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, 2024

OR

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

For the transition period from _____ to _____

Commission file number: 001-33277

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 2, 2024, the registrant had 21,712,677 shares of common stock outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 494,597	$ 99,915
Restricted cash	5,000	—
Marketable securities	563,197	534,216
Trade receivables, net	6,899	—
Inventory	7,072	—
Prepaid expenses and other current assets	14,963	3,150
Total current assets	1,091,728	637,281
Property and equipment, net	1,695	1,553
Intangible assets, net	4,910	—
Right-of-use asset	1,456	1,713
Total assets	$ 1,099,789	$ 640,547
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,994	$ 28,041
Accrued expenses	115,611	89,980
Lease liability	557	527
Total current liabilities	125,162	118,548
Long term liabilities:		
Loan payable, net of discount	116,607	115,480
Lease liability	900	1,186
Total long term liabilities	117,507	116,666
Total liabilities	242,669	235,214
Stockholders' equity:		
Preferred stock, par value $0.0001 per share authorized: 5,000,000 shares at June 30, 2024 and December 31, 2023; 2,369,797 and 2,369,797 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Common stock, par value $0.0001 per share authorized: 200,000,000 at June 30, 2024 and December 31, 2023; 21,700,893 and 19,875,427 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in-capital	2,493,288	1,741,153
Accumulated other comprehensive income (loss)	(368)	468
Accumulated deficit	(1,635,802)	(1,336,290)
Total stockholders' equity	857,120	405,333
Total liabilities and stockholders' equity	$ 1,099,789	$ 640,547

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 14,638	$ —	$ 14,638	$ —
Operating expenses:				
Cost of sales	636	—	636	—
Research and development	71,091	68,605	142,328	130,759
Selling, general and administrative	105,448	17,845	186,249	34,027
Total operating expenses	177,175	86,450	329,213	164,786
Loss from operations	(162,537)	(86,450)	(314,575)	(164,786)
Interest income	14,222	3,551	22,556	7,327
Interest expense	(3,656)	(2,901)	(7,493)	(5,237)
Net loss	$ (151,971)	$ (85,800)	$ (299,512)	$ (162,696)
Net loss per common share:				
Basic and diluted net loss per common share	$ (7.10)	$ (4.69)	$ (14.47)	$ (8.91)
Basic and diluted weighted average number of common shares outstanding	21,402,646	18,310,952	20,702,041	18,249,778

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net Loss	$ (151,971)	$ (85,800)	$ (299,512)	$ (162,696)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(196)	(3)	(836)	(57)
Comprehensive loss	$ (152,167)	$ (85,803)	$ (300,348)	$ (162,753)

See accompanying notes to condensed consolidated financial statements.

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

	Preferred stock		Common stock		Additional paid-in Capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	2,369,797	$ —	19,875,427	$ 2	$1,741,153	$ 468	$(1,336,290)	$ 405,333
Issuance of common shares and sale of warrants in equity offerings, excluding to related parties, net of transaction costs	—	—	750,000	—	311,560	—	—	311,560
Sale of warrants to related parties in equity offerings, exercise of common stock options, and restricted stock vesting, net of transaction costs	—	—	59,236	—	262,145	—	—	262,145
Stock-based compensation expense related to equity-classified awards	—	—	—	—	19,902	—	—	19,902
Unrealized loss on marketable securities	—	—	—	—	—	(640)	—	(640)
Net loss	—	—	—	—	—	—	(147,541)	(147,541)
Balance at March 31, 2024	2,369,797	$ —	20,684,663	$ 2	$2,334,760	$ (172)	$(1,483,831)	$ 850,759
Issuance of common shares in equity offering, excluding to related parties, net of transaction costs	—	—	346,153	—	85,950	—	—	85,950
Sale of common shares to related parties and exercise of common stock options, net of transaction costs	—	—	670,077	—	48,174	—	—	48,174
Stock-based compensation expense related to equity-classified awards	—	—	—	—	24,404	—	—	24,404
Unrealized loss on marketable securities	—	—	—	—	—	(196)	—	(196)
Net loss	—	—	—	—	—	—	(151,971)	(151,971)
Balance at June 30, 2024	2,369,797	$ —	21,700,893	$ 2	$2,493,288	$ (368)	$(1,635,802)	$ 857,120
Balance at December 31, 2022	2,369,797	$ —	18,102,523	$ 2	$1,160,079	$ (32)	$ (962,660)	$ 197,389
Sale of common shares to related parties and exercise of common stock options, net of transaction costs	—	—	180,551	—	17,903	—	—	17,903
Stock-based compensation expense related to equity-classified awards	—	—	—	—	11,250	—	—	11,250
Unrealized loss on marketable securities	—	—	—	—	—	(54)	—	(54)

Hercules warrant	—	—	—	—	544	—	—	544
Net loss	—	—	—	—	—	—	(76,896)	(76,896)
Balance at March 31, 2023	2,369,797	$ —	18,283,074	$ 2	$ 1,189,776	$ (86)	$ (1,039,556)	$ 150,136
Issuance of common shares in equity offering, excluding to related parties, net of transaction costs	—	—	85,901	—	21,754	—	—	21,754
Sale of common shares to related parties and exercise of common stock options, net of transaction costs	—	—	90,058	—	6,251	—	—	6,251
Compensation expense related to stock options for services	—	—	—	—	10,973	—	—	10,973
Unrealized loss on marketable securities	—	—	—	—		(3)	—	(3)
Hercules warrant	—	—	—	—	195	—	—	195
Net loss	—	—	—	—	—	—	(85,800)	(85,800)
Balance at June 30, 2023	2,369,797	$ —	18,459,033	$ 2	$ 1,228,949	$ (89)	$ (1,125,356)	$ 103,506

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (299,512)	$ (162,696)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	44,306	22,223
Depreciation and amortization expense	435	250
Amortization of debt issuance costs and discount	1,127	987
Changes in operating assets and liabilities:		
Trade receivables, net	(6,899)	—
Prepaid expenses and other current assets	(11,813)	(582)
Inventory	(7,072)	—
Accounts payable	(19,047)	(6,297)
Accrued expense	25,631	(9,700)
Accrued interest, net of interest received on maturity of investments	(11,258)	(3,562)
Net cash used in operating activities	(284,102)	(159,377)
Cash flows from investing activities:		
Purchases of marketable securities	(364,988)	(290,696)
Sales and maturities of marketable securities	346,431	100,204
Acquisition of intangible asset	(5,000)	—
Purchases of property and equipment, net of disposals	(488)	(104)
Net cash used in investing activities	(24,045)	(190,596)
Cash flows from financing activities:		
Proceeds from issuances of stock, excluding related parties, net of transaction costs	397,510	21,754
Proceeds from related parties - warrants, exercise of common stock options, net of transaction costs	310,319	24,154
Proceeds from issuance of loan payable	—	50,000
Payment of debt issuance costs	—	(288)
Net cash provided by financing activities	707,829	95,620
Net increase (decrease) in cash, cash equivalents, and restricted cash	399,682	(254,353)
Cash, cash equivalents, and restricted cash at beginning of period	99,915	331,549
Cash, cash equivalents, and restricted cash at end of period	$ 499,597	$ 77,196

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 biopharmaceutical company dedicated to transforming care for patients with nonalcoholic steatohepatitis ("NASH"), a serious liver disease that can lead to cirrhosis, liver failure and premature mortality. The Company's medication, Rezdiffra (resmetirom), is a once-daily, oral, liver-directed THR-β agonist designed to target key underlying causes of NASH. In March 2024, Rezdiffra became the first and only FDA-approved therapy for patients with NASH. Rezdiffra became commercially available in the United States in April 2024. Rezdiffra is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

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, the Company believes that the disclosures included in these financial statements are adequate to make the information presented not misleading. The unaudited condensed consolidated financial statements, in the opinion of management, reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of such interim results. The interim results are not necessarily indicative of the results that the Company will have for the full year ending December 31, 2024 or any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes to those statements for the year ended December 31, 2023.

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 and transactions have been eliminated in consolidation.

Use of Estimates

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

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606 - Revenue from Contracts with Customers. Revenue is recognized at a point in time when the customer obtains control of promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligation(s).

Revenue from product sales is recorded net of adjustments for estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns, and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. The Company reflects these accruals as either a reduction in the related account receivable from the customer or as an accrued liability, depending on the means by

which the deduction is settled. Sales deductions are based on management's estimates that involve a substantial degree of judgment.

Net Product Revenue

On March 14, 2024, the Company announced that the U.S. Food and Drug Administration ("FDA") granted accelerated approval of Rezdiffra (resmetirom) in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis ("NASH") with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). The Company enters into agreements with specialty pharmacies and specialty distributors, each a "Customer" and collectively the "Customers", to sell Rezdiffra in the U.S. Revenues from product sales are recognized when the Customer obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the Customer.

