
**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 June 30, 2018

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 400
West Conshohocken, Pennsylvania
(Address of principal executive offices)

19428
(Zip Code)

Registrant's telephone number, including area code: **(484) 380-9263**

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	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 August 2, 2018, the registrant had 15,366,634 shares of common stock outstanding.

MADRIGAL PHARMACEUTICALS, INC.

TABLE OF CONTENTS

<u>Item</u>	<u>Description</u>	<u>Page</u>
	<u>Part I. Financial Information</u>	3
<u>Item 1.</u>	<u>Financial Statements (Unaudited):</u>	3
	<u>Condensed Consolidated Balance Sheets at June 30, 2018 and December 31, 2017</u>	3
	<u>Condensed Consolidated Statements of Operations for the Three Months and Six Months Ended June 30, 2018 and 2017</u>	4
	<u>Condensed Consolidated Statements of Comprehensive Loss for the Three Months and Six Months Ended June 30, 2018 and 2017</u>	5
	<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2018 and 2017</u>	6
	<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
<u>Item 4.</u>	<u>Controls and Procedures</u>	20
	<u>Part II. Other Information</u>	21
<u>Item 1.</u>	<u>Legal Proceedings</u>	21
<u>Item 1A.</u>	<u>Risk Factors</u>	21
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	41
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	41
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	41
<u>Item 5.</u>	<u>Other Information</u>	41
<u>Item 6.</u>	<u>Exhibits</u>	41
	<u>Signatures</u>	43

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 264,861	\$ 148,627
Marketable securities	225,444	42,900
Prepaid expenses and other current assets	968	485
Total current assets	491,273	192,012
Property and equipment, net	255	301
Total assets	<u>\$ 491,528</u>	<u>\$ 192,313</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 588	\$ 1,929
Accrued expenses	4,848	8,125
Total current liabilities	5,436	10,054
Total liabilities	5,436	10,054
Stockholders' equity:		
Preferred stock, par value \$0.0001 per share authorized: 5,000,000 shares at June 30, 2018 and December 31, 2017; 1,969,797 shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, par value \$0.0001 per share authorized: 200,000,000 at June 30, 2018 and December 31, 2017; 15,365,384 and 14,227,634 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	2	1
Additional paid-in-capital	605,418	288,750
Accumulated other comprehensive loss	(43)	(31)
Accumulated deficit	(119,285)	(106,461)
Total stockholders' equity	486,092	182,259
Total liabilities and stockholders' equity	<u>\$ 491,528</u>	<u>\$ 192,313</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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenues:				
Total revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	5,109	6,816	10,307	11,196
General and administrative	2,717	1,623	4,588	3,318
Total operating expenses	7,826	8,439	14,895	14,514
Loss from operations	(7,826)	(8,439)	(14,895)	(14,514)
Interest income	1,166	92	1,871	168
Other income	200	—	200	—
Net loss	\$ (6,460)	\$ (8,347)	\$ (12,824)	\$ (14,346)
Net loss per common share:				
Basic and diluted net loss per common share	\$ (0.45)	\$ (0.69)	\$ (0.90)	\$ (1.20)
Basic and diluted weighted average number of common shares outstanding	14,383,720	12,039,005	14,256,501	11,997,602

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Net Loss	\$ (6,460)	\$ (8,347)	\$ (12,824)	\$ (14,346)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	131	(28)	(12)	11
Comprehensive loss	<u>\$ (6,329)</u>	<u>\$ (8,375)</u>	<u>\$ (12,836)</u>	<u>\$ (14,335)</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>
Cash flows from operating activities:		
Net loss	\$ (12,824)	\$ (14,346)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,394	1,278
Depreciation and amortization expense	47	8
Prepaid expenses and other current assets	(3)	3
Accounts payable	(1,341)	523
Accrued expense	(3,277)	1,113
Net cash used in operating activities	<u>(14,004)</u>	<u>(11,421)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(251,869)	(31,113)
Sales and maturities of marketable securities	68,834	20,033
Purchases of property and equipment, net of disposals	(1)	(125)
Net cash used in investing activities	<u>(183,036)</u>	<u>(11,205)</u>
Cash flows from financing activities:		
Proceeds from issuance of stock, net of transaction costs	311,825	38,278
Proceeds from exercise of common stock options	1,449	—
Net cash provided by financing activities	<u>313,274</u>	<u>38,278</u>
Net increase in cash and cash equivalents	116,234	15,652
Cash and cash equivalents at beginning of period	148,627	19,145
Cash and cash equivalents at end of period	<u>\$ 264,861</u>	<u>\$ 34,797</u>

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, is being advanced for non-alcoholic steatohepatitis (“NASH”), a liver disease that commonly affects people with metabolic diseases such as obesity and diabetes, and indications in dyslipidemia, particularly genetic dyslipidemias such as familial hypercholesterolemia (“FH”), including both homozygous and heterozygous forms of the disease. The Company initiated a Phase 2 study of MGL-3196 in NASH in October 2016. In February 2017, the Company initiated a Phase 2 study of MGL-3196 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.

Madrigal was originally incorporated as a private company (“Private Madrigal”) on August 19, 2011 and commenced operations 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. The Company, or Madrigal, as used in the accompanying notes to the unaudited condensed consolidated financial statements, refers to Private Madrigal prior to the completion of the Merger and Public Madrigal subsequent to the completion of the Merger.

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 ended December 31, 2018 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, 2017.

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, the disclosure of contingent assets and liabilities at the date of the financial statements, 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

[Table of Contents](#)

financial institutions in the United States. The Company invests in money market funds and high-grade, short-term commercial paper and corporate bonds, which management believes are subject to minimal credit and market risk.

Marketable Securities

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

The Company adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. The Company includes such amortization and accretion as a component of interest income, net. Realized gains and losses and declines in value, if any, that the Company judges to be 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 six months ended June 30, 2018 and 2017, 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 six months ended June 30, 2018 and 2017, 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 June 30, 2018, 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 six months ended June 30, 2018 and 2017, the Company did not have any transfers of financial assets between Levels 1 and 2. As of June 30, 2018 and December 31, 2017, 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, and other costs associated with the Company's preclinical and clinical programs. In particular, Madrigal has conducted safety studies in animals, optimized and implemented the API manufacturing process, and conducted Phase 1 & 2 clinical trials, all of which are considered research and development expenditures.

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.

