

**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, 2019

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

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 01, 2019, the registrant had 15,429,154 shares of common stock outstanding.

MADRIGAL PHARMACEUTICALS, INC.

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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)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 89,486	\$ 57,379
Marketable securities	364,124	426,339
Prepaid expenses and other current assets	1,712	1,483
Total current assets	455,322	485,201
Property and equipment, net	181	227
Right-of-use asset	751	—
Total assets	<u>\$ 456,254</u>	<u>\$ 485,428</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 773	\$ 2,487
Accrued expenses	14,381	5,957
Lease liability	310	—
Total current liabilities	15,464	8,444
Long term liabilities:		
Lease liability	441	—
Total long term liabilities	441	—
Total liabilities	15,905	8,444
Stockholders' equity:		
Preferred stock, par value \$0.0001 per share authorized: 5,000,000 shares at September 30, 2019 and December 31, 2018; 1,969,797 shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, par value \$0.0001 per share authorized: 200,000,000 at September 30, 2019 and December 31, 2018; 15,429,154 and 15,409,023 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	2	2
Additional paid-in-capital	635,535	616,573
Accumulated other comprehensive gain (loss)	292	(319)
Accumulated deficit	(195,480)	(139,272)
Total stockholders' equity	440,349	476,984
Total liabilities and stockholders' equity	<u>\$ 456,254</u>	<u>\$ 485,428</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>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenues:				
Total revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	19,447	6,211	47,414	16,518
General and administrative	4,748	5,122	17,604	9,710
Total operating expenses	<u>24,195</u>	<u>11,333</u>	<u>65,018</u>	<u>26,228</u>
Loss from operations	(24,195)	(11,333)	(65,018)	(26,228)
Interest income	2,766	2,821	8,810	4,692
Other income	—	—	—	200
Net loss	<u>\$ (21,429)</u>	<u>\$ (8,512)</u>	<u>\$ (56,208)</u>	<u>\$ (21,336)</u>
Net loss per common share:				
Basic and diluted net loss per common share	\$ (1.39)	\$ (0.56)	\$ (3.65)	\$ (1.46)
Basic and diluted weighted average number of common shares outstanding	15,415,096	15,307,872	15,383,034	14,610,809