Revenue is recorded net of variable consideration, which includes prompt pay discounts, returns, chargebacks, rebates, and co-payment assistance. The variable consideration is estimated based on contractual terms as well as management assumptions. The amount of variable consideration is calculated by using the expected value method, which is the sum of probability-weighted amounts in a range of possible outcomes, or the most likely amount method, which is the single most likely amount in a range of possible outcomes. Estimates are reviewed quarterly and adjusted as necessary.

Prompt Pay: Customers receive a 2% prompt pay discount for payments made within a contractually agreed number of days before the due date. The discounts are accounted for as a reduction of the transaction price and recorded as a contra receivable.

Returns: The Company records allowances for product returns as a reduction of revenue at the time product sales are recorded. Product returns are estimated based on forecasted sales and historical and industry data. Returns are permitted under certain contractual circumstances, including product expiration date. A returns reserve is recorded as an accrued liability.

Chargebacks: Chargebacks are reserved for from eligible healthcare providers, resulting from discounted sales prices offered to qualified customers. The Company is charged back for the difference between the sale price and the discounted price, which is recorded as a contra receivable.

Co-Payment Assistance: Co-payment assistant programs are offered to eligible end-users as price concessions and are recorded as accrued liabilities and a reduction of the transaction price. The Company uses a third-party to administer the co-payment program for pharmacy benefit claims.

Rebates: Rebates include mandated discounts relating to the Medicaid Drug Rebate Program and Medicare coverage gap rebates. The discount obligations result in decreases to revenue and are recorded to accrued liabilities.

The Company generates revenue from a small number of large, reputable customers. The following customers accounted for over 10% of total gross product revenue during three months ended June 30, 2024. As the Company launched Rezdiffra in April 2024, there were no sales and no corresponding customer concentrations in prior periods.

	Three Months Ended June 30,	
	2024	2023
Customer A	39 %	— %
Customer B	19 %	— %
Customer C	16 %	— %
Customer D	14 %	— %

Cash and Cash Equivalents

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

The primary objective of the Company's investment activities is to preserve its capital for the purpose of funding operations and the Company does not enter into investments for trading or speculative purposes. The Company's cash is

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

Marketable Securities

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

The Company adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. The Company includes such amortization and accretion as a component of interest income, net. Realized gains and losses and declines in value, if any, that the Company judges to be the result of impairment or as a result of recognizing an allowance for credit losses on available-for-sale securities are reported as a component of interest income. To determine whether an impairment exists, the Company considers whether it intends to sell the debt security and, if the Company does not intend to sell the debt security, it considers available evidence to assess whether it is more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. During the six months ended June 30, 2024 and 2023, 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 six months ended June 30, 2024 and 2023, 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, 2024, the Company's financial assets valued based on Level 1 inputs consisted of cash and cash equivalents in a money market fund, its financial assets valued based on Level 2 inputs consisted of high-grade corporate and government agency bonds and commercial paper, and it had no financial assets valued based on Level 3 inputs. During the six months ended June 30, 2024 and 2023, the Company did not have any transfers of financial assets between Levels 1 and 2. As of June 30, 2024 and December 31, 2023, the Company did not have any financial liabilities that were recorded at fair value on a recurring basis on the balance sheet.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value, using actual cost, based on a first-in, first-out ("FIFO") method. The Company analyzes its inventory levels quarterly and writes down inventory subject to expiry or

in excess of expected requirements, or that has a cost basis in excess of its expected net realizable value. These write downs are charged to cost of goods sold in the accompanying Consolidated Statements of Income.

The Company considered regulatory approval of its product candidate to be uncertain and product manufactured prior to regulatory approval could not have been sold unless regulatory approval was obtained. As such, the manufacturing costs incurred prior to regulatory approval were not capitalized as inventory, but were expensed as incurred as research and development expenses.

Research and Development Costs

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

Patents

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

Intangible Assets

Intangible assets with finite lives are amortized to cost of goods sold over their estimated useful lives using the straight-line method. Intangible assets are tested for recoverability whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable.

Stock-Based Compensation

The Company recognizes stock-based compensation expense based on the grant date fair value of stock options, restricted stock units, and other stock-based compensation awards granted to employees, officers, directors, and consultants. Awards that vest as the recipient provides service are expensed on a straight-line basis over the requisite service period.

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

For other stock-based compensation awards granted to employees and directors that vest based on market conditions, such as the trading price of the Company's common stock achieving or exceeding certain price targets, the Company uses a Monte Carlo simulation model to estimate the grant date fair value and recognize stock compensation expense over the derived service period. The Monte Carlo simulation model requires key inputs for risk-free interest rate, dividend yield, volatility, and expected life.

The assumptions used in computing the fair value of equity awards reflect the Company's best estimates but involve uncertainties related to market and other conditions. Changes in any of these assumptions may materially affect the fair value of awards granted and the amount of stock-based compensation recognized.

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. 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 six months ended June 30, 2024 and 2023, diluted net loss per share is the same as basic net loss per share because the inclusion of weighted average shares of common stock issuable upon the exercise of stock options and warrants or vesting of restricted stock units, and common stock issuable upon the conversion of preferred stock would be anti-dilutive. The following table summarizes outstanding securities not included in the computation of diluted net loss per common share, as their inclusion would be anti-dilutive:

	Outstanding at June 30,	
	2024	2023
Common stock options	1,772,807	2,583,540
Restricted stock units	508,947	222,300
Performance-based restricted stock units	235,520	—
Preferred stock	2,369,797	2,369,797
Warrants	3,625,244	18,403

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which enhances the disclosures required for operating segments in the Company's annual and interim consolidated financial statements. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-07 on its financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which enhances the disclosures required for income taxes in the Company's annual consolidated financial statements. The amendments are effective for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-09 on its financial statements.

3. Liquidity and Uncertainties

The Company is subject to risks common to development stage companies and early commercial companies in the biopharmaceutical industry including, but not limited to, uncertainty of product development and commercialization, dependence on key personnel, uncertainty of market acceptance of products and product reimbursement, product liability, uncertain protection of proprietary technology, potential inability to raise additional financing necessary for development

and commercialization, and compliance with the U.S. Food and Drug Administration ("FDA") and other government regulations.

The Company has incurred losses since inception, including approximately $299.5 million for the six months ended June 30, 2024, resulting in an accumulated deficit of approximately $1,635.8 million as of June 30, 2024. To date, the Company has funded its operations primarily through proceeds from sales of the Company's capital stock and debt financings. In March 2024, the FDA approved Rezdiffra in the U.S. for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Rezdiffra became commercially available in the U.S. in April 2024. In March 2024, the Company completed a public offering and received approximately $574.0 million net cash proceeds. In April 2024, underwriters exercised in full their option to purchase additional shares as part of the public offering, resulting in additional net cash proceeds of approximately $85.9 million. The Company believes that its cash, cash equivalents and marketable securities will be sufficient to fund operations past one year from the issuance of these financial statements. The Company's future long-term liquidity requirements will be substantial and will depend on many factors, including the Company's ability to effectively commercialize Rezdiffra. To meet its future capital needs, the Company may need 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, if at all, 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

The Company held restricted cash of $5.0 million as of June 30, 2024 as collateral to its corporate credit card program. The Company had no restricted cash as of December 31, 2023.

A summary of cash, cash equivalents and available-for-sale marketable securities held by the Company as of June 30, 2024 and December 31, 2023 is as follows (in thousands):

	June 30, 2024			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash and cash equivalents:				
Cash (Level 1)	$ 20,323	$ —	$ —	$ 20,323
Money market funds (Level 1)	476,755	—	—	476,755
Corporate debt securities due within 3 months of date of purchase (Level 2)	2,519	—	—	2,519
Total cash and cash equivalents	499,597	—	—	499,597
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	344,202	5	(224)	343,983
U.S. government and government sponsored entities due within 1 year of date of purchase (Level 2)	219,363	—	(149)	219,214
Total cash, cash equivalents, restricted cash, and marketable securities	$ 1,063,162	$ 5	$ (373)	$ 1,062,794

	December 31, 2023			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash and cash equivalents:				
Cash (Level 1)	$ 2,729	$ —	$ —	$ 2,729
Money market funds (Level 1)	78,555	—	—	78,555
US government and government sponsored entities (Level 1)	14,967	—	—	14,967
Corporate debt securities due within 3 months of date of purchase (Level 2)	3,664	—	—	3,664
Total cash and cash equivalents	99,915	—	—	99,915
Marketable securities:				
Corporate debt securities due within 1 year of date of purchase (Level 2)	382,028	195	(7)	382,216
US government and government sponsored entities due within 1 year of date of purchase (Level 2)	150,743	280	(1)	151,022
Corporate debt securities due within 1 to 2 years of date of purchase (Level 2)	977	1	—	978
Total cash, cash equivalents and marketable securities	$ 633,663	$ 476	$ (8)	$ 634,131