[Table of Contents](#)

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 three and six months ended June 30, 2018 and 2017, 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:

	Six months ended June 30,	
	2018	2017
Common Stock Options	1,137,507	976,711
Unvested Restricted Common Stock	104,127	157,262
Preferred Stock	1,969,797	1,969,797

Recent Accounting Pronouncements

In June 2018, The Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting" to simplify the accounting for share-based payment transactions with non-employees of the Company. The guidance within this accounting standard update generally requires that share-based payment transactions for acquiring goods or services from non-employees of the Company be accounted for under the same guidance and model as all other share-based payment transactions, including employees of the Company. For public business entities, ASU 2018-07 is effective for annual and interim reporting periods beginning after December 15, 2018, with early adoption permitted.

[Table of Contents](#)

The Company elected to early adopt the guidance within this accounting standard update in the second quarter of 2018. There was no significant impact from the adoption.

In May 2017, the FASB issued ASU No. 2017-09, “Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting,” to provide clarity and reduce both diversity in practice, and cost and complexity when a change is made to the terms or conditions of a share-based payment award. For public business entities, ASU 2017-09 is effective for annual and interim reporting periods beginning after December 15, 2017, with early adoption permitted. The update should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU No. 2017-09 effective January 1, 2018. There was no significant impact from the adoption.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows (Topic 230): Clarification of Certain Cash Receipts and Cash Payments.” The objective of ASU No. 2016-15 is to eliminate the diversity in practice related to the classification of certain cash receipts and payments in the statement of cash flows, by adding or clarifying guidance on eight specific cash flow issues. For public business entities, ASU 2016-15 is effective for annual and interim reporting periods beginning after December 15, 2017, with early adoption permitted. ASU 2016-15 provides that the amendments in the update should be applied retrospectively to all periods presented, unless deemed impracticable, in which case, prospective application is permitted. The Company adopted ASU No. 2016-15 effective January 1, 2018. There was no significant impact from the adoption.

In January 2016, the FASB issued ASU No. 2016-01, “Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities,” which amends the guidance in U.S. generally accepted accounting principles on the classification and measurement of financial instruments. Changes to the prior guidance primarily affect the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, the ASU clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The amendments in this ASU are effective for fiscal years and interim periods beginning after December 15, 2017, and are to be adopted by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The Company adopted ASU No. 2016-01 effective January 1, 2018. There was no significant impact from the adoption.

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 \$12.8 million for the six months ended June 30, 2018, resulting in an accumulated deficit of approximately \$119.3 million as of June 30, 2018. 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 (see Note 5).

The Company believes that its cash, cash equivalents and marketable securities at June 30, 2018 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 June 30, 2018 and December 31, 2017 is as follows (in thousands):

[Table of Contents](#)

	June 30, 2018			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash and cash equivalents:				
Cash (Level 1)	\$ 1,615	\$ —	\$ —	\$ 1,615
Money market funds (Level 1)	230,822	—	—	230,822
Corporate debt securities due within 3 months of date of purchase (Level 2)	32,424	—	—	32,424
Total cash and cash equivalents	264,861	—	—	264,861
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	225,487	41	(84)	225,444
Total cash, cash equivalents and marketable securities	\$ 490,348	\$ 41	\$ (84)	\$ 490,305
	December 31, 2017			
	Cost	Unrealized Gains	Unrealized losses	Fair value
Cash and cash equivalents:				
Cash (Level 1)	\$ 2,725	\$ —	\$ —	\$ 2,725
Money market funds (Level 1)	145,902	—	—	145,902
Corporate debt securities due within 3 months of date of purchase (Level 2)	—	—	—	—
Total cash and cash equivalents	148,627	—	—	148,627
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	42,931	—	(31)	42,900
Total cash, cash equivalents and marketable securities	\$ 191,558	\$ —	\$ (31)	\$ 191,527

5. 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.

June 2018 Registered Offering

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.

December 2017 Registered Offering

In December 2017, the Company entered into an underwriting agreement with Goldman Sachs & Co. LLC, as representative of the several underwriters named therein (the "December 2017 Underwriters"), relating to an underwritten public offering (the "December 2017 Offering") of 1,731,929 shares of the Company's common stock, including 225,904 shares of the Company's common stock purchased by the December 2017 Underwriters pursuant to a 30-day option to purchase such additional shares granted therein, at a public offering price of \$83.00 per share. The December 2017 Offering resulted in net proceeds to the Company of approximately \$135.5 million, after deducting the December 2017 Underwriters' discount and other offering costs. The December 2017 Offering closed on December 21, 2017.

June 2017 Private Placement Offering and its Series A Convertible Preferred Stock

In June 2017, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with a group of institutional accredited investors, who were existing, non-controlling stockholders of the Company, pursuant to which the Company sold securities to the Investors in a private placement transaction (the “June 2017 Offering”). Under the terms of the Purchase Agreement, the Company sold 328,300 shares of its common stock at a price of \$15.23 per share, and 1,969,797 shares of its Series A Convertible Preferred Stock (the “Series A Preferred Stock”) at a price of \$15.23 per share. The June 2017 Offering resulted in gross proceeds to the Company of approximately \$35.0 million, and net proceeds to the Company of approximately \$34.9 million. The June 2017 Offering closed on June 23, 2017.

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 Purchase Agreement. The terms of the Series A Preferred Stock are set forth 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. Each share of the Series A Preferred Stock is convertible into shares of Common Stock at any time 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 October 2015, the Company entered into an at-the-market issuance sales agreement (the “October 2015 Sales Agreement”), with Cowen and Company, LLC (“Cowen”), pursuant to which the Company may issue and sell shares of its common stock, having an aggregate offering price of up to \$100 million, from time to time, at the Company’s option, through Cowen as its sales agent. Sales of common stock through Cowen may be made by any method that is deemed an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including by means of ordinary brokers’ transactions at market prices, in block transactions or as otherwise agreed by the Company and Cowen. Subject to the terms and conditions of the October 2015 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). The Company is not obligated to make any sales of its common stock under the October 2015 Sales Agreement. Any shares sold will be sold pursuant to an effective shelf registration statement on Form S-3 (file no. 333-206135). The Company will pay Cowen a commission of up to 3% of the gross proceeds. The October 2015 Sales Agreement may be terminated by the Company at any time upon 10 days’ notice.

As of June 30, 2018, 597,356 shares have been sold under the October 2015 Sales Agreement for an aggregate of approximately \$9.6 million in gross proceeds. Net proceeds to the Company were approximately \$9.4 million after deducting commissions and other transactions costs. Of those shares sold, none were sold in 2018, and 215,539 were sold in 2017. Approximately \$90.4 million remained reserved under the Company’s shelf registration statement and the applicable prospectus supplement for possible future issuance under the October 2015 Sales Agreement.