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Net Loss	\$ (21,429)	\$ (8,512)	\$ (56,208)	\$ (21,336)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	(193)	(100)	611	(112)
Comprehensive loss	<u>\$ (21,622)</u>	<u>\$ (8,612)</u>	<u>\$ (55,597)</u>	<u>\$ (21,448)</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, 2018	1,969,797	\$ —	15,409,023	\$ 2	\$616,573	\$ (319)	\$ (139,272)	\$ 476,984
Exercise of common stock options	—	—	8,041	—	83	—	—	83
Compensation expense related to stock options for services	—	—	—	—	6,022	—	—	6,022
Unrealized gain on marketable securities	—	—	—	—	—	497	—	497
Net loss	—	—	—	—	—	—	(15,080)	(15,080)
Balance at March 31, 2019	1,969,797	\$ —	15,417,064	\$ 2	\$622,678	\$ 178	\$ (154,352)	\$ 468,506
Exercise of common stock options	—	—	9,233	—	117	—	—	117
Compensation expense related to stock options for services	—	—	—	—	7,755	—	—	7,755
Unrealized gain on marketable securities	—	—	—	—	—	307	—	307
Net loss	—	—	—	—	—	—	(19,699)	(19,699)
Balance at June 30, 2019	1,969,797	\$ —	15,426,297	\$ 2	\$630,550	\$ 485	\$ (174,051)	\$ 456,986
Exercise of common stock options	—	—	2,857	—	35	—	—	35
Compensation expense related to stock options for services	—	—	—	—	4,950	—	—	4,950
Unrealized gain on marketable securities	—	—	—	—	—	(193)	—	(193)
Net loss	—	—	—	—	—	—	(21,429)	(21,429)
Balance at September 30, 2019	<u>1,969,797</u>	<u>\$ —</u>	<u>15,429,154</u>	<u>\$ 2</u>	<u>\$635,535</u>	<u>\$ 292</u>	<u>\$ (195,480)</u>	<u>\$ 440,349</u>
Balance at December 31, 2017	1,969,797	\$ —	14,227,634	\$ 1	\$288,750	\$ (31)	\$ (106,461)	\$ 182,259
Exercise of common stock options	—	—	23,092	—	265	—	—	265
Compensation expense related to stock options for services	—	—	—	—	1,167	—	—	1,167
Unrealized loss on marketable securities	—	—	—	—	—	(143)	—	(143)
Net loss	—	—	—	—	—	—	(6,364)	(6,364)
Balance at March 31, 2018	1,969,797	\$ —	14,250,726	\$ 1	\$290,182	\$ (174)	\$ (112,825)	\$ 177,184
Exercise of common stock options	—	—	35,078	—	1,185	—	—	1,185
Issuance of common shares in equity offering, excluding related parties, net of transaction costs	—	—	1,079,580	1	311,824	—	—	311,825
Compensation expense related to stock options for services	—	—	—	—	2,227	—	—	2,227
Unrealized gain on marketable securities	—	—	—	—	—	131	—	131
Net loss	—	—	—	—	—	—	(6,460)	(6,460)
Balance at June 30, 2018	1,969,797	\$ —	15,365,384	\$ 2	\$605,418	\$ (43)	\$ (119,285)	\$ 486,092
Exercise of common stock options	—	—	27,925	—	451	—	—	451
Compensation expense related to stock options for services	—	—	—	—	4,976	—	—	4,976
Unrealized gain on marketable securities	—	—	—	—	—	(100)	—	(100)
Net loss	—	—	—	—	—	—	(8,512)	(8,512)
Balance at September 30, 2018	<u>1,969,797</u>	<u>\$ —</u>	<u>15,393,309</u>	<u>\$ 2</u>	<u>\$610,845</u>	<u>\$ (143)</u>	<u>\$ (127,797)</u>	<u>\$ 482,907</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>
Cash flows from operating activities:		
Net loss	\$ (56,208)	\$ (21,336)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	18,727	8,370
Depreciation and amortization expense	84	71
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(229)	(281)
Accounts payable	(1,714)	(898)
Accrued expense	8,424	(2,514)
Accrued interest, net of interest received on maturity of investments	1,574	(2,654)
Net cash used in operating activities	<u>(29,342)</u>	<u>(19,242)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(407,073)	(524,935)
Sales and maturities of marketable securities	468,325	119,885
Purchases of property and equipment, net of disposals	(38)	(14)
Net cash provided by (used in) investing activities	<u>61,214</u>	<u>(405,064)</u>
Cash flows from financing activities:		
Proceeds from issuances of stock, excluding related parties, net of transaction costs	—	311,825
Proceeds from the exercise of common stock options	235	1,900
Net cash provided by financing activities	<u>235</u>	<u>313,725</u>
Net increase (decrease) in cash and cash equivalents	<u>32,107</u>	<u>(110,581)</u>
Cash and cash equivalents at beginning of period	57,379	148,627
Cash and cash equivalents at end of period	<u>\$ 89,486</u>	<u>\$ 38,046</u>
Supplemental disclosure of cash flow information:		
Obtaining a right-of-use asset in exchange for a lease liability	\$ 900	\$ —

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 a Phase 2 study of resmetirom in NASH in October 2016. In February 2017, the Company initiated a Phase 2 study of resmetirom in patients with Heterozygous Familial Hypercholesterolemia (“HeFH”). Both Phase 2 studies were fully enrolled in 2017, the HeFH study was completed in February 2018, and the NASH study was completed in May 2018. The Company initiated a Phase 3 study of resmetirom in NASH in March 2019.