5. Inventory

The following table summarizes the Company's inventory balances as of June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024	December 31, 2023
Raw Materials	$ —	$ —
Work In Process	5,728	—
Finished Goods	1,344	—
Total	$ 7,072	$ —

6. Accrued Liabilities

Accrued liabilities as of June 30, 2024 and December 31, 2023 consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Contract research organization costs	$ 65,473	$ 50,737
Other clinical study related costs	4,206	3,724
Manufacturing and drug supply	2,045	9,705
Compensation and benefits	21,341	17,030
Professional fees	15,496	6,814
Gross to net accrued expenses	1,931	—
Other	5,119	1,970
Total accrued liabilities	$ 115,611	$ 89,980

7. Long Term Debt

In May 2022, the Company and its wholly-owned subsidiary, Canticle Pharmaceuticals, Inc., entered into the $250.0 million Loan Facility with the several banks and other financial institutions or entities party thereto (each, a “Lender” and collectively referred to as the “Lenders”), and Hercules Capital, Inc. (“Hercules”), in its capacity as administrative agent and collateral agent for itself and the Lenders. Under the terms of the Loan Facility, the first $50.0 million tranche was drawn at closing. The Company also could draw up to an additional $125.0 million in two separate

tranches upon achievement of certain resmetirom clinical and regulatory milestones. A fourth tranche of $75.0 million could have been drawn by the Company, subject to the approval of Hercules. The Loan Facility had a minimum interest rate of 7.45% and adjusted with changes in the prime rate. The Company was originally scheduled to pay interest-only monthly payments of accrued interest under the Loan Facility through May 1, 2025, for a period of 36 months. In March 2024, the interest-only period was extended to May 1, 2026 when the Company achieved a milestone when Rezdiffra received FDA approval. The interest only period can further be extended to May 3, 2027, upon the achievement of future revenue milestones, subject to compliance with applicable covenants. The Loan Facility originally matured in May 2026, but the maturity date was extended to May 2027 when the Company achieved a milestone upon receipt of FDA approval in March 2024. The Loan Facility is secured by a security interest in substantially all of the Company's assets, other than intellectual property. It includes an end of term charge of 5.35% of the aggregate principal amount, which is accounted for in the loan discount. In connection with the first tranche drawn at closing, the Company issued Hercules a warrant to purchase 14,899 shares of Company common stock, which had a Black-Scholes value of $0.6 million.

On February 3, 2023, the Company entered into the First Amendment (the "First Amendment") to the Loan Facility (as amended, the "Amended Loan Facility"). Under the Amended Loan Facility, an additional $35.0 million was drawn under a second, expanded, $65.0 million tranche ("Tranche 2") in February of 2023 following the Company's achievement of the Phase 3 clinical development milestone. An additional $15.0 million was drawn under Tranche 2 in June of 2023. The remaining $15.0 million available under Tranche 2 was drawn in September of 2023 in accordance with the Amended Loan Facility.

The third tranche ("Tranche 3") of $75.0 million was unchanged by the First Amendment, and such borrowings became available when the Company achieved a milestone with FDA approval for Rezdiffra in March 2024. The Company did not elect to draw Tranche 3 before it expired in June 2024. Coincident with the expansion of Tranche 2 borrowing capacity by $15.0 million, the Amendment reduced the fourth tranche under the Loan Facility ("Tranche 4") by $15.0 million to $60.0 million. In connection with the $35.0 million drawn under Tranche 2 at the closing of the First Amendment, $15.0 million drawn in June of 2023, and $15.0 million drawn in September of 2023, the Company issued to Hercules and affiliates Tranche 2 Warrants to purchase an aggregate of 4,555 shares of common stock, which had a Black-Scholes value of $0.9 million. The First Amendment reduced the interest rate under the Amended Loan Facility to the greater of (i) the prime rate as reported in The Wall Street Journal plus 2.45% and (ii) 8.25%. The First Amendment and the Amended Loan Facility summary terms were disclosed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 9, 2023.

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

As of June 30, 2024, the outstanding principal under the Loan Facility was $115.0 million. The interest rate as of June 30, 2024 was 10.95%. As of June 30, 2024, the Company was in compliance with all loan covenants and provisions.

Future minimum payments, including interest and principal, under the loans payable outstanding as of June 30, 2024 are as follows (in thousands):

Period Ending June 30, 2024:	Amount
2024	$ 6,400
2025	12,768
2026	79,604
Thereafter	53,387
	$ 152,159
Less amount representing interest	(31,007)
Less unamortized discount	(4,545)
Loans payable, net of discount	$ 116,607

8. 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 "Board"). The Company has never declared cash dividends on its common stock and does not expect to do so in the foreseeable future.

Preferred Stock

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

2024 Public Offering

On March 18, 2024, the Company entered into an Underwriting Agreement with Goldman Sachs & Co. LLC, Jefferies LLC, Cowen and Company, LLC, Evercore Group L.L.C. and Piper Sandler & Co, as representatives of the several underwriters named therein (the "2024 Underwriters"), pursuant to which the Company sold to the 2024 Underwriters in an underwritten public offering (the "2024 Offering"): (i) 750,000 shares of common stock at a public offering price of $260.00 per share, (ii) pre-funded warrants (the "2024 Pre-Funded Warrants") to purchase 1,557,692 shares of common stock at a public offering price of $259.9999 per 2024 Pre-Funded Warrant, which represents the per share public offering price for the common stock less a $0.0001 per share exercise price for each such Pre-Funded Warrant, and (iii) a 30-day option for the 2024 Underwriters to purchase up to 346,153 additional shares of common stock at the public offering price of $260.00 per share (the "Underwriters' Option"). The 2024 Offering closed on March 21, 2024. The gross proceeds of the 2024 Offering was $600.0 million, and the Company received net proceeds, after deducting the underwriting discount and commissions and other estimated offering expenses payable by the Company, of approximately $574.0 million.

The Underwriters' Option was later exercised in full, and closed on April 2, 2024. The net proceeds to the Company for the exercise of the Underwriters' Option, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company, was approximately $85.9 million.

The Company intends to use the net proceeds from the 2024 Offering for its commercial activities in connection with the launch of Rezdiffra in the U.S. and for general corporate purposes, including, without limitation, research and development expenditures, ongoing clinical trial expenditures, manufacture and supply of drug substance and drug products, potential ex-U.S. commercialization or partnering opportunities, potential acquisitions or licensing of new technologies, capital expenditures and working capital.

The 2024 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of 2024 Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of 2024 Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days prior notice to the Company.

2023 Public Offering

On September 28, 2023, the Company entered into an Underwriting Agreement with Goldman Sachs & Co. LLC, as representative of the several underwriters named therein (the "2023 Underwriters"), pursuant to which the Company sold to the 2023 Underwriters in an underwritten public offering (the "2023 Offering"): (i) 1,248,098 shares of common stock at a public offering price of $151.69 per share, and (ii) pre-funded warrants (the "2023 Pre-Funded Warrants") to purchase 2,048,098 shares of common stock at a public offering price of $151.6899 per 2023 Pre-Funded Warrant, which represents the per share public offering price for the common stock less a $0.0001 per share exercise price for each such 2023 Pre-Funded Warrant. The 2023 Offering closed on October 3, 2023.

The gross proceeds of the 2023 Offering was $500.0 million, and the Company received net proceeds, after deducting the underwriting discount and commissions and other estimated offering expenses payable by the Company, of approximately $472.0 million. The Company intends to use the net proceeds from the Offering for its clinical and commercial activities in preparation for the launch of resmetirom in the U.S. and for general corporate purposes, including, without limitation, research and development expenditures, clinical trial expenditures, manufacture and supply of drug substance and drug products, potential acquisitions or licensing of new technologies, capital expenditures and working capital.

The 2023 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of 2023 Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of 2023 Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days prior notice to the Company.

At-The-Market Issuance Sales Agreement

In June 2021, the Company entered into an at-the-market sales agreement (the "2021 Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company could, from time to time, issue and sell shares of its common stock. The 2021 Sales Agreement initially authorized an aggregate offering of up to $200.0 million in shares of the Company's common stock, at the Company's option, through Cowen as its sales agent. Sales of common stock through Cowen could be made by any method that is deemed an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by the Company and Cowen. Subject to the terms and conditions of the 2021 Sales Agreement, Cowen would use commercially reasonable efforts consistent with its normal trading and sales practices to sell the common stock based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company imposed).