6. Stock-based Compensation

In June 2015, upon obtaining stockholder approval at its annual shareholder meeting, the Company implemented its new 2015 Stock Plan. The 2015 Stock Plan replaced the 2006 Stock Plan, which was terminated upon adoption of the 2015 Stock Plan. Shares of common stock reserved for outstanding awards under the 2006 Stock Plan that lapse or are canceled will be added back to the share reserve available for future awards under 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 exercise price of the stock options is determined by the compensation committee of the board of directors, provided that incentive stock options are granted with an exercise price not less than fair market value of the common stock on the date of grant and expire no later than ten years from the date the option is granted. As of June 30, 2018, the Company had options outstanding to purchase 1,137,507 shares of its common stock, which includes options outstanding under its 2006 Stock Plan that was terminated in June 2015. As of June 30, 2018, 1,239,595 shares were available for future issuance.

[Table of Contents](#)

The following table summarizes stock option activity during the six months ended June 30, 2018:

	Shares	Weighted average exercise price
Outstanding at January 1, 2018	976,777	\$ 11.97
Options granted	218,900	164.00
Options exercised	(58,170)	24.90
Options canceled	—	—
Outstanding at June 30, 2018	<u>1,137,507</u>	<u>\$ 40.57</u>
Exercisable at June 30, 2018	478,898	\$ 11.19

The total cash received by the Company as a result of stock option exercises was \$1.4 million and \$0, respectively, for the six months ended June 30, 2018 and 2017. The weighted-average grant date fair values, based on the Black-Scholes option model, of options granted during the six months ended June 30, 2018 and 2017 were \$129.03 and \$12.68, 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. There were 104,127 unvested restricted shares outstanding at a weighted average grant date fair value of \$9.45 at June 30, 2018 and December 31, 2017.

Stock-Based Compensation Expense

Stock-based compensation expense during the three and six months ended June 2018 and 2017 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Stock-based compensation expense by type of award:				
Stock options	\$ 2,104	\$ 527	\$ 3,150	\$ 981
Restricted stock	123	149	244	297
Total stock-based compensation expense	<u>\$ 2,227</u>	<u>\$ 676</u>	<u>\$ 3,394</u>	<u>\$ 1,278</u>
Effect of stock-based compensation expense by line item:				
Research and development	\$ 732	\$ 168	\$ 1,108	\$ 305
General and administrative	1,495	508	2,286	973
Total stock-based compensation expense included in net loss	<u>\$ 2,227</u>	<u>\$ 676</u>	<u>\$ 3,394</u>	<u>\$ 1,278</u>

[Table of Contents](#)

Unrecognized stock-based compensation expense as of June 30, 2018 was as follows (in thousands):

	Unrecognized stock compensation expense	Weighted average remaining period (in years)
Stock options	\$ 26,400	2.38
Restricted stock	520	1.06
Total	<u>\$ 26,920</u>	<u>2.35</u>

7. 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, the remainder of which total \$10 million and are earned by the commencement of Phase 3 clinical trials as well as future regulatory approval in the United States and Europe of a product developed from MGL-3916. A single-digit royalty payment range is based on net sales of products developed from MGL-3196, subject to certain reductions. In October 2016, the Company commenced a Phase 2 study in Non-Alcoholic Steatohepatitis (NASH), which triggered a milestone payment under the agreement. Except as described above, the Company has not achieved any additional product development or regulatory milestones to date and has no Licensed Product sales for the six months ended June 30, 2018 and 2017.

The Company has entered into customary contractual arrangements and letters of intent in preparation for and in support of the Phase 2 clinical trials.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on our beliefs and assumptions and on information currently available to us. Forward-looking statements include information with respect to our clinical trials, research and development activities, the timing and success of future development of MGL-3196, 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 include all statements that are not historical facts and, in some cases, can be identified by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “seeks,” “should,” “will,” “would” or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements, including those described in “Risk Factors” and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Any forward-looking statement made by us in this report speaks only as of the date on which it is made. Except as required by law, we disclaim any obligation to update these 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.

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, 2017 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. 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 sections entitled “Risk Factors” 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.

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, 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. For NASH, we enrolled 125 patients in a Phase 2 clinical trial. 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 an ongoing 36-week, open-label extension study in 31 participating NASH patients from the Phase 2 clinical trial, which includes 14 patients who received placebo in the main study. We are also developing MGL-3196 for dyslipidemia, including genetic dyslipidemias such as heterozygous familial hypercholesterolemia, or HeFH. We enrolled 116 patients and completed a Phase 2 clinical trial in HeFH patients, and we reported the results in February 2018. In addition to the NASH and HeFH Phase 2 clinical trials, MGL-3196 has also been studied in six completed Phase 1 trials in a total of 183 subjects. MGL-3196 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, and a single dose relative bioavailability study of tablet formulations versus capsule formulation.

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 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.

[Table of Contents](#)

Our research and development expenses consist primarily of:

- 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 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 initiate our Phase 3 clinical program and continue to conduct our Phase 2 clinical program and 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, due primarily 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 increased between 2017 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 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 U.S. Securities and Exchange Commission, or 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 six months ended June 30, 2018, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 13, 2018.

[Table of Contents](#)**Results of Operations****Three months ended June 30, 2018 and 2017**

The following table provides comparative unaudited results of operations for the three months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Increase / (Decrease)	
	2018	2017	\$	%
Research and Development Expenses	\$ 5,109	\$ 6,816	(1,707)	-25%
General and Administrative Expenses	2,717	1,623	1,094	67%
Interest Income	(1,166)	(92)	(1,074)	1167%
Other Income	(200)	—	(200)	100%
	\$ 6,460	\$ 8,347	(1,887)	-23%

Revenue

We had no revenue for the three months ended June 30, 2018 and 2017.

Research and Development Expenses

Our research and development expenses were \$5.1 million for the three months ended June 30, 2018, compared to \$6.8 million in the corresponding period in 2017. Research and development expenses decreased by \$1.7 million in the 2018 period due primarily to the completion of treatment in our Phase 2 clinical trials in 2018. We expect our research and development expenses to increase over time as we advance our clinical and preclinical development programs for MGL-3196.

General and Administrative Expenses

Our general and administrative expenses were \$2.7 million for the three months ended June 30, 2018, compared to \$1.6 million in the corresponding period in 2017. General and administrative expenses increased by \$1.1 million in the 2018 period due primarily to 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, 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 \$1.2 million for the three months ended June 30, 2018, compared to \$0.1 million for the three months ended June 30, 2017. The increase in interest income was due primarily to a higher average principal balance in our investment account in 2018.