Madrigal was originally incorporated as a private company (“Private Madrigal”) on August 19, 2011 and operations commenced in September 2011. On July 22, 2016, Private Madrigal completed a reverse merger (the “Merger”) into Synta Pharmaceuticals Corp. (“Synta”). Upon the consummation of the Merger, the historical financial statements of Private Madrigal became the Company’s historical financial statements.

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 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, 2019 or any subsequent period. These unaudited condensed 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, 2018.

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.

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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 other-than-temporary on available-for-sale securities are reported as a component of interest income, net. 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 three and nine months ended September 30, 2019 and 2018, 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 and nine months ended September 30, 2019 and 2018, 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, 2019, the Company's financial assets valued based on Level 1 inputs consisted of cash and cash equivalents in a money market fund and its financial assets valued based on Level 2 inputs consisted of high-grade corporate bonds and commercial paper. During the three and nine months ended September 30, 2019 and 2018, the Company did not have any transfers of financial assets between Levels 1 and 2. As of September 30, 2019 and December 31, 2018, 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. Significant judgment and estimates are made in determining the amount of research and development costs recognized in each reporting period. The Company analyzes the progress of its clinical trials, completion of milestones under its license agreements, invoices received and contracted costs when estimating research and development costs. Actual results could differ from the Company's estimates. The Company's historical estimates for research and development costs have not been materially different from the actual costs.

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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 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 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, 2019 and 2018, 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:

	Three and Nine Months Ended September 30,	
	2019	2018
Common Stock Options	1,461,237	1,123,582
Unvested Restricted Common Stock	—	52,063
Preferred Stock	1,969,797	1,969,797

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, "Leases," which, together with amendments comprising ASC 842, requires lessees to identify arrangements that should be accounted for as leases and generally recognized, for operating and finance leases with terms exceeding twelve months, a right-of-use asset (or "ROU") and lease liability on the balance sheet. For public business entities,

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ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018, with early adoption permitted. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. The Company adopted ASU 2016-02 effective January 1, 2019. There was no significant retrospective impact from the adoption. The new standard provides a number of optional practical expedients in transition. We have elected the package of practical expedients, which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. The new standard also provides practical expedients for an entity's ongoing accounting. We have elected the short-term lease exception and we will not recognize ROU assets or lease liabilities for qualifying leases (leases with a term of less than 12 months from lease commencement). In 2019, the Company accounted for a new lease under the guidance (see Note 8).

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 \$56.2 million for the nine months ended September 30, 2019, resulting in an accumulated deficit of approximately \$195.5 million as of September 30, 2019. Management expects to incur losses for the foreseeable future. To date, the Company has funded its operations primarily through the issuance of convertible debt, the proceeds from the Merger on July 22, 2016, and proceeds from sales of the Company's equity securities.

The Company believes that its cash, cash equivalents and marketable securities at September 30, 2019 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 September 30, 2019 and December 31, 2018 is as follows (in thousands):

	September 30, 2019			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash and cash equivalents:				
Cash (Level 1)	\$ 1,975	\$ —	\$ —	\$ 1,975
Money market funds (Level 1)	87,511	—	—	87,511
Corporate debt securities due within 3 months of date of purchase (Level 2)	—	—	—	—
Total cash and cash equivalents	89,486	—	—	89,486
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	278,707	264	(9)	278,962
Corporate debt securities due within 1 to 2 years of date of purchase (Level 2)	85,125	59	(22)	85,162
Total cash, cash equivalents and marketable securities	<u>\$453,318</u>	<u>\$ 323</u>	<u>\$ (31)</u>	<u>\$453,610</u>

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	December 31, 2018			Fair value
	Cost	Unrealized gains	Unrealized losses	
Cash and cash equivalents:				
Cash (Level 1)	\$ 2,004	\$ —	\$ —	\$ 2,004
Money market funds (Level 1)	43,401	—	—	43,401
Corporate debt securities due within 3 months of date of purchase (Level 2)	11,974	—	—	11,974
Total cash and cash equivalents	<u>57,379</u>	<u>—</u>	<u>—</u>	<u>57,379</u>
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	426,658	14	(333)	426,339
Total cash, cash equivalents and marketable securities	<u>\$484,037</u>	<u>\$ 14</u>	<u>\$ (333)</u>	<u>\$483,718</u>

5. Accrued Liabilities

Accrued liabilities as of September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued contract research costs	\$ 7,882	\$ 571
Compensation and benefits	1,936	1,797
Other	4,563	3,589
	<u>\$ 14,381</u>	<u>\$ 5,957</u>

6. 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 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.

