this Form 10-Q and in the “Risk Factors” sections contained in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 25, 2021. 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 focused on the development and commercialization of innovative therapeutic candidates for the treatment of cardiovascular, metabolic, and liver diseases. Our lead product candidate, MGL-3196 (resmetirom), is a proprietary, liver-directed, selective thyroid hormone receptor- β , or THR- β , agonist being developed as a once-daily oral pill that can potentially be used to treat a number of disease states with high unmet medical need, including non-alcoholic steatohepatitis, or 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 2016, in the United States alone, NAFLD was estimated to affect approximately 26% of the population, or an estimated 85 million people, and approximately 20% of this population was projected to progress from NAFLD to NASH. Current estimates place NASH prevalence at approximately 17 million people in the United States, or five percent of the population. Slightly lower prevalence is seen in the EU and Asia, with approximately 2.5-4.5% of the population having NASH.

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. We also completed a 116 patient Phase 2 clinical trial and announced results in February 2018 for the use of resmetirom in patients with heterozygous familial hypercholesterolemia, or HeFH. In addition to the NASH and HeFH Phase 2 clinical trials, resmetirom has also been studied in multiple completed Phase 1 trials in a total of more than 300 subjects. Resmetirom appeared to be safe and was well-tolerated in these trials, which included a single ascending dose trial, a multiple ascending dose trial, several drug interaction studies, a multiple dose mass balance study, a single dose relative bioavailability study of tablet formulation versus capsule formulation, a multiple dose drug interaction study, a multiple dose drug interaction with food effect study, and a hepatic impairment study.

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 200 sites in the United States and the rest of the world. Patients with liver biopsy confirmed NASH with stage 2 or 3 fibrosis are being randomized 1:1:1 to receive a single oral daily dose of placebo, resmetirom 80 mg or resmetirom 100 mg. A second liver biopsy at week 52 in the first 900 patients will be the basis of filing for Subpart H-accelerated approval; the primary endpoint will be the percent of patients treated with either dose of resmetirom as compared with placebo who achieve NASH resolution on the week 52 liver biopsy, defined as the absence of hepatocyte ballooning (score=0), and minimal lobular inflammation (score 0-1), associated with at least a 2-point reduction in NAS (NAFLD Activity Score), and no worsening of fibrosis stage. Two key secondary endpoints are reduction in LDL-cholesterol and a 1-point or more improvement in fibrosis stage on the week 52 biopsy with no worsening of NASH. Patients will continue in the study for a total of approximately 54 months, and will be evaluated for a composite clinical outcome including cirrhosis on liver biopsy, or a liver related event such as hepatic decompensation. The total anticipated enrollment is approximately 2,000 patients, and will include up to 15% high risk F1 fibrosis stage NASH patients whose efficacy responses will be evaluated as exploratory

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endpoints. On June 30, 2021 we announced our achievement of the requisite enrollment of patients to support the planned Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) submission to the US Food and Drug Administration (FDA). 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 with resmetirom doses of 80 mg or 100 mg or placebo. In October 2020, we completed enrollment of the double-blind, placebo-controlled arms of the study. Enrollment objectives for this study have been 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 NASH in patients with F2 or F3 fibrosis (MAESTRO-NASH, NASH resolution surrogate endpoint). 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.

COVID-19 Pandemic Effects on Madrigal

In April 2020 we announced that in response to guidance from regulatory agencies, measures for COVID-19 at impacted sites have been put in place for our Phase 3 MAESTRO-NASH and MAESTRO-NAFLD-1 studies, allowing both studies to continue without changes to the protocol. At a recently conducted Data Monitoring Committee (DMC) meeting it was recommended that Phase 3 studies proceed without modification. The COVID-19 pandemic had no material adverse impact on our operating results, MAESTRO-NAFLD-1 study or liquidity for the period ended September 30, 2021 and year ended December 31, 2020, but it did introduce clinical trial and operational risks and uncertainties that are both general in nature and relate specifically to our MAESTRO-NASH study. These risks and uncertainties, which are beyond our control, are summarized in the section entitled “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 25, 2021.

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 2021 and 2020 and we expect that our research and development expenses will increase substantially 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.

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General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation expenses for non-R&D employees, management costs, costs associated with obtaining and maintaining our patent portfolio, professional fees for accounting, auditing, consulting and legal services, liability insurance, and allocated overhead expenses. We expect that our general and administrative expenses may increase in the future as we advance our clinical and preclinical development programs for resmetirom and expand our operating activities, including substantially expanding our workforce for commercial hires, and maintaining and expanding our patent portfolio. We expect these potential increases will likely include management and personnel 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 nine months ended September 30, 2021, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC on February 25, 2021.

Results of Operations

Three months Ended September 30, 2021 and 2020

The following table provides comparative unaudited results of operations for the three months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Increase / (Decrease)	
	2021	2020	\$	%
Research and development Expenses	\$ 54,873	\$ 53,292	1,581	3%
General and administrative Expenses	8,287	5,494	2,793	51%
Interest (income)	(60)	(823)	(763)	(93%)
	\$ 63,100	\$ 57,963	5,137	9%

Revenue

We had no revenue for the three months ended September 30, 2021 and 2020.

Research and Development Expenses

Our research and development expenses were \$54.9 million for the three months ended September 30, 2021, compared to \$53.3 million in the corresponding period in 2020. Research and development expenses increased by \$1.6 million in the 2021 period due primarily to the additional activities related to the Phase 3 clinical trials, and an increase in head count. We expect our research and development expenses to increase over time as we advance our clinical and preclinical development programs for resmetirom.