Six months ended June 30, 2018 and 2017

The following table provides comparative unaudited results of operations for the six months ended June 30, 2018 and 2017 (in thousands):

	Six Months Ended June 30,		Increase / (Decrease)	
	2018	2017	\$	%
Research and Development Expenses	\$ 10,307	\$ 11,196	(889)	-8%
General and Administrative Expenses	4,588	3,318	1,270	38%
Interest Income	(1,871)	(168)	(1,703)	1014%
Other Income	(200)	—	(200)	100%
	\$ 12,824	\$ 14,346	(1,522)	-11%

[Table of Contents](#)

Revenue

We had no revenue for the six months ended June 30, 2018 and 2017.

Research and Development Expenses

Our research and development expenses were \$10.3 million for the six months ended June 30, 2018, compared to \$11.2 million in the corresponding period in 2017. Research and development expenses decreased by \$0.9 million in the 2018 period due primarily to completion of treatment in our Phase 2 clinical trials in 2018. We expect our research and development expenses to increase over time as we advance our clinical and preclinical development programs for MGL-3196.

General and Administrative Expenses

Our general and administrative expenses were \$4.6 million for the six months ended June 30, 2018, compared to \$3.3 million in the corresponding period in 2017. General and administrative expenses increased by \$1.3 million in the 2018 period due primarily to 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, 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 \$1.9 million for the six months ended June 30, 2018, compared to \$0.2 million for the six months ended June 30, 2017. The increase in interest income was due primarily to a higher average principal balance in our investment account in 2018.

Liquidity and Capital Resources

As of June 30, 2018, we had cash, cash equivalents and marketable securities totaling \$490.3 million compared to \$191.5 million as of December 31, 2017, with the increase primarily attributable to the proceeds from the June 2018 Offering, partially offset by our net operating loss. To date, we have funded our operations primarily through the issuance of convertible debt, the issuance of shares of common stock and preferred stock, and the proceeds from the merger with Synta.

Our most significant use of capital pertains to salaries and benefits for our employees, hiring additional personnel, 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. 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 June 30, 2018 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 would be harmed. Furthermore, any sales of additional equity securities may result in dilution to our stockholders, and any debt financing may include covenants that restrict our business.

Cash Flows

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

[Table of Contents](#)

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	\$ (14,004)	\$ (11,421)
Net cash used by investing activities	(183,036)	(11,205)
Net cash provided by financing activities	313,274	38,278
Net increase in cash and cash equivalents	\$ 116,234	\$ 15,652

Net cash used in operating activities was \$14.0 million for the six months ended June 30, 2018, compared to \$11.4 million for the six months ended June 30, 2017. 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 \$183.0 million for the six months ended June 30, 2018, compared to \$11.2 million used in investing activities for six months ended June 30, 2017. Net cash used in investing activities for the six months ended June 30, 2018 consisted of \$251.9 million of purchases of marketable securities for our investment portfolio, partially offset by \$68.8 million from sales and maturities of marketable securities. Net cash used by investing activities for the six months ended June 30, 2017 consisted of \$31.1 million of purchases of marketable securities for our investment portfolio, partially offset by \$20.0 million from sales and maturities of marketable securities.

Net cash provided by financing activities was \$313.3 million for the six months ended June 30, 2018, compared to \$38.3 million for the six months ended June 30, 2017. Net cash provided by financing activities for the six months ended June 30, 2018 consisted of net proceeds from the issuance of common stock pursuant to the June 2018 Offering and the exercise of stock options. Net cash provided by financing activities for the six months ended June 30, 2017 consisted of net proceeds from the sale of common stock under the October 2015 Sales Agreement and net proceeds from the sale of preferred stock and common stock in the June 2017 Offering.

Contractual Obligations and Commitments

No significant changes to contractual obligations and commitments occurred during the six months ended June 30, 2018, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 13, 2018.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash, cash equivalents and marketable securities as of June 30, 2018 consisted of readily available checking account balances, money market funds, and high-grade corporate and government obligations that are classified as available-for-sale. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not believe that our cash, cash equivalents and marketable securities have a significant risk of default or illiquidity. While we believe our cash, cash equivalents and marketable securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

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.

Risks Related to Our Business

We have limited operating history, we have incurred significant operating losses since inception and we expect to incur significant operating losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future as we continue our clinical trial and development programs for MGL-3196 and other future product candidates. As of June 30, 2018, we had an accumulated deficit of approximately \$119.3 million. Losses have principally resulted from costs incurred in our preclinical and clinical trials, research and development programs and from our general and administrative expenses. As of June 30, 2018, we had cash, cash equivalents and marketable securities of approximately \$490.3 million. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance and, if MGL-3196 or other future product candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in us incurring further significant losses for the foreseeable future.

We currently generate no revenue from product sales, and we may never be able to commercialize MGL-3196 or other future product candidates. We do not currently have the required approvals to market MGL-3196 or any other future product candidates, and we may never receive them. We may not be profitable even if we or any of our future development partners succeed in commercializing any of our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our business depends on the success of MGL-3196, which is still in clinical development and has not completed a pivotal trial. If we are unable to obtain regulatory approval for and successfully commercialize MGL-3196, or we experience significant delays in doing so, our business will be materially harmed.

To date, the sole focus of our product development has been MGL-3196, a liver-directed selective thyroid hormone receptor beta agonist for potential use in non-alcoholic steatohepatitis, or NASH, and familial hypercholesterolemia, or FH. Successful continued development and ultimate regulatory approval of MGL-3196 for NASH or genetic dyslipidemias, such as FH, is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of MGL-3196. We will need to raise sufficient funds to successfully complete our clinical development program for MGL-3196 in NASH and FH. The future regulatory and commercial success of MGL-3196 is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for MGL-3196, including, but not limited to, our currently ongoing Phase 2 clinical trials and our planned registrational clinical trials to obtain drug approval;
- the mechanism of action of MGL-3196 is complex and we do not know the degree to which it will translate into a therapeutic benefit, if any, in NASH, FH or any other indication, and we do not know the degree to which the complex mechanism of action may contribute to long term safety issues or adverse events, if any, when MGL-3196 is taken for prolonged periods such as in the treatment of NASH, FH or any other indication;
- we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for MGL-3196 in NASH, FH or any other indication;
- we do not know the degree to which MGL-3196 will be accepted as a therapy by physicians, patients and payors, even if approved;

[Table of Contents](#)