June 2018 Registered Offering of Common Stock

In June 2018, the Company entered into an underwriting agreement with Goldman Sachs & Co. LLC, as representative of the several underwriters named therein (the "June 2018 Underwriters"), relating to an underwritten public offering (the "June 2018 Offering") of 1,079,580 shares of the Company's common stock, including 95,973 shares of the Company's common stock purchased by the June 2018 Underwriters pursuant to a 30-day option to purchase such additional shares granted therein, at a public offering price of \$305.00 per share. The June 2018 Offering resulted in net proceeds to the Company of approximately \$311.8 million, after deducting the June 2018 Underwriters' discount and other offering costs. The June 2018 Offering closed on June 11, 2018.

7. Stock-based Compensation

The 2015 Stock Plan, as amended, is our primary plan through which equity based grants are awarded. We ceased making new awards under the 2006 Stock Plan upon adoption of the 2015 Stock Plan. 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. As of September 30, 2019, the Company had options outstanding to purchase 1,461,237 shares of its common stock, which includes options outstanding under its 2006 Stock Plan. As of September 30, 2019, 1,352,095 shares were available for future issuance.

The following table summarizes stock option activity during the nine months ended September 30, 2019:

	<u>Shares</u>	<u>Weighted average exercise price</u>
Outstanding at January 1, 2019	1,132,618	\$ 48.52
Options granted	369,500	119.29
Options exercised	(20,131)	11.67
Options cancelled	(20,750)	173.79
Outstanding at September 30, 2019	<u>1,461,237</u>	<u>\$ 65.15</u>
Exercisable at September 30, 2019	922,149	\$ 40.55

The total cash received by the Company as a result of stock option exercises was \$0.2 million and \$1.9 million, respectively, for the nine months ended September 30, 2019 and 2018. The weighted-average grant date fair values, based on the Black-Scholes option model, of options granted during the nine months ended September 30, 2019 and 2018 were \$91.65 and \$136.43, respectively.

Restricted Common Stock

The Company's share-based compensation plan provides for awards of restricted shares of common stock to employees, officers, directors and consultants to the Company. Restricted stock awards are subject to forfeiture if employment or service terminates during the prescribed retention period. Restricted shares vest over the service period.

The following table summarizes unvested restricted share activity during the nine months ended September 30, 2019:

	<u>Shares</u>	<u>Weighted average exercise price</u>
Outstanding at January 1, 2019	52,063	\$ 9.45
Vested	(52,063)	9.45
Outstanding at September 30, 2019	<u>—</u>	<u>\$ —</u>

[Table of Contents](#)**Stock-Based Compensation Expense**

Stock-based compensation expense during the three and nine months ended September 30, 2019 and 2018 was as follows (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Stock-based compensation expense by type of award:				
Stock options	\$ 4,922	\$ 4,852	\$ 18,455	\$ 8,002
Restricted stock	28	124	272	368
Total stock-based compensation expense	<u>\$ 4,950</u>	<u>\$ 4,976</u>	<u>\$ 18,727</u>	<u>\$ 8,370</u>
Effect of stock-based compensation expense by line item:				
Research and development	\$ 2,404	\$ 1,179	\$ 6,647	\$ 2,287
General and administrative	2,546	3,797	12,080	6,083
Total stock-based compensation expense included in net loss	<u>\$ 4,950</u>	<u>\$ 4,976</u>	<u>\$ 18,727</u>	<u>\$ 8,370</u>