In May 2023, the Company entered into an amendment to the 2021 Sales Agreement (the "Sales Agreement Amendment"), with Cowen, pursuant to which the Company could, from time to time, issue and sell an additional $200.0 million in shares of its common stock, until it was terminated in May 2024. The Company was not obligated to make any sales of its common stock under this arrangement. Any shares sold would be sold pursuant to the Registration Statement and prospectus supplement filed pursuant to the Registration Statement. The 2021 Sales Agreement, as amended by the Sales Agreement Amendment, authorized sales of shares of the Company's common stock, from time to time, at the Company's option, through Cowen as its sales agent. Sales of common stock through Cowen may be made by any method that is deemed an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, and as described in the prospectus supplement.

Since the entry into the Sales Agreement Amendment in May 2023, the Company sold 98,101 shares in total under the 2021 Sales Agreement, as amended by the Sales Agreement Amendment, for an aggregate of $25.2 million in gross proceeds, with net proceeds to the Company of approximately $24.5 million after deducting commissions and other transaction costs. All shares were sold pursuant to the Company's effective Registration Statement and the prospectus supplement relating thereto. In total, the Company sold 1,334,044 shares of Common Stock having an aggregate offering price of $225.1 million pursuant to the 2021 Sales Agreement, as amended by the Sales Agreement Amendment.

In May 2024, the Company entered into a Sales Agreement (the "2024 Sales Agreement") with Cowen, replacing and superseding the 2021 Sales Agreement, as amended by the Sales Agreement Amendment which was terminated effective upon the entry into the 2024 Sales Agreement. The Company is authorized to issue and sell up to $300.0 million in shares of the Company's common stock under the 2024 Sales Agreement. The Company sold no shares in the three and six months ended June 30, 2024 under either the 2021 Sales Agreement, as amended by the Sales Agreement Amendment, or the 2024 Sales Agreement.

9. Stock-based Compensation

2015 Stock Plan

The Company's 2015 Stock Plan, as amended (the "2015 Stock Plan"), is one of the Company's equity incentive compensation plans through which equity based grants are awarded. The 2015 Stock Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock, restricted stock units and other stock-based compensation awards to employees, officers, directors, and consultants of the Company. The administration of the 2015 Stock Plan is under the general supervision of the Compensation Committee of the Board. The terms of stock options awarded under the 2015 Stock Plan, in general, are determined by the Compensation Committee, provided the exercise price per share generally shall not be set at less than the fair market value of a share of the common stock on the date of grant and the term shall not be greater than ten years from the date the option is granted. On June 25, 2024, the Company's stockholders approved an amendment to the 2015 Stock Plan to increase the total number of shares of common stock available for issuance by 750,000 and extend its duration by 10 years until April 23, 2035. As of June 30, 2024, 1,264,199 shares were available for future issuance under the 2015 Stock Plan.

2023 Inducement Plan

In September 2023, the Company adopted the 2023 Inducement Plan (the "Inducement Plan"), pursuant to which the Company may from time to time make equity grants to new employees as a material inducement to their employment. The Inducement Plan was adopted without stockholder approval, pursuant to Nasdaq Listing Rule 5635(c)(4), and is administered by the Compensation Committee of the Board. The Inducement Plan provides for the granting of non-statutory stock options, restricted stock, restricted stock units, performance stock units and other stock-based compensation awards to new employees, but does not allow for the granting of incentive stock options. The terms of the stock options under the Inducement Plan, in general, are determined by the Compensation Committee, provided the exercise price per share generally shall not be set at less than the fair market value of a share of the common stock on the date of grant and the term shall not be greater than ten years from the date the option or award is granted. A total of 500,000 shares of the Company's common stock were reserved for issuance under the Inducement Plan. As of June 30, 2024, 19,097 shares were available for future issuance under the 2023 Inducement Plan.

Stock Options

The following table summarizes stock option activity during the six months ended June 30, 2024:

	Shares	Weighted average exercise price
Outstanding at December 31, 2023	2,355,779	$ 79.94
Options granted	148,970	232.88
Options exercised	(671,947)	73.91
Options cancelled	(59,995)	118.98
Outstanding at June 30, 2024	1,772,807	$ 93.76
Exercisable at June 30, 2024	1,323,994	$ 79.14

The total cash received by the Company as a result of stock option exercises was $49.7 million and $21.8 million, respectively, for the six months ended June 30, 2024 and 2023. The total intrinsic value of options exercised was $121.1 million and $48.9 million, respectively, for the six months ended June 30, 2024 and 2023. The weighted-average grant date fair values, based on the Black-Scholes option model, of options granted during the six months ended June 30, 2024 and 2023 were $153.98 and $219.02, respectively.

Restricted Stock Units

The Company's 2015 Stock Plan provides for awards of restricted stock units ("RSUs") to employees, officers, directors and consultants to the Company. The Company's Inducement Plan provides for awards of RSUs to new employees. RSUs vest over a period of months or years, or upon the occurrence of certain performance criteria or the attainment of stated goals or events, and are subject to forfeiture if employment or service terminates before vesting. As of June 30, 2024, the Company had 508,947 restricted stock units outstanding, with a weighted average grant date fair value of $230.61 per unit.

The following table summarizes RSU activity, excluding performance-based RSUs, during the six months ended June 30, 2024:

	Shares	Weighted average grant date fair value
Outstanding at December 31, 2023	376,117	$ 241.45
RSUs granted	248,517	231.96
RSUs vested	(63,825)	289.45
RSUs forfeited	(51,862)	243.28
Outstanding at June 30, 2024	508,947	$ 230.61

Performance-Based Restricted Stock Units

The Company has granted various performance-based restricted stock units ("PSUs") to certain members of senior leadership. Depending on the terms of the PSUs and the outcome of the pre-established performance criteria, which may include a market and/or performance condition, a recipient may ultimately earn the target number of PSUs granted or a specified multiple thereof at the end of the vesting period.

The following table summarizes PSU activity during the six months ended June 30, 2024:

	PSUs	Eligible to Earn PSUs	Weighted average grant date fair value
Outstanding PSUs at December 31, 2023	50,000	150,000	$ 146.37
PSUs granted	51,202	102,404	388.02
PSUs attained	—	—	—
PSUs forfeited	(8,442)	(16,884)	388.02
Outstanding at June 30, 2024	92,760	235,520	$ 257.77

Outstanding Awards

As of June 30, 2024, the Company had restricted stock units, performance stock units, and options outstanding pursuant to which an aggregate of 2,517,274 shares of its common stock may be issued pursuant to the terms of all awards granted under the 2015 Stock Plan and Inducement Plan.

Stock-Based Compensation Expense

Stock-based compensation expense during the three and six months ended June 30, 2024 and 2023 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Stock-based compensation expense by type of award:				
Stock options	$ 10,027	$ 7,431	$ 16,913	$ 16,029
Restricted stock units	9,918	3,542	18,543	6,194
Performance-based restricted stock units	4,459	—	8,850	—
Total stock-based compensation expense	$ 24,404	$ 10,973	$ 44,306	$ 22,223
Effect of stock-based compensation expense by line item:				
Research and development	$ 5,582	$ 5,184	$ 11,489	$ 10,570
Selling, general and administrative	18,822	5,789	32,817	11,653
Total stock-based compensation expense included in net loss	$ 24,404	$ 10,973	$ 44,306	$ 22,223

Unrecognized stock-based compensation expense as of June 30, 2024 was $149.1 million with a weighted average remaining period of 2.09 years.

10. Commitments and Contingencies

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

The agreement requires future milestone payments to Roche. In March 2024, upon receiving FDA approval of Rezdiffra, a milestone was achieved and $5.0 million became due to Roche. Remaining milestones under the agreement total $3.0 million and are payable upon the Company achieving specified objectives related to future regulatory approval in Europe of resmetirom or a product developed from resmetirom. Furthermore, a tiered single-digit royalty is payable on net sales of resmetirom or a product developed from resmetirom, subject to certain reductions. The Company launched Rezdiffra in the U.S. in April 2024. The company did not achieve any product development or regulatory milestones for the six months ended June 30, 2023.

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

In August 2023, the Company entered into the Fifth Amendment to the Office Lease (the "Fifth Lease Amendment"). The Lease Amendment extended the term of the lease through November 2026. As a result of the Lease Amendment, an incremental $1.6 million right-of-use asset and lease liabilities were recorded during the year ended December 31, 2023.

In April 2024 and May 2024, the Company entered into the Sixth (the "Sixth Lease Amendment") and Seventh (the "Seventh Lease Amendment") Amendments to the Office Lease, respectively, expanding the amount of office space available in the same premises. The lease commencement date had not yet occurred as of June 30, 2024 and therefore there was no impact to the financial statements.