- in our clinical programs for MGL-3196, we may experience variability in patients, adjustments to clinical trial procedures and the need for additional clinical trial sites, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to MGL-3196, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time;
- we cannot be certain what efficacy endpoints FDA or foreign clinical or regulatory agencies may require in a Phase 3 clinical trial of NASH or FH or for approval of our product candidates; we also cannot be certain if we will be able to gain accelerated approval of any of our product candidates based on surrogate endpoints;
- the FDA or foreign clinical or regulatory agencies will likely require efficacy endpoints for Phase 3 clinical trials for the treatment of NASH or FH that differ from the endpoints of our current Phase 2 trials and the results of our Phase 3 clinical trials may not be as favorable as the results we have observed to date in our current trials;
- other differences in the design of our planned Phase 3 clinical trials of the treatment of NASH, including the use of a new tablet formulation of MGL-3196 and the inclusion of patients with more advanced NASH, could cause the results of our Phase 3 trials to be less favorable than the results we observed in our Phase 2 trials in NASH;
- if we obtain accelerated approval of a product candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the product candidate and if the post-approval trial is not successful we may not be able to continue marketing the product;
- we cannot be certain of the number and type of clinical trials and non-clinical studies that FDA or other regulatory agencies will require in order to approve MGL-3196 for NASH or FH;
- if approved for NASH, MGL-3196 will likely compete with the off-label use of currently marketed products and other therapies in development that may reach approval for NASH prior to MGL-3196;
- if approved for FH, MGL-3196 will likely compete with currently approved and marketed products and other therapies in development that may reach approval for FH prior to MGL-3196; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage results in the submission of a new drug application, or NDA, to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market MGL-3196, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize MGL-3196. If we or any of our future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize MGL-3196, we may not be able to generate sufficient revenue to continue our business.

Clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, the results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials, including MGL-3196, may not have favorable results in later clinical trials or receive regulatory approval.

Drug development has inherent risk. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective, with a favorable benefit-risk profile, for use in our target indications before we can seek regulatory approvals for its commercial sale. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. Delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials may be conducted in broader patient populations and involve different study designs. For instance, our Phase 1 results and our Phase 2 primary endpoint results in NASH may not be predictive of any future Phase 2 results or of results in

[Table of Contents](#)

any Phase 3 clinical trial in NASH. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy in significantly larger patient populations for approval by regulatory authorities. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In addition, only a small percentage of drugs under development result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

We cannot be certain that any of our ongoing or future clinical trials will be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Because MGL-3196 has not yet received regulatory approval for any indication, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development and obtain the necessary regulatory approvals for commercialization.

MGL-3196 has not yet received regulatory approval for the treatment of NASH, FH or any other indication, and unexpected problems may arise that could cause us to delay, suspend or terminate our development efforts in any or all indications. Further, MGL-3196 has not yet demonstrated efficacy in patients with NASH or FH, and the long-term safety consequences of a liver-directed thyroid hormone receptor beta agonist are not known. Regulatory approval of new product candidates such as MGL-3196 can be more expensive and take longer than approval for candidates for the treatment of more well-understood diseases with previously approved products.

If clinical trials or regulatory approval processes for our product candidates are prolonged, delayed or suspended, we may be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay, suspend, or terminate those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay or impede completely the completion of our ongoing and planned clinical trials and negatively affect our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- insufficient supply of our product candidates or other materials necessary to conduct and complete our clinical trials;
- slow enrollment and retention rate of subjects in our clinical trials; and
- serious and unexpected drug-related side effects related to the product candidate being tested.

Commercialization of our product candidates may be delayed by the imposition of additional conditions on our clinical trials by the FDA or any other applicable foreign regulatory authority or the requirement of additional supportive studies by the FDA or such foreign regulatory authority.

We do not know whether our clinical trials will begin as planned, will need to be restructured, will enroll an adequate number of patients on time, or will be completed on schedule, if at all. Delays in the initiation, enrollment or completion of our clinical trials will result in increased development costs for our product candidates, and our financial resources may be insufficient to fund any incremental costs. In addition, if our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our product candidates could be limited.

If we inadvertently fail to comply with foreign regulatory requirements governing human clinical trials and marketing approval for drugs, we could be prevented from selling our drug candidates in foreign markets, which may adversely affect our operating results and financial condition.

The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement for marketing our drug candidates outside the United States vary greatly from country to country and may require additional testing. We expect that our future clinical development of our drug candidates will involve a number of clinical trials in foreign jurisdictions, particularly in Europe. We

[Table of Contents](#)

have no experience in obtaining foreign regulatory approvals. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not guarantee approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our drug candidates and may have a material adverse effect on our results of operations and financial condition.

We depend on enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may not be able to initiate, continue, or complete clinical trials required by the FDA or foreign regulatory agencies for MGL-3196 if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. We expect our Phase 3 clinical trials of MGL-3196 will require that we enroll significantly more patients than were enrolled in our Phase 2 trials. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages and disadvantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. For instance, we are aware that other companies conducting clinical trials in NASH patients have had delays in recruiting patients for their trials. In the proposed clinical trials, patient willingness to undergo a liver biopsy in our NASH trials, and identification of patients willing to participate in our FH trials due to the rarity of the disease, are also risk factors. Potential patients for MGL-3196 may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for our studies.

The FDA typically requires sponsors of lipid-lowering product candidates to conduct drug-drug interaction studies with statins because statins may have increased safety risks when administered together with other drug therapies that affect their pharmacokinetic profile. We have completed two Phase 1 clinical drug interaction studies of MGL-3196 and statins in 39 normal healthy volunteers, which showed MGL-3196 to have a favorable safety profile and to be well-tolerated. We have completed a Phase 2 clinical trial in NASH including patients taking low dose statins. We have also completed a Phase 2 clinical trial in HeFH including patients taking high dose statins. In general, drug interactions between MGL-3196 and statins and any other drug that might result in adverse events could delay development in later clinical trials.

We will be required to identify and enroll a sufficient number of patients for each of our ongoing and planned clinical trials of MGL-3196 for NASH and FH indications, respectively. We also may encounter difficulties in identifying and enrolling NASH patients and FH patients with a stage of disease appropriate for our ongoing or future clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other foreign regulatory agencies. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials.

Any product candidate in our current or future clinical trials may cause unacceptable adverse events or side effects or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.

Unacceptable adverse events or undesirable side effects caused by any of our product candidates in current or future clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn could prevent us from completing development of or commercializing the affected product candidate and generating revenue from its sale. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product candidate.