Unrecognized stock-based compensation expense as of September 30, 2019 was as follows (in thousands):

	<u>Unrecognized stock compensation expense</u>	<u>Weighted average remaining period (in years)</u>
Stock options	\$ 35,429	2.86
Restricted stock	—	—
Total	<u>\$ 35,429</u>	<u>2.86</u>

8. Leases

In 2019, the Company entered into an operating lease for office space. As described within Note 2, we adopted ASU 2016-02, "Leases," on January 1, 2019 requiring, among other changes, operating and finance leases with terms exceeding twelve months to be recognized as ROU assets and lease liabilities on the balance sheet. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The lease term is determined to be the non-cancelable period including any lessee renewal options that are considered reasonably certain of exercise. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company used judgment to determine an appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term in a similar economic environment.

Future minimum payments under the Company's operating leases related to the ROU asset and lease liability as of September 30, 2019 was as follows (in thousand):

	<u>Operating Leases</u>
2019	\$ 89
2020	363
2021	371
2022	31
Thereafter	—
Total minimum payments	\$ 854
Less: imputed interest	103
Present value of lease liabilities	\$ 751

As of September 30, 2019, the weighted average remaining operating lease term was 2.3 years and the weighted average discount rate used to determine the operating lease liabilities was 5.5%. Operating lease costs were \$93 thousand and \$267 thousand, short-term lease costs were \$23 thousand and \$138 thousand, and there were no variable lease costs for the three and nine months ended September 30, 2019, respectively.

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. In 2019, the Company commenced a Phase 3 study in Non-Alcoholic Steatohepatitis (NASH), which triggered a \$2 million milestone payment under the agreement. 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 MGL-3196 (resmetirom). A single-digit royalty payment range is based on net sales of products developed from resmetirom, subject to certain reductions. Except as described above, 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, 2019 and 2018.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains 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. Forward-looking statements include but are not limited to statements or references concerning: our clinical trials, research and development activities, the timing and results associated with the future development of our lead product candidate, MGL-3196 (resmetirom); our primary and secondary study endpoints for resmetirom and the potential for achieving such endpoints; optimal dosing levels for resmetirom; projections regarding potential future NASH resolution, fibrosis treatment, cardiovascular effects and lipid treatment; the achievement of enrollment objectives concerning patient number and/or timing for our studies; potential NASH or NAFLD patient risk profile benefits; our possible or assumed future results of operations and expenses, business strategies and plans, capital needs and financing plans, trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things. 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 "anticipates," "be," "believes," "continue," "could," "estimates," "expects," "future," "intends," "may," "might," "plans," "potential," "predicts," "projects," "seeks," "should," "will," "would" or similar expressions and the negatives of those terms. 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: the company's clinical development of resmetirom; enrollment uncertainties; outcomes or trends from competitive studies; the risks of achieving potential benefits in a study that includes substantially more patients than our prior study; the timing and outcomes of clinical studies of resmetirom; the uncertainties inherent in clinical testing; and the risks affecting our development objectives, business, financial condition, prospects and resources, as set forth in detail under "Risk Factors" as disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the SEC on February 27, 2019. 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 also refer to Madrigal's past and future filings 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.

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, 2018 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 the section entitled "Special Note Regarding Forward-Looking Statements" included elsewhere in this report. 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 the United States alone, NAFLD is estimated to affect approximately 27% to 34% of the population, or an estimated 86 million to 108 million people, and approximately 10% to 20% of this population is projected to progress from NAFLD to NASH. Current estimates place NASH prevalence at approximately 9 million to 15 million people in the United States, or three percent to five percent of the population, with similar prevalence in Europe and Asia.

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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 have completed treatment in a 36-week, open-label extension study in 31 participating NASH patients from our Phase 2 clinical trial, which includes 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 eight completed Phase 1 trials in a total of 219 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, two drug interaction trials with statins, a multiple dose mass balance study, a single dose relative bioavailability study of tablet formulation versus capsule formulation, a multiple dose drug interaction study, and a multiple dose drug interaction with food effect study.