General and Administrative Expenses

Our general and administrative expenses were \$8.3 million for the three months ended September 30, 2021, compared to \$5.5 million in the corresponding period in 2020. General and administrative expenses increased by \$2.8 million in the 2021 period due primarily to increases in commercial preparation activities, including a corresponding increase in head count, 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 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 \$0.1 million for the three months ended September 30, 2021, compared to \$0.8 million in the corresponding period in 2020. The decrease in interest income was due primarily to decreased interest rates over the period.

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Nine months Ended September 30, 2021 and 2020

The following table provides comparative unaudited results of operations for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine Months Ended September 30,		Increase / (Decrease)	
	2021	2020	\$	%
Research and development Expenses	\$ 152,275	\$ 131,380	20,895	16%
General and administrative Expenses	25,606	15,738	9,868	63%
Interest (Income)	(311)	(3,897)	(3,586)	(92%)
Other (income)	(273)	(100)	173	173%
	<u>\$ 177,297</u>	<u>\$ 143,121</u>	<u>34,176</u>	<u>24%</u>

Revenue

We had no revenue for the nine months ended September 30, 2021 and 2020.

Research and Development Expenses

Our research and development expenses were \$152.3 million for the nine months ended September 30, 2021, compared to \$131.4 million in the corresponding period in 2020. Research and development expenses increased by \$20.9 million in the 2021 period due primarily to the additional activities related to the Phase 3 clinical trials, an increase in head count, and an increase in stock compensation expense. We expect our research and development expenses to increase over time as we advance our clinical and preclinical development programs for resmetrom.

General and Administrative Expenses

Our general and administrative expenses were \$25.6 million for the nine months ended September 30, 2021, compared to \$15.8 million in the corresponding period in 2020. General and administrative expenses increased by \$9.9 million in the 2021 period due primarily to increases in commercial preparation activities, including a corresponding increase in head count, 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 resmetrom, which will likely result in an increase in our headcount, commercially related activities, consulting services, and related overhead needed to support those efforts.

Interest Income

Our net interest income was \$0.3 million for the nine months ended September 30, 2021, compared to \$3.9 million in the corresponding period in 2020. The decrease in interest income was due primarily to decreased interest rates over the period.

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 capital stock. Our most significant use of capital pertains to salaries and benefits for our employees, including clinical, scientific, operational, commercial, financial and management personnel, and external research and development expenses, such as clinical trials and preclinical activity related to our product candidates.

As of September 30, 2021, we had cash, cash equivalents and marketable securities totaling \$299.1 million compared to \$284.1 million as of December 31, 2020, with the increase attributable to net proceeds of \$151.2 million raised from the sale of 1,347,290 shares under our at-the-market (ATM) sales agreements, partially offset by funding of operations. 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, we believe our available cash resources as of September 30, 2021 will be sufficient to fund our operations past one year from the issuance of the financial statements contained herein, and this outlook takes into account circumstances that are currently reasonably foreseeable in connection with the COVID-19 pandemic. For a description of COVID-19 pandemic risks, including risks and uncertainties beyond our control, see Part I, Item 1A, "Risk Factors" on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 25, 2021. Our future long-term liquidity requirements will be substantial and will depend on many factors. To meet future long-term liquidity requirements, we will need to and intend to raise additional capital to fund our operations, primarily through equity or debt financings. 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. This includes, but is not limited to, the use of the \$200 million at-the-market sales agreement. Additional capital may not be available on terms acceptable to us, or at all. 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 non-equity financing may include covenants that restrict our business.

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Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	\$ (135,866)	\$ (102,614)
Net cash (used in) provided by investing activities	(20,698)	164,578
Net cash provided by financing activities	151,734	459
Net (decrease) increase in cash and cash equivalents	\$ (4,830)	\$ 62,423

Net cash used in operating activities was \$135.9 million for the nine months ended September 30, 2021, compared to \$102.6 million for the corresponding period in 2020. 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 \$20.7 million for the nine months ended September 30, 2021, compared to \$164.6 million provided for the corresponding period in 2020. Net cash used in investing activities for the nine months ended September 30, 2021 consisted of \$339.4 million of purchases of marketable securities for our investment portfolio and \$0.1 million of purchases of property and equipment, partially offset by \$318.8 million from sales and maturities of marketable securities. Net cash provided by investing activities for the nine months ended September 30, 2020 consisted of \$378.1 million from sales and maturities of marketable securities, partially offset by \$213.2 million of purchases of marketable securities for our investment portfolio and \$0.3 million of purchases of property and equipment.

Net cash provided by financing activities was \$151.7 million for the nine months ended September 30, 2021, which consisted of \$151.2 million from net proceeds from issuances of stock under our At The Market (ATM) sales agreements and \$0.5 million of proceeds from the exercise of stock options. Financing activities for the corresponding period in 2020 consisted of proceeds from the exercise of stock options.

Contractual Obligations and Commitments

No significant changes to contractual obligations and commitments occurred during the nine months ended September 30, 2021, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC on February 25, 2021.

Off-Balance Sheet Arrangements

We do not have any off balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

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. 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.

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, 2020, filed with the SEC on February 25, 2021.

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	
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.

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: November 4, 2021

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

Date: November 4, 2021

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

**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: November 4, 2021

**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

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: November 4, 2021

**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 September 30, 2021 (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: November 4, 2021

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

Paul A. Friedman, M.D.

Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

Dated: November 4, 2021

/s/ Alex G. Howarth

Alex G. Howarth

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.