Occurrence of serious treatment-related side effects could impede subject recruitment and clinical trial enrollment or the ability of enrolled patients to complete the trial, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA. They could also adversely affect physician or patient acceptance of our product candidates or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

[Table of Contents](#)

Our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any approved commercial products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, and record keeping related to the product will remain subject to extensive regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS Program as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities, or previously unknown problems with any approved product, manufacturer, or manufacturing process are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers, or manufacturing processes;
- warning letters or untitled letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- pressure to initiate voluntary product recalls;
- suspension or withdrawal of regulatory approvals; and
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

If any of these events occurs, our ability to sell such products may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

We operate in a highly competitive and rapidly changing industry, and our product candidates may become obsolete.

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than us. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining regulatory approval and in manufacturing and marketing pharmaceutical products. Our competitors may succeed in obtaining regulatory approval for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these competitive products may have an entirely different approach or means of accomplishing the desired therapeutic effect than products being developed by us. Our competitors may succeed in developing products that are more effective and/or cost competitive than those we are developing, or that would render our product candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection earlier than we may, which could materially adversely affect our business.

[Table of Contents](#)

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our or any of our partners' product candidates, the sales of our product candidates would be adversely affected.

Once an NDA or marketing authorization application outside the United States is approved, the product covered thereby becomes a "listed drug" that can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application in the United States. Agency regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an abbreviated new drug application or other application for generic substitutes in the United States and in nearly every pharmaceutical market around the world. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use, or labeling, as our product and that the generic product is bioequivalent to our product, meaning it is absorbed in the body at the same rate and to the same extent as our product. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than our product to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our product or any of our partners' future products, if any, would materially adversely affect our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made and expect to make in our or any of our partners' product candidates, including MGL-3196.

Competition that our or any of our partners' products may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

If physicians and patients do not accept our future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

Even if any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, and third-party payers. Efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations. Physicians may decide not to recommend its treatments for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- restrictions in the label of the drug;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support of its products.

If any of our product candidates are approved, but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer.

As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully.

As we advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, and marketing and sales capabilities and may need to further contract with third parties to provide these capabilities. As our operations expand, we likely will need to manage additional relationships with such third parties, as well as additional collaborators, distributors, marketers and suppliers.

[Table of Contents](#)

Maintaining third party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to effectively manage our development efforts, recruit and train sales and marketing personnel, effectively manage our participation in the clinical trials in which our product candidates are involved and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

If we enter into arrangements with third parties to perform sales, marketing or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop without the involvement of these third parties. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.

The uncertainty associated with pharmaceutical reimbursement and related matters may adversely affect our business.

Market acceptance and sales of any one or more of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any of our product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, or ACA, became law in the United States. The goal of ACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both government and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receives regulatory approval. We also cannot predict the impact of ACA on us as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which have not yet been fully implemented.

If any product liability lawsuits are successfully brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;

[Table of Contents](#)

- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;
- product recalls or a change in the indications for which products may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Also, because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our results of operations.

We do not currently hold product liability insurance coverage. Prior to commercialization of our product candidates, we will need to purchase insurance coverage. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business, financial condition and results of operations.

Our employees, contractors, vendors and partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, contractors, vendors or partners. Misconduct by these parties could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our potential sublicensees' exercise of rights under the agreements. With respect to our commercial agreements, we indemnify our vendors from any

[Table of Contents](#)

third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we are denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

If we fail to develop and commercialize other product candidates, we may be unable to grow our business.

Although the development and commercialization of MGL-3196 is our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of other therapies related to thyroid hormone, orphan and other diseases. We will evaluate internal opportunities from our compound libraries, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from thyroid hormone, orphan or other disorders with high unmet medical needs and limited treatment options. These other product candidates may require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace, or be more effective than other commercially available alternatives.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify, develop and commercialize products will be impaired.

We are highly dependent on principal members of our management team, including our Chief Executive Officer, Paul A. Friedman, M.D., and our Chief Medical Officer, Rebecca Taub, M.D. These executives each have significant pharmaceutical industry experience. The loss of any member of our management team or scientific staff, including Drs. Friedman and Taub, would impair our ability to identify, develop and market new products. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not receive adequate compensation for the loss of the services of these individuals.

We currently have no marketing, sales or distribution infrastructure with respect to our product candidates. If we are unable to develop our sales, marketing and distribution capabilities on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities and have limited sales or marketing experience within our organization. If our product candidate, MGL-3196, is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize MGL-3196, or to outsource this function to a third party. Either of these options would be expensive and time-consuming. Some or all of these costs may be incurred in advance of any approval of MGL-3196. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of MGL-3196 and other future product candidates.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or as an alternative to our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are

[Table of Contents](#)

unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Even if we obtain FDA approval of MGL-3196 or any other future product candidate, we may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding clinical trial design, safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our partners fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product may not extend beyond the current patent expiration dates and our competitors may obtain approval to market competing products sooner. As a result, our revenue could be potentially materially reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may fail to obtain orphan drug designations from the FDA for our product candidates, as applicable, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

We have not obtained orphan designation for any product candidates to date, although we believe some of the potential indications of our product candidates could qualify for orphan drug designation and the related benefits if approved for such indications and we may file for orphan drug designation with respect to such indications. Even if we obtain such designations, we may not be the first to obtain regulatory approval of a product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation

[Table of Contents](#)

was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug designation exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations. Failure to obtain an orphan drug designation for our product candidates may have a material adverse effect on our business, results of operations and financial condition.

If we or our partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or our partners violate government price reporting laws, we or our partners may be subject to administrative civil and/or criminal penalties.

Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations. These laws include, among others, the U.S. federal Anti-Kickback Statute and the U.S. federal civil and criminal false claims laws. At such time, if ever, as we or any of our partners market any of our future approved products, it is possible that some of our business activities and/or our partners could be subject to challenge under one or more of these laws.

Federal false claims, false statements and civil monetary penalties laws prohibit, among others, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor.

In addition, we and/or our partners may be subject to patient data privacy and security regulation, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, which impose specified requirements relating to the privacy, security and transmission of individually identifiable health information.

Most states also have statutes or regulations similar to these federal laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. We and/or our partners may be subject to administrative, civil and criminal sanctions for violations of any of these federal and state laws. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.

We use third-party service providers to conduct and/or oversee the clinical trials of our product candidates and expect to continue to do so for the foreseeable future. We rely heavily on these parties for successful execution of our clinical trials. Nonetheless, we are

[Table of Contents](#)

responsible for confirming that each of our clinical trials is conducted in accordance with FDA requirements and our general investigational plan and protocol.