Our Ongoing and Planned Studies. On March 28, 2019, the Company announced that it had initiated a Phase 3 trial in NASH with its once daily, oral thyroid hormone receptor beta selective agonist, resmetirom. This double-blind, placebo-controlled study will be conducted at more than 150 sites in the United States and the rest of the world. Patients with liver biopsy confirmed NASH with stage 2 or 3 fibrosis will be 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, 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 a 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 endpoints. We are also planning a second Phase 3 trial in NASH and NAFLD patients to further assess effects on LDL-cholesterol, other atherogenic lipids, biomarkers of fibrosis, MRI-PDFF and fibroscans to better characterize potential clinical benefits of resmetirom on cardiovascular and liver related endpoints using noninvasive measures.

Recent Developments

Initiation of Phase 3 clinical trial in NASH

In March of 2019 we initiated a Phase 3 trial in NASH, described in detail above under “About Madrigal; Our Ongoing and Planned Studies.” In the second quarter, the Phase 3 NASH trial triggered a \$2 million milestone payment under our Research, Development and Commercialization Agreement with Hoffmann-La Roche (“Roche”).

FDA grants Fast Track designation for resmetirom in NASH

In October 2019, FDA granted Fast Track designation to resmetirom for NASH.

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 costs 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 providers 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;

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- 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 year over year in each of 2019 and 2018 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 early research programs, results of ongoing and future clinical trials, our ability to enter into 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 may increase in the future as we expand our operating activities, 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 nine months ended September 30, 2019, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the SEC on February 27, 2019.

[Table of Contents](#)**Results of Operations****Three Months Ended September 30, 2019 and 2018**

The following table provides comparative unaudited results of operations for the three months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Increase / (Decrease)	
	2019	2018	\$	%
Research and Development Expenses	\$19,447	\$ 6,211	13,236	213%
General and Administrative Expenses	4,748	5,122	(374)	(7%)
Interest Expense (Income)	(2,766)	(2,821)	(55)	(2%)
Other (income)	—	—	—	—
	<u>\$21,429</u>	<u>\$ 8,512</u>	<u>12,917</u>	<u>152%</u>

Revenue

We had no revenue for the three months ended September 30, 2019 and 2018.

Research and Development Expenses

Our research and development expenses were \$19.4 million for the three months ended September 30, 2019, compared to \$6.2 million in the corresponding period in 2018. Research and development expenses increased by \$13.2 million in the 2019 period due primarily to the additional activities related to the initiation of the Phase 3 clinical trial in NASH, an increase in head count, and an increase in non-cash stock compensation from stock option awards. We expect our research and development expenses to increase over time as we advance our clinical and preclinical development programs for MGL-3196 (resmetirom).

General and Administrative Expenses

Our general and administrative expenses were \$4.7 million for the three months ended September 30, 2019, compared to \$5.1 million in the corresponding period in 2018. General and administrative expenses decreased by \$0.4 million in the 2019 period due primarily to a decrease in non-cash stock compensation from stock option awards, partially offset by increases in other general and administrative expenses. We believe our general and administrative expenses may increase over time as we advance our clinical and preclinical development programs for MGL-3196 (resmetirom), 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 \$2.8 million for the three months ended September 30, 2019, compared to \$2.8 million in the corresponding period in 2018.

Nine Months Ended September 30, 2019 and 2018

The following table provides comparative unaudited results of operations for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,		Increase / (Decrease)	
	2019	2018	\$	%
Research and Development Expenses	\$47,414	\$16,518	30,896	187%
General and Administrative Expenses	17,604	9,710	7,894	81%
Interest Expense (Income)	(8,810)	(4,692)	4,118	88%
Other (income)	—	(200)	(200)	(100%)
	<u>\$56,208</u>	<u>\$21,336</u>	<u>34,872</u>	<u>163%</u>

Revenue

We had no revenue for the nine months ended September 30, 2019 and 2018.