11. Subsequent Events

None.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- Anticipated or estimated future results, including the risks and uncertainties associated with our future operating performance and financial position;
- Our possible or assumed future results of operations and expenses, business strategies and plans (including potential ex-U.S. commercial or partnering opportunities), capital needs and financing plans, including incurrence of indebtedness and compliance with debt covenants under the Loan and Security Agreement with Hercules Capital, Inc., as agent and lender, market trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things;
- Post-approval requirements and commitments, including verification of a clinical benefit in confirmatory trials;
- Our ability to delay certain research activities and related clinical expenses as necessary;
- Our clinical trials, including the anticipated timing of disclosure, presentations of data from, or outcomes from our trials;
- Research and development activities, and the timing and results associated with the future development of our Rezdiffra/resmetirom, including projected market size, sector leadership, and patient treatment estimates for NASH and nonalcoholic fatty liver disease ("NAFLD") patients;
- The timing and completion of projected future clinical milestone events, including enrollment, additional studies, top-line data and open label projections;
- Rezdiffra's potential to be a cost-effective specialty therapy for NASH patients with significant liver fibrosis (consistent with fibrosis stages 2 and 3);
- Projections or objectives for obtaining full approval for resmetirom for NASH patients with significant fibrosis (or non-cirrhotic NASH patients) and NASH patients with compensated cirrhosis, including all statements concerning potential clinical benefit to support approval and/or potential approval;
- Estimates of patients diagnosed with NASH;
- Our primary and key secondary study endpoints for resmetirom, and the potential for achieving such endpoints and projections, including NASH resolution, safety, fibrosis treatment, cardiovascular effects and lipid treatment with resmetirom;
- Optimal dosing levels for resmetirom and projections regarding potential NASH or NAFLD and potential patient benefits with resmetirom, including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment and/or biomarker effects with resmetirom;
- The relationship between NASH progression and adverse patient outcomes;
- The estimated clinical burden of uncontrolled NASH;
- Analyses for patients with NASH with significant fibrosis concerning potential progression to cirrhosis, decompensated cirrhosis, liver transplant or death, and cardiovascular risks, comorbidities and outcomes;
- Our ability to address the unmet needs of patients suffering from NASH with significant fibrosis,
- The potential efficacy and safety of resmetirom for non-cirrhotic NASH patients and cirrhotic NASH patients,
- The potential for resmetirom to become the best-in-class treatment option for patients with NASH and significant fibrosis;

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

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

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to: our clinical and commercial development of resmetirom; the challenges with the commercial launch of a new product, particularly for a company that does not have commercial experience; enrollment and trial outlook uncertainties, generally, based on blinded, locked or limited trial data; our potential inability to raise sufficient capital to fund our ongoing operations as currently planned or to obtain financings on terms similar to those we have arranged in the past; our ability to meet post-approval commitments and requirements, including completion of enrollment of—and ability to obtain positive data from—any confirmatory studies required by the FDA; our ability to service our indebtedness and otherwise comply with our debt covenants; outcomes or trends from competitive studies; future topline data timing or results; the risks of achieving potential benefits in studies that includes substantially more patients, and patients with different disease states, than our prior studies; our ability to prevent and/or mitigate cybersecurity attacks, unauthorized exfiltration of data or other security incidents; limitations associated with early stage or non-placebo controlled study data; the timing and outcomes of clinical studies of resmetirom; and the uncertainties inherent in clinical testing; and uncertainties concerning analyses or assessments outside of a controlled clinical trial. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Madrigal undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events. Please refer to Madrigal's submissions filed or furnished with the U.S. Securities and Exchange Commission for more detailed information regarding these risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied. We specifically discuss these risks and uncertainties in greater detail in the section appearing in Part II, Item 1A of this Quarterly Report on Form 10-Q and Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 28, 2024 (the "2023 Form

10-K"), as well as in our other filings with the SEC. You should read the 2023 Form 10-K, this Quarterly Report, and the other documents that we file or have filed with the SEC, with the understanding that our actual future results may be materially different from the results expressed or implied by these forward-looking statements.

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

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

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

The consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our audited financial statements and accompanying notes for year ended December 31, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are included in our Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As disclosed in this report under "Cautionary Note Regarding Forward-Looking Statements," our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" sections contained in our Annual Report on Form 10-K for the year ended December 31, 2023,. Our operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period. As used herein, "Rezdiffra" refers to resmetirom approved by the FDA for the treatment of adults with NASH with moderate to advanced liver fibrosis, and "resmetirom" refers to, where applicable, Rezdiffra as well as resmetirom for the treatment of indications beyond NASH with moderate to advanced liver fibrosis.

About Madrigal Pharmaceuticals, Inc.

We are a biopharmaceutical company dedicated to transforming care for patients with NASH, a serious liver disease that can lead to cirrhosis, liver failure and premature mortality. Our medication, Rezdiffra (resmetirom), is a once-daily, oral, liver-directed THR-β agonist designed to target key underlying causes of NASH. In March 2024, Rezdiffra became the first and only FDA-approved therapy for patients with NASH. Rezdiffra became commercially available in the United States in April 2024. Rezdiffra is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

NASH Disease State Overview. NASH is a more advanced form of nonalcoholic fatty liver disease (NAFLD). NAFLD has become the most common liver disease in the United States and other developed countries and is characterized by an accumulation of fat in the liver with no other apparent causes. NASH can progress to cirrhosis or liver failure, require liver transplantation and can also result in liver cancer. NASH is the leading cause of liver transplants in the U.S. for women, and is expected to soon be the leading cause of liver transplants overall. Additionally, patients with NASH, especially those with more advanced metabolic risk factors (hypertension, concomitant type 2 diabetes), are at increased risk for adverse cardiovascular events and increased morbidity and mortality. Once patients progress to NASH with moderate to advanced fibrosis (consistent with fibrosis stages F2 and F3), the risk of adverse liver outcomes increases substantially.

NASH is also known as metabolic dysfunction-associated steatohepatitis ("MASH") following a change in disease nomenclature introduced by hepatology medical societies in 2023.

Our Patient Focus. Madrigal estimates that approximately 1.5 million patients have been diagnosed with NASH in the U.S., of which approximately 525,000 have NASH with moderate to advanced fibrosis. Madrigal estimates that approximately 315,000 diagnosed patients with NASH with moderate to advanced fibrosis are under the care of specialist physicians Madrigal will be targeting during the launch of Rezdiffra.

Our Clinical Development Program. Madrigal is currently conducting multiple Phase 3 clinical trials to evaluate the safety and efficacy of Rezdiffra for the treatment of NASH, including the pivotal MAESTRO-NASH biopsy study in patients with significant fibrosis, the MAESTRO-NASH Outcomes study in patients with NASH with compensated cirrhosis and the MAESTRO-NAFLD-1 OLE safety study. Positive results from the pivotal MAESTRO-NASH biopsy study were published in the *New England Journal of Medicine* in February 2024.

Data from the 52-week first 1,000 patient portion of MAESTRO-NASH, together with data from MAESTRO-NAFLD-1, the open-label extension of the MAESTRO-NAFLD-1 study, Phase 2 and Phase 1 data, including safety parameters, formed the basis for Madrigal's successful subpart H submission to the FDA for accelerated approval of Rezdiffra for treatment of NASH with moderate to advanced liver fibrosis.

Key Developments

On June 6, 2024, we announced new data from the Phase 3 MAESTRO-NASH study of Rezdiffra presented at the European Association for the Study of the Liver (EASL) Congress. Our key Rezdiffra presentations at the EASL Congress

included (i) a late-breaking artificial intelligence-based analysis of MAESTRO-NASH biopsy data that demonstrated Rezdiffra improved key fibrotic features that are predictive of progression to decompensated cirrhosis; (ii) noninvasive test data through three years of treatment that demonstrated durable treatment response to Rezdiffra, with 91% of patients achieving improvement or stabilization of liver stiffness; (iii) the first analysis of health-related quality of life data from MAESTRO-NASH, which demonstrated Rezdiffra improved patient worry, health distress and stigma; and (iv) the first analysis of Rezdiffra treatment in metabolic dysfunction and alcohol-associated liver disease (MetALD), which demonstrated patients achieved similar rates of fibrosis improvement and steatohepatitis resolution compared to the NASH population. Additionally, we presented multiple health economics outcomes research abstracts at the EASL Congress highlighting the clinical and economic burden of NASH.

On May 7, 2024, we entered into a Sales Agreement (the "2024 Sales Agreement") with TD Securities (USA) LLC, ("TD Cowen"), pursuant to which we may issue and sell through or to TD Cowen, acting as agent or principal, shares of our common stock, par value $0.0001 per share (the "Common Stock"), from time to time having an aggregate sales price of up to $300.0 million (the "ATM Offering"). The 2024 Sales Agreement replaces and supersedes the prior sales agreement, dated June 1, 2021 and amended on May 9, 2023, between the us and Cowen and Company, LLC, an affiliate of TD Cowen (the "Prior Sales Agreement"), which was terminated effective upon the entry into the 2024 Sales Agreement. We sold 1,334,044 shares of Common Stock having an aggregate offering price of $225.1 million pursuant to the Prior Sales Agreement.