The FDA requires us and our third-party service providers to comply with regulations and standards, commonly referred to as good clinical practices, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory or GCP requirements or the respective trial plans and protocols. In addition, third parties may not be able to repeat their past successes in clinical trials. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

If our relationship with these third-party providers terminates, we may not be able to enter into arrangements with alternative providers or do so on commercially reasonable terms. Switching or adding additional third-party providers involves substantial cost and requires management time and focus, and could delay development and commercialization of our product candidates. Though we intend to carefully manage our relationships with our third-party providers, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

We have relied on, and expect to continue to rely on, third-party manufacturers to produce our product candidates.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to rely for the foreseeable future, on third-party manufacturers to supply our product candidates. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates or products ourselves, including:

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current good manufacturing practices, or cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, European Medicines Agency, or EMA, and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

We previously identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud; and in that case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock.

Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. If we fail to maintain an effective system of internal controls, we may be unable to report our financial results accurately or prevent fraud; and, in that case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock. On March 31, 2017, we filed with the SEC an amendment to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 to correct certain errors therein. Management reported a material weakness in our system of internal controls over financial reporting as of September 30, 2016. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial

[Table of Contents](#)

statements will not be prevented or detected on a timely basis. We remediated this material weakness. We cannot assure you that the measures we have taken to date will be sufficient to avoid future material weaknesses. Even when we conclude that our internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles, or GAAP, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements.

Our reporting obligations as a public company will require significant managerial, operational and financial resources for the foreseeable future. If we fail to maintain the adequacy of our internal control over financial reporting, we may not be able to produce reliable financial reports or help prevent fraud. Our failure to maintain effective internal control over financial reporting could prevent us from filing our periodic reports on a timely basis which could result in the loss of investor confidence in the reliability of our financial statements, harm our business and negatively impact the trading price of our common stock.

Risks Relating to Our Intellectual Property

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of a license to MGL-3196 granted to us by Roche.

We entered into a Research, Development and Commercialization Agreement, or the Roche Agreement, with Hoffmann-La Roche, or Roche, on December 18, 2008. Pursuant to the terms of the Roche Agreement, we assumed control of all development and commercialization of MGL-3196 and hold exclusive worldwide rights for all potential indications. Under the Roche Agreement, Roche exclusively licensed certain patent rights and know-how relating to MGL-3196 in exchange for consideration consisting of an upfront payment, milestone payments tied to the achievement of product development and regulatory milestones, and royalty payments based on net sales of products containing MGL-3196 or another licensed product, subject to certain reductions. We must use commercially reasonable efforts to conduct clinical and commercial development programs for products containing MGL-3196. If we determine that it is not reasonable to continue clinical trials or other development of MGL-3196, we may elect to cease further development and Roche may terminate the license. If we determine not to pursue the development or commercialization of MGL-3196 in certain jurisdictions, including the United States, Roche may terminate the license for such territories. The Roche Agreement will expire, unless earlier terminated pursuant to other provisions thereof, on the last to occur of (i) the expiration of the last valid claim of a licensed patent covering the manufacture, use or sale of products containing MGL-3196, or (ii) ten years after the first sale of a product containing MGL-3196.

Under the Roche Agreement, Roche controls prosecution of the licensed patent rights, although we have a right to comment.

We do not have, nor have we had, any material disputes with Roche regarding the Roche Agreement. However, if there is any future dispute between us and Roche regarding the parties' rights under the Roche Agreement, our ability to develop and commercialize MGL-3196, or any other product candidate covered by the Roche Agreement, may be materially harmed. Any uncured, material breach under the Roche Agreement could result in our loss of exclusive rights to MGL-3196 and may lead to a complete termination of the Roche Agreement and force us to cease product development efforts for MGL-3196.

We may fail to comply with any of our obligations under agreements pursuant to which we license rights or technology, which could result in the loss of rights or technology that are material to our business.

We may enter into license agreements from time to time. Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a license agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by us and our licensors and collaborators; and

[Table of Contents](#)

- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our success depends on our ability to protect our intellectual property and our proprietary technologies. Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses, as well as our ability to operate without infringing upon the proprietary rights of others.

We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can we provide any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredients are generally considered to offer the strongest protection of intellectual property and provide the broadest scope of patent protection for pharmaceutical products, as such patents provide protection without regard to any method of use or any method of manufacturing. While we have licensed rights to issued composition-of-matter patents in the United States and other jurisdictions for MGL-3196, we cannot be certain that the claims in issued composition-of-matter patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in owned and licensed patent applications covering our product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, and valid by courts in the United States or by the patent offices and courts in foreign jurisdictions. Even if we owned and licensed patent applications covering our product candidates, the patents may not be enforced against competitors. For example, a formulation patent will not be enforced against those making and marketing a product that has the same active pharmaceutical ingredient in a different formulation that is not claimed in the formulation patent. Method-of-use patents protect the use of a product for the specified method or for treatment of a particular indication. This type of patent may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient but is used for a method not claimed in the patent. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Our licensed composition-of-matter patent licensed from Roche for MGL-3196 is expected to expire in the United States in 2026. Our co-owned patents and pending patent applications that cover our particular solid form, dosage, method of manufacturing, and uses of MGL-3196 to treat various indications are expected to expire in 2033. While patent term adjustments or patent term extensions could result in later expiration dates for each of these patents, there can be no assurances that we will receive any patent adjustments or patent term extensions. The patent application process and patent maintenance and enforcement are subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process and after a patent has issued. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- we and our licensor(s) may not have been the first to make the inventions covered by pending patent applications or issued patents;

[Table of Contents](#)

- we and our licensor(s) may not have been the first to file patent applications for our product candidates or the compositions developed, or for their uses;
- others may independently develop identical, similar or alternative products or compositions and uses thereof;
- we and our licensor(s)' disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- others may design around our owned and licensed patent claims to produce competitive products which fall outside of the scope of the patents;
- others may identify prior art or other bases which could invalidate our or licensor(s)' patents;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where us and our licensor(s) do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in major commercial markets;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that any of these parties would not breach the agreements to disclose any proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. Further, third parties may still obtain this information by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Moreover, third parties may come upon this or similar information lawfully and independently. We would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Further, intellectual property rights have limitations and do not necessarily address all potential threats to our competitive position. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and a patent may become subject to post-grant proceedings including opposition, derivation, reexamination, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications

[Table of Contents](#)

are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of MGL-3196 or our other product candidates. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing MGL-3196 for NASH or FH or our other product candidates until the asserted patent expires or is held finally invalid or not infringing in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of patent infringement against us as of the filing date of this report, others may hold proprietary rights that could prevent MGL-3196 or our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidate or processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market MGL-3196 or our other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing MGL-3196 or our other product candidates, which could harm our business, financial condition and operating results.