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Research and Development Expenses

Our research and development expenses were \$47.4 million for the nine months ended September 30, 2019, compared to \$16.5 million in the corresponding period in 2018. Research and development expenses increased by \$30.9 million in the 2019 period due primarily to the additional activities related to the initiation of the Phase 3 clinical trial in NASH, including a payment due related to a milestone achieved under our agreement with Roche, an increase in head count, and an increase in non-cash stock compensation from stock option awards. We expect our research and development expenses to increase over time as we advance our clinical and preclinical development programs for MGL-3196 (resmetirom).

General and Administrative Expenses

Our general and administrative expenses were \$17.6 million for the nine months ended September 30, 2019, compared to \$9.7 million in the corresponding period in 2018. General and administrative expenses increased by \$7.9 million in the 2019 period due primarily to an increase in non-cash stock compensation from stock option awards. We believe our general and administrative expenses may increase over time as we advance our clinical and preclinical development programs for MGL-3196 (resmetirom), 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 \$8.8 million for the nine months ended September 30, 2019, compared to \$4.7 million in the corresponding period in 2018. The increase in interest income was due primarily to a higher average principal balance in our investment account in 2019.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and we have funded our operations primarily through the issuance of convertible debt, the issuance of shares of our common stock and shares of our preferred stock, and the proceeds from the Merger. 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 September 30, 2019, we had cash, cash equivalents and marketable securities totaling \$453.6 million compared to \$483.7 million as of December 31, 2018, with the decrease primarily attributable to our net operating loss. 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 may 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, 2019 will be sufficient to fund our operations past one year from the issuance of the financial statements contained herein. Future capital requirements will be substantial and will depend on many factors. To meet future capital requirements, we will need to raise additional capital to fund our operations through equity or debt financing. 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. 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 could 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.

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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,	
	2019	2018
Net cash used in operating activities	\$ (29,342)	\$ (19,242)
Net cash (used in) provided by investing activities	61,214	(405,064)
Net cash provided by financing activities	235	313,725
Net increase (decrease) in cash and cash equivalents	\$ 32,107	\$ (110,581)

Net cash used in operating activities was \$29.3 million for the nine months ended September 30, 2019, compared to \$19.2 million for the corresponding period in 2018. 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 provided by investing activities was \$61.2 million for the nine months ended September 30, 2019, compared to \$405.1 million used in investing activities for the corresponding period in 2018. Net cash provided by investing activities for the nine months ended September 30, 2019 consisted of \$468.3 million from sales and maturities of marketable securities, partially offset by \$407.1 million of purchases of marketable securities for our investment portfolio. Net cash used by investing activities for the nine months ended September 30, 2018 consisted of \$524.9 million of purchases of marketable securities for our investment portfolio, partially offset by \$119.9 million from sales and maturities of marketable securities.

Net cash provided by financing activities was \$0.2 million for the nine months ended September 30, 2019, compared to \$313.7 million for the corresponding period in 2018. Net cash provided by financing activities for the nine months ended September 30, 2019 consisted of proceeds from exercise of stock options. Net cash provided by financing activities for the nine months ended September 30, 2018 consisted of net proceeds from the issuance of common stock pursuant to the June 2018 Offering and 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, 2019, as compared to those disclosed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed with the SEC on May 8, 2019.

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 an effective 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 our Annual Report on Form 10-K for the annual period ended December 31, 2018.

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	XBRL Instance Document—the instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.				X	

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101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101).	

* Certain portions of this exhibit have been redacted in accordance with Item 601(b)(10) of Regulation S-K.

** 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 6, 2019

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

Paul A. Friedman, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2019

By: /s/ Marc R. Schneebaum

Marc R. Schneebaum
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 6, 2019

**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, Marc R. Schneebaum, 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/ Marc R. Schneebaum

Marc R. Schneebaum
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 6, 2019

**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, 2019 (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 6, 2019

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

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

Dated: November 6, 2019

/s/ Marc R. Schneebaum

Marc R. Schneebaum
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.