On March 14, 2024, we announced that the U.S. Food and Drug Administration ("FDA") granted accelerated approval of Rezdiffra (resmetirom) in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis ("NASH") with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). On April 9, 2024, we announced U.S. availability of Rezdiffra for the treatment of patients with noncirrhotic NASH with moderate to advanced liver fibrosis.

On March 18, 2024, we announced we had commenced an underwritten public offering of $500.0 million in shares of our common stock and pre-funded warrants to purchase shares of our common stock. The size of the offering was increased by $100.0 million subsequent to the initial announcement, for a total of approximately $600.0 million gross proceeds before underwriting discounts, commissions, and other expenses. The $600.0 million offering closed on March 21, 2024, and we received net proceeds totaling approximately $574.0 million in the three months ended March, 31, 2024. The underwriters exercised in full their 30-day option to purchase additional shares of common stock, resulting in an additional $90.0 million gross proceeds. The exercise of the underwriters' option closed on April 2, 2024 and we received net proceeds totaling approximately $85.9 million. We collectively sold an aggregate of 1,096,153 shares of our common stock and pre-funded warrants to purchase 1,557,692 shares of our common stock in the underwritten offering.

Basis of Presentation

Revenue

In March 2024, the FDA approved Rezdiffra for the treatment of noncirrhotic NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Rezdiffra is a once-daily, oral, liver-directed, THR-ß agonist designed to target key underlying causes of NASH. Rezdiffra was launched for sale in the U.S. in April 2024.

Research and Development Expenses

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

Our research and development expenses consist primarily of:

- salaries and related expense, including stock-based compensation;
- external expenses paid to clinical trial sites, contract research organizations, laboratories, database software and consultants that conduct clinical trials;
- expenses related to development and the production of nonclinical and clinical trial supplies, including fees paid to contract manufacturers;

- expenses related to preclinical studies;
- expenses related to compliance with drug development regulatory requirements; and
- other allocated expenses, which include direct and allocated expenses for depreciation of equipment and other supplies.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we conduct our clinical study programs, manufacturing and toxicology studies. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, additional drug manufacturing requirements, and later stage toxicology studies such as carcinogenicity studies. 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.

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

Selling, General and Administrative Expenses

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

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities as of the date of the financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses, stock-based compensation expense, gross to net expenses, and inventory valuation. 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 as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on February 28, 2024, aside from the addition of estimates related to revenue recognition and inventory valuation. Refer to Note 2 to the condensed consolidated financial statements for details of accounting policies over revenue and inventory.

Revenue Recognition

Our accounting policy over revenue recognition has a significant impact on the financial results and involves substantial judgement and estimation. The amount of revenue we recognize is impacted by variable consideration, as described in Note 2. Our gross to net estimates are based on contracts with customers, government agencies, healthcare providers, industry data, historical information, and other factors. The judgements and estimates involved in determining

variable consideration are reviewed each reporting period, as all are subject to adjustments as new information becomes available.

Inventory

We value our inventories at the lower of cost or estimated net realizable value using the first-in, first-out ("FIFO") method, as described in Note 2. The value of our inventories is impacted by excess, slow-moving, and obsolete items, which could lead to write downs in value. We periodically review our inventory for factors that could impact the future recoverability and realization of future sales, which requires estimates and judgements.

Results of Operations

Three Months Ended June 30, 2024 and 2023

The following table provides comparative unaudited results of operations for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Increase / (Decrease)	
	2024	2023	$	%
Product revenue, net	$ 14,638	$ —	$ 14,638	100 %
Operating expenses:				
Cost of sales	636	—	636	100 %
Research and development	71,091	68,605	2,486	4 %
Selling, general and administrative	105,448	17,845	87,603	491 %
Interest income	(14,222)	(3,551)	10,671	301 %
Interest expense	3,656	2,901	755	26 %
	$ (151,971)	$ (85,800)	$ (66,171)	77 %

Revenue

We began selling Rezdiffra in April 2024. For the three months ended June 30, 2024, we recorded $14.6 million of product revenue, net.

Cost of Sales

Cost of sales were incurred as a result of sales of Rezdiffra. For the three months ended June 30, 2024, we recorded $0.6 million of cost of sales. We expect cost of sales to increase in the future, as a portion of the inventory sold was previously expensed to research and development costs prior to achieving regulatory approval, as approval was considered uncertain.

Research and Development Expenses

The following table represents our research and development expenses for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Increase / Decrease	
	2024	2023	$	%
Personnel and Internal Expense	$ 17,295	$ 12,651	$ 4,644	37 %
External Expense	53,796	55,954	(2,158)	(4)%
Total	$ 71,091	$ 68,605	$ 2,486	4 %

Our research and development expenses were $71.1 million for the three months ended June 30, 2024, compared to $68.6 million in the corresponding period in 2023. Research and development expenses increased by $2.5 million in the 2024 period due primarily to an increase in headcount and timing of clinical studies.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses were $105.4 million for the three months ended June 30, 2024, compared to $17.8 million in the corresponding period in 2023. Selling, general and administrative expenses increased by $87.6 million in the 2024 period due primarily to increases in commercial preparation activities, including a corresponding increase in headcount, and an increase in stock compensation expense.

Interest Income

Our net interest income was $14.2 million for the three months ended June 30, 2024, compared to $3.6 million in the corresponding period in 2023. The increase in interest income was due primarily to higher principal balances and interest rates in 2024.

Interest Expense

Our interest expense was $3.7 million for the three months ended June 30, 2024, compared to $2.9 million in the corresponding period in 2023. The increase in interest expense was primarily the result of a higher outstanding principal balance during the period under the Loan Facility with Hercules.

Six Months Ended June 30, 2024 and 2023

	Six Months Ended June 30,		Increase / (Decrease)	
	2024	2023	$	%
Product revenue, net	$ 14,638	$ —	$ 14,638	100 %
Operating expenses:				
Cost of sales	636	—	636	100 %
Research and development	142,328	130,759	11,569	9 %
General and administrative	186,249	34,027	152,222	447 %
Interest income	(22,556)	(7,327)	15,229	208 %
Interest expense	7,493	5,237	2,256	43 %
	$ (299,512)	$ (162,696)	$ (136,816)	84 %

Revenue

We began selling Rezdiffra in April 2024. For the six months ended June 30, 2024, we recorded $14.6 million of product revenue, net.

Cost of Sales

Cost of sales were incurred as a result of sales of Rezdiffra. For the six months ended June 30, 2024, we recorded $0.6 million of cost of sales. We expect cost of sales to increase in the future, as a portion of the inventory sold was previously expensed to research and development costs prior to achieving regulatory approval, as approval was considered uncertain.

Research and Development Expenses

The following table represents our research and development expenses for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		Increase / Decrease	
	2024	2023	$	%
Personnel and Internal Expense	$ 34,011	$ 24,910	$ 9,101	37 %
External Expense	108,317	105,849	2,468	2 %
Total	$ 142,328	$ 130,759	$ 11,569	9 %

Our research and development expenses were $142.3 million for the six months ended June 30, 2024, compared to $130.8 million in the corresponding period in 2023. Research and development expenses increased by $11.6 million in the 2024 period due primarily to an increase related to timing of manufacturing, an increase in headcount, and timing of clinical studies.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses were $186.2 million for the six months ended June 30, 2024, compared to $34.0 million in the corresponding period in 2023. Selling, general and administrative expenses increased by $152.2 million in the 2024 period due primarily to increases in commercial preparation activities, including a corresponding increase in headcount, and an increase in stock compensation expense. We believe our selling, general and administrative expenses will likely increase over time as we continue with commercialization activities and expand our operating activities.

Interest Income

Our net interest income was $22.6 million for the six months ended June 30, 2024, compared to $7.3 million in the corresponding period in 2023. The increase in interest income was due primarily to higher principal balances and interest rates in 2024.

Interest Expense

Our interest expense was $7.5 million for the six months ended June 30, 2024, compared to $5.2 million in the corresponding period in 2023. The increase in interest expense was primarily the result of a higher outstanding principal balance during the period under the Loan Facility with Hercules.

Liquidity and Capital Resources

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

As of June 30, 2024, we had cash, cash equivalents, restricted cash, and marketable securities totaling $1,062.8 million compared to $634.1 million as of December 31, 2023, with this increase attributable to our 2024 public offering, where we received net proceeds of approximately $574.0 million in March 2024. Additionally, in April 2024 we received net proceeds of approximately $85.9 million as a result of the underwriters' exercise in full of their option to purchase additional shares as part of the March 2024 offering. 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.