Moreover, we may be subject to a third party preissuance submission of prior art to the USPTO or in addition to interference proceedings, may become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or other post-grant proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

If we or any of our future development partners were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could

[Table of Contents](#)

require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own or co-own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may collaborate with U.S. and foreign academic institutions and industry collaborators to accelerate our preclinical or clinical research. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any of these could impair our competitive position.

In addition, these agreements typically restrict the ability of our advisors, employees, third party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of

[Table of Contents](#)

our agreements with third parties, independent development or publication of information by any of our third party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We may not be able to protect our intellectual property rights throughout the world.

While we have licensed from Roche issued composition-of-matter patents directed at MGL-3196 in the United States and other countries, filing, prosecuting and defending patents on MGL-3196 in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries may not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing their inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with MGL-3196, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Financial Position and Need for Capital

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize MGL-3196 and other future product candidates.

Although we believe that our existing cash and cash equivalents will be sufficient to fund our current operations through at least the next 12 months, we may require additional working capital in order to complete the remaining clinical development for MGL-3196 and our other product candidates through potential regulatory approval and through potential commercialization of these product candidates. In particular, in order to initiate our Phase 3 clinical program for MGL-3196 in NASH, we may need to collaborate with a strategic partner or raise additional working capital. We expect our spending levels to increase in connection with our clinical trials of MGL-3196 as well as other corporate activities. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the type, number, scope, progress, expansion costs, results of and timing of our ongoing or future clinical trials or the need for additional clinical trials of MGL-3196 for NASH and FH or any of our other product candidates which we are pursuing or may choose to pursue in the future;

[Table of Contents](#)

- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the costs and timing of obtaining regulatory approval for MGL-3196 for NASH and FH and any of our other product candidates;
- the costs and timing of obtaining or maintaining manufacturing for MGL-3196 for NASH and FH and any of our other product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales, marketing and reimbursement capabilities and enhanced internal controls over financial reporting;
- the terms and timing of establishing and maintaining collaborations, license agreements and other partnerships;
- costs associated with any new product candidates that we may develop, in-license or acquire;
- the effect of competing technological and market developments; and
- the costs associated with operating as a public company.

Some of these factors are outside of our control. We do not expect our existing capital resources to be sufficient to enable us to fund the completion of our clinical trials and commercialization of our product candidates. We expect that we will need to raise substantial additional funds in the future.

We have not sold any products, and we do not expect to sell or derive revenue from any product sales for the foreseeable future. We may seek additional funding through future debt and equity financings, as well as potential additional collaborations or strategic partnerships with other companies or through non-dilutive financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain additional funding on a timely basis, we may be unable to complete ongoing and planned clinical trials for MGL-3196 for NASH and FH and any of our other product candidates, and we may be required to significantly curtail some or all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidates or otherwise agree to terms unfavorable to us.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code.

Our net operating losses have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Similar rules may apply under state tax laws. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code, or similar state provisions, has previously occurred. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us and may be substantial.

Risks Relating to Ownership of Our Common Stock

The price of our common stock has been, and may continue to be, volatile.

Historically, the market price of our common stock has fluctuated over a wide range, and it is likely that the price of our common stock will continue to be volatile in the future. The market price of our common stock could be impacted due to a variety of factors, including, in addition to global and industry-wide events:

- the losses we may incur;

[Table of Contents](#)

- developments in patent or other proprietary rights owned or licensed by us, our collaborative partners or our competitors;
- public concern as to the safety and efficacy of products developed by us or others; and
- litigation.

In addition, due to one or more of the foregoing factors in one or more future quarters, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could materially decline.

A small number of our stockholders beneficially own a substantial amount of our common stock and have substantial control over us; therefore, your ability to influence corporate matters may be limited.

Certain stockholders affiliated with our officers and directors collectively beneficially own or control approximately 39.3% of our outstanding common stock as of June 30, 2018 and acting together, may have the ability to affect matters submitted to our stockholders for approval. This concentration of ownership may have the effect of delaying, deferring or preventing a strategic transaction, even if such a transaction would benefit other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our charter and bylaws may delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include a classified board of directors. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits, with some exceptions, stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market by us, by our existing stockholders, or by the holders of our Series A Convertible Preferred Stock upon conversion, or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

We do not anticipate paying cash dividends on our common stock, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid any cash dividend on our common stock and do not anticipate paying cash dividends on our common stock in the future. As a result, the only return to stockholders will be appreciation in the price of our common stock, which may never occur. Investors seeking cash dividends should not invest in our common stock.

[Table of Contents](#)

Risks Related to Stockholders' Sales of Shares, Including Those Issued under the Securities Purchase Agreement

Sales of a significant number of shares of our common stock in the public markets or significant short sales of our common stock, or the perception that such sales could occur, could depress the market price of our common stock and impair our ability to raise capital.

As of June 30, 2018, there were 1,969,797 shares of Series A Convertible Preferred stock outstanding, all of which are readily convertible into common stock at the option of the holders. In addition, there are an additional 1,137,507 shares of our common stock issuable upon the exercise of outstanding stock options. Sales of a substantial number of shares of our common stock or other equity-related securities in the public markets, could depress the market price of our common stock. If there are significant sales or short sales of our stock, the price decline that could result from this activity may cause the share price to decline further, which, in turn, may cause long holders of the common stock to sell their shares, thereby contributing to sales of common stock in the market. Such sales also may impair our ability to raise capital through the sale of additional shares in the future at a time and price that our management deems acceptable, if at all.

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		
1.1	Underwriting Agreement, dated June 6, 2018, by and between Madrigal Pharmaceuticals, Inc., Goldman Sachs & Co. LLC as Representative of the Underwriters set forth therein, and the selling stockholders of Madrigal Pharmaceuticals, Inc. named therein.	8-K	001-33277	1.1	2018-06-08	
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

[Table of Contents](#)

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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.					X
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

* 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: August 7, 2018

By: /s/ Paul A. Friedman, M.D.
Paul A. Friedman, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2018

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: August 7, 2018

**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 Officer)
Date: August 7, 2018

**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 June 30, 2018 (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: August 7, 2018

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

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

Dated: August 7, 2018

/s/ Marc R. Schneebaum

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