While our rate of cash usage will likely increase in the future, in particular to support our product development and clinical trial efforts, as well as commercialization activities, we believe our available cash resources are sufficient to fund our operations past one year from the issuance of the financial statements contained herein. Our future long-term

liquidity requirements will be substantial and will depend on many factors, including our ability to effectively commercialize Rezdiffra. To meet future long-term liquidity requirements, as well as maintain compliance with certain of our Loan Facility covenants, we may need to raise additional capital to fund our operations through equity or debt financings, collaborations, partnerships or other strategic transactions. We regularly consider fundraising opportunities and may decide, from time to time, to raise capital based on various factors, including market conditions and our plans of operation. Additional capital, if needed, may not be available on terms acceptable to us, or at all. We also have the ability to delay certain research activities and related clinical expenses, as well as commercial investments, if necessary due to liquidity concerns until a date when those concerns are relieved. If adequate funds are not available, or if the terms of potential funding sources are unfavorable, our business and our ability to develop our product candidates would be harmed. Furthermore, any sales of additional equity securities may result in dilution to our stockholders, and any debt financing may include covenants that restrict our business.

At-the-Market Sales Agreement

In May 2023, we entered into Amendment No. 1 (the "Sales Agreement Amendment") to our existing sales agreement (the "2021 Sales Agreement") with Cowen, which was subsequently terminated in May 2024 when we entered into a Sales Agreement (the "2024 Sales Agreement") with Cowen, replacing and superseding the 2021 Sales Agreement, as amended by the Sales Agreement Amendment. We are authorized to issue and sell up to $300.0 million in shares of our common stock under the 2024 Sales Agreement. We sold no shares in the three and six months ended June 30, 2024 under either the 2021 Sales Agreement, as amended by the Sales Agreement Amendment or the 2024 Sales Agreement.

As of June 30, 2024, $300.0 million remained reserved and available for sale under the 2024 Sales Agreement and our related prospectus supplement.

Sales of our common stock, if any, under the 2024 Sales Agreement will be made by any method that is deemed to be an "at the market" offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended. We have no obligation to sell any common stock and may at any time suspend offers under the 2024 Sales Agreement or terminate the 2024 Sales Agreement pursuant to its terms.

Loan Facility

In May 2022 we entered into the $250.0 million Loan Facility (the "Loan Facility") with Hercules Capital, Inc. ("Hercules"). On February 3, 2023, we entered into the First Amendment (the "First Amendment") to the Loan Facility (as amended, the "Amended Loan Facility"). Under the terms of the Loan Facility, the first $50.0 million tranche ("Tranche 1") was drawn at closing. Under the Amended Loan Facility, $65.0 million was drawn in 2023 under the second tranche ("Tranche 2"). The third tranche ("Tranche 3") of $75.0 million became available to us when we obtained FDA approval for Rezdiffra in March 2024. We did not draw on Tranche 3 prior to its expiration in June 2024.

In connection with Tranche 1, in 2022 we issued Hercules warrants to purchase 14,899 shares of our common stock, which had a Black-Scholes value of $0.6 million. In connection with Tranche 2, in 2023 we issued to Hercules warrants to purchase an aggregate of 4,555 shares of common stock, which had a Black-Scholes value of $0.9 million.

The Loan Facility had a minimum interest rate of 7.45% and adjusted with changes in the prime rate. The Amendment reduced the interest rate under the Amended Loan Facility to the greater of (i) the prime rate as reported in The Wall Street Journal plus 2.45% and (ii) 8.25%. We were to originally pay interest-only monthly payments of accrued interest under the Loan Facility through May 1, 2025, for a period of 36 months. That period was extended in March 2024 to May 1, 2026 upon achievement of a milestone related to FDA approval. The period can further be extended to May 3, 2027, upon the achievement of a future revenue milestone, subject to compliance with applicable covenants. The Loan Facility originally matured in May 2026, but was extended to May 2027 upon the achievement a milestone related to FDA approval. The Loan Facility is secured by a security interest in substantially all of our assets, other than intellectual property. It includes an end of term charge of 5.35% of the aggregate principal amount, which is accounted for in the loan discount.

The Loan Facility includes affirmative and restrictive financial covenants which commenced on January 1, 2023, including maintenance of a minimum cash, cash equivalents and liquid funds covenant of $35.0 million, which may decrease in certain circumstances if we achieve certain clinical milestones and a revenue milestone, and a revenue-based covenant that could apply commencing at or after the time that financial reporting is due for the quarter ending September 30, 2024. The Loan Facility contains event of default provisions for: our failure to make required payments or maintain compliance with covenants under the Loan Facility; our breach of certain representations or default under certain obligations outside the Loan Facility; insolvency, attachment or judgment events affecting us; and any circumstance which has occurred or could reasonably be expected to have a material adverse effect on us, provided that, any failure to achieve

approval or certain other milestones under the Loan Facility shall not in and of itself constitute a material adverse effect. The Loan Facility also includes customary covenants associated with a secured loan facility, including covenants concerning financial reporting obligations, and certain limitations on indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, and deposit accounts.

As of June 30, 2024, the outstanding principal under the Loan Facility was $115.0 million. The interest rate as of June 30, 2024 was 10.95%. As of June 30, 2024, we were in compliance with all loan covenants and provisions.

March 2024 Public Offering

On March 18, 2024, we entered into an Underwriting Agreement with Goldman Sachs & Co. LLC, Jefferies LLC, Cowen and Company, LLC, Evercore Group L.L.C. and Piper Sandler & Co, as representatives of the several underwriters named therein (the "2024 Underwriters"), pursuant to which we sold to the 2024 Underwriters in an underwritten public offering (the "2024 Offering"): (i) 750,000 shares of common stock at a public offering price of $260.00 per share, (ii) pre-funded warrants (the "2024 Pre-Funded Warrants") to purchase 1,557,692 shares of common stock at a public offering price of $259.9999 per 2024 Pre-Funded Warrant, which represents the per share public offering price for the common stock less a $0.0001 per share exercise price for each such Pre-Funded Warrant, and (iii) a 30-day option for the 2024 Underwriters to purchase up to 346,153 additional shares of common stock at the public offering price of $260.00 per share (the "Underwriters' Option"). The 2024 Offering closed on March 21, 2024.

The gross proceeds of the 2024 Offering was $600.0 million, and we received net proceeds, after deducting the underwriting discount and commissions and other estimated offering expenses payable by us, of approximately $574.0 million.

The Underwriters' Option was later exercised in full, and closed on April 2, 2024. We received net proceeds for the exercise of the Underwriters' Option, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, of approximately $85.9 million.

We intend to use the net proceeds from the 2024 Offering for our commercial activities in connection with the launch of Rezdiffra in the U.S. and for general corporate purposes, including, without limitation, research and development expenditures, ongoing clinical trial expenditures, manufacture and supply of drug substance and drug products, potential ex-U.S. commercialization or partnering opportunities, potential acquisitions or licensing of new technologies, capital expenditures and working capital.

The 2024 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of 2024 Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of 2024 Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days prior notice to the Company.

2023 Public Offering

On September 28, 2023, we entered into an Underwriting Agreement with Goldman Sachs & Co. LLC, as representative of the several underwriters named therein, pursuant to which we sold to the underwriters in an underwritten public offering (the "2023 Offering"): (i) 1,248,098 shares of common stock at a public offering price of $151.69 per share, and (ii) pre-funded warrants (the "2023 Pre-Funded Warrants") to purchase 2,048,098 shares of common stock at a public offering price of $151.6899 per 2023 Pre-Funded Warrant, which represents the per share public offering price for the common stock less a $0.0001 per share exercise price for each such 2023 Pre-Funded Warrant. The 2023 Offering closed on October 3, 2023.

The gross proceeds of the 2023 Offering was $500.0 million, and we received net proceeds, after deducting the underwriting discount and commissions and other estimated offering expenses payable by us, of approximately $472.0 million. We intend to use the net proceeds from the 2023 Offering for our clinical and commercial activities for the launch of resmetirom in the U.S. and for general corporate purposes, including, without limitation, research and development expenditures, clinical trial expenditures, manufacture and supply of drug substance and drug products, potential acquisitions or licensing of new technologies, capital expenditures and working capital.

The 2023 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of 2023 Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of

2023 Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days prior notice to us.

Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
Net cash used in operating activities	$ (284,102)	$ (159,377)
Net cash used in investing activities	(24,045)	(190,596)
Net cash provided by financing activities	707,829	95,620
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 399,682	$ (254,353)

Net cash used in operating activities was $284.1 million for the six months ended June 30, 2024, compared to $159.4 million for the corresponding period in 2023. 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 $24.0 million for the six months ended June 30, 2024, compared to $190.6 million used in for the corresponding period in 2023. Net cash used in investing activities for the six months ended June 30, 2024 primarily consisted of $365.0 million of purchases of marketable securities for our investment portfolio, partially offset by $346.4 million from sales and maturities of marketable securities. Net cash used in investing activities for the corresponding period in 2023 primarily consisted of $290.7 million of purchases of marketable securities for our investment portfolio, partially offset by $100.2 million from sales and maturities of marketable securities.

Net cash provided by financing activities was $707.8 million for the six months ended June 30, 2024, compared to $95.6 million for the corresponding period in 2023. Financing activities for the six months ended June 30, 2024 consisted of $574.0 million of proceeds from our March 2024 public offering, $85.9 million of net proceeds from the Underwriter's Option in April 2024, and $49.7 million from exercises of stock options. Net cash provided by financing activities for the corresponding period in 2023 consisted primarily of $50.0 million from issuance of the Loan Facility, $24.2 million from proceeds from the exercise of common stock options and $21.8 million from sales of our common stock under the 2023 Sales Agreement.

Contractual Obligations and Commitments

In August 2023, we entered into the Fifth Amendment to our Office Lease (the "Lease Amendment"). The Lease Amendment extends the term of the lease through November 2026. As a result of the Lease Amendment, an incremental $1.6 million right-of-use asset and lease liabilities were recorded during the year ended December 31, 2023.

In May 2022 we entered into the $250.0 million Loan Facility. As of June 30, 2024, we had drawn $115.0 million under the facility. We are scheduled to pay interest-only monthly payments of accrued interest under the Loan Facility through May 1, 2026, which period may be extended to May 3, 2027 upon the achievement of future revenue milestones, and subject to compliance with applicable covenants.

We have 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. We received FDA approval for Rezdiffra in March 2024. A tiered single-digit royalty is payable to Roche on net sales of Rezdiffra, subject to certain reductions.

Except as noted above and the future minimum payments due on the Loan Facility with Hercules set forth in "Note 7 – Long Term Debt" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, no significant changes to contractual obligations and commitments occurred during the six months ended June 30, 2024, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on February 28, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

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

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

Capital Market Risk

We began generating revenue from the sale of Rezdiffra in the second quarter of 2024, but we have historically depended on, and will continue to depend on, funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price.

Effects of Inflation

We do not believe inflation has had a material effect on our business, financial condition or results of operations during three and six months ended June 30, 2024 and June 30, 2023, respectively.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act 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.

Under the supervision of our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Report. Based on that
evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2024.

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

During the quarter ended June 30, 2024, we designed and implemented controls over revenue, trade receivables, and inventory which we determined to be a material change in our internal control over financial reporting. There were no other changes to 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 legal proceedings.

Item 1A. Risk Factors.

Except as set forth below, there have been no material changes to the risk factors included in detail in the "Risk Factors" sections appearing in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 28, 2024 (the "Annual Report")

In order to execute our business plan and achieve profitability, we need to effectively commercialize Rezdiffra, which received FDA approval in March 2024 for the treatment of adults with NASH with moderate to advanced liver fibrosis. We may not be able to meet expectations with respect to sales of Rezdiffra or attain profitability and positive cash-flow from operations.

Rezdiffra is our only drug that has been approved for sale and it has been approved only for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis in the United States. Rezdiffra became commercially available in the United States in April 2024. We are focusing a significant portion of our activities and resources on Rezdiffra, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize Rezdiffra for the treatment of adults with NASH with moderate to advanced liver fibrosis in the United States.

Successful commercialization of Rezdiffra is subject to many risks. We have never, as an organization, launched or commercialized any product other than Rezdiffra, and there is no guarantee that we will be able to successfully commercialize Rezdiffra for its approved indication. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. We are in the process of building our commercial organization and hiring our U.S. sales force and will need to refine and further develop our commercial organization in order to successfully commercialize Rezdiffra. We expect that the initial commercial success of Rezdiffra for the treatment of NASH will depend on many factors, including the following:

- the efficacy, cost, approved use, and side-effect profile of Rezdiffra regimens relative to competitive treatment regimens for the treatment of NASH;
- Rezdiffra may compete with the off-label use of currently marketed products and other therapies in development that may in the future obtain approval for NASH;
- the effectiveness of our commercial strategy for the marketing of Rezdiffra, including our pricing strategy and the effectiveness of our efforts to obtain adequate third-party reimbursements;
- developing, maintaining and successfully monitoring commercial manufacturing arrangements for Rezdiffra with third-party manufacturers to ensure they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to negotiate and enter into any additional commercial, supply and distribution contracts to support commercialization efforts, and to hire and manage additional qualified personnel;
- our ability to meet the demand for commercial supplies of Rezdiffra at acceptable costs;
- the acceptance of Rezdiffra by physicians, patients and third-party payors;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- the actual market-size, ability to identify targeted patients and the demographics of patients eligible for Rezdiffra, which may be different than what we currently expect;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas;
- our ability to obtain, maintain or enforce our patents and other intellectual property rights; and
- the effect of recent or potential health care legislation in the United States.

While we believe that Rezdiffra for the treatment of NASH should have a commercially competitive profile, we cannot accurately predict the amount of time needed to attain a commercially successful profile or the amount of revenue that would be generated from the sale of Rezdiffra. If we do not effectively commercialize Rezdiffra, we will not be able to

execute our business plan and may not be able to achieve profitability. If our revenues, market share and/or other indicators of market acceptance of Rezdiffra do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

Rezdiffra has received accelerated approval from the FDA, and therefore faces future post-approval development and regulatory requirements, which present additional challenges for us to successfully navigate.

The FDA granted accelerated approval of Rezdiffra for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis in the United States in March 2024. Under the accelerated approval pathway, continued approval may be contingent upon verification of a clinical benefit in confirmatory trials. These post- approval requirements and commitments may not be feasible and/or could impose significant burdens and costs on us; could negatively impact our development, manufacturing and supply of our products; and could negatively impact our financial results. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. Failure to meet post-approval commitments and requirements, including completion of enrollment of—and in particular, any failure to obtain positive data from—any confirmatory studies required by the FDA, could result in negative regulatory action from the FDA and/or withdrawal of such accelerated approval. The recently enacted Food and Drug Omnibus Reform Act has expanded FDA's expedited withdrawal procedures for drugs approved through the accelerated approval pathway if a sponsor fails to conduct any required post-approval study with due diligence.

Unless otherwise informed by the FDA, an applicant must submit to the FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. If we or the manufacturing facilities for our products fail to comply with applicable regulatory requirements, the FDA may, among other actions: issue warning letters or untitled letters; seek an injunction or impose civil or criminal penalties or monetary fines; suspend or withdraw or alter the conditions of our marketing approval; suspend any ongoing clinical trials; refuse to approve pending applications or supplements to applications submitted by us; suspend or impose restrictions on operations, including costly new manufacturing requirements; and seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

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.

During the quarter ended June 30, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Director and Executive Officer 10b5-1 Plans

Our Section 16 officers and directors may enter into plans or arrangements for the purchase or sale of our securities that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act. Such plans and arrangements must comply in all respects with our insider trading policies, including our policy governing entry into and operation of 10b5-1 plans and arrangements.

The following table shows the number of shares of our common stock subject to the current Rule 10b5-1 trading arrangements of our Section 16 officers and directors in place as of August 2, 2024:

Name of Director or Section 16 Officer	Title of Director or Section 16 Officer	Date of Adoption, Modification, or Termination	Duration of the Plan	Aggregate Number of Shares of Common Stock that may be Sold under the Plan
Richard Levy, MD	Director	11/30/2023	June 16, 2025	15,000
Fred B. Craves, Ph.D.	Director	12/15/2023	August 31, 2024	30,000

Item 6. Exhibits.

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
1.1	Sales Agreement, dated May 7, 2024, by and between the Registrant and TD Securities (USA) LLC.	8-K	001-33277	1.1	May 7, 2024	
10.1*	Madrigal Pharmaceuticals, Inc. 2015 Amended Stock Plan, as amended and restated as of June 25, 2024.	8-K	001-33277	10.1	June 27, 2024	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1**	Certifications of Principal Executive Officer and Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Certifications of Principal Executive Officer and Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
104	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.					

* Indicates a management contract, compensatory plan or arrangement.

** 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, 2024

By: /s/ William J. Sibold

William J. Sibold
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2024

By: /s/ Mardi C. Dier

Mardi C. Dier
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, William J. Sibold, 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/ William J. Sibold

William J. Sibold
President and Chief Executive Officer
(Principal Executive Officer)
Date: August 7, 2024

Exhibit 31.2

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

I, Mardi C. Dier, 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/ Mardi C. Dier

Mardi C. Dier
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: August 7, 2024

Exhibit 32.1

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

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

The Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024 (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, 2024

/s/ William J. Sibold

William J. Sibold
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 7, 2024

/s/ Mardi C. Dier

Mardi C. Dier
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

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