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

FORM 10-Q

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

For the quarterly period ended March 31, 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 001-36464

Agile Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**23-2936302**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

500 College Road East, Suite 300
Princeton, New Jersey 08540
(Address including zip code of principal executive offices)

(609) 683-1880
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, par value $0.0001 per share**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

There were 6,856,229 shares of the registrant's common stock, $0.0001 par value, outstanding as of May 14, 2024.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended March 31, 2024

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "designed," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, growth and strategies, including expense reduction strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the attractiveness of our business to potential investors or business partners, our ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla®, the development of our other potential product candidates, the strength and breadth of our intellectual property, our planned clinical studies, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our potential product candidates, the legal and regulatory landscape impacting our business, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical study data, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

In addition, with respect to all our forward looking statements, we claim the protection of the safe harbor for forward looking statements contained in the Private Securities Litigation Reform Act of 1995.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- our ability to pay our obligations as they come due;
- we are quoted on the OTC markets, which could affect the liquidity in trading of our common stock and affect our ability to raise capital;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to successfully maintain and enhance the commercialization of and increase the uptake for Twirla, our only approved product;
- the rate and degree of market acceptance of Twirla by physicians, patients, clinics, institutions, third-party payors and others in the healthcare community;
- our ability to obtain adequate coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- the size and growth of the markets for Twirla and our ability to serve those markets;

- shortages of key materials in the supply chain affecting the manufacture and distribution of Twirla;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- the growth in demand for Twirla and our ability to manage the levels of Twirla inventory, which could result in our having to write off inventory and our inability to meet the minimum requirements under our supply agreement with Corium Innovations, Inc. ("Corium");
- our ability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of Twirla or other materials to supply commercial demand and/or a clinical trial or other tests and studies;
- the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla;
- the performance and financial condition of Corium or any of the suppliers;
- our ability to design and successfully complete a post-marketing long-term, prospective observational safety study comparing risks for venous thromboembolism, or VTE, and arterial thromboembolism, or ATE, in new users of Twirla to new users of oral combined hormonal contraceptives, or CHCs, and new users of Xulane in U.S. women of reproductive age using CHCs and the outcomes of our discussions with the United States Food and Drug Administration, or FDA, regarding the results of our post-marketing commitment, or PMC, to assess the residual drug content of Twirla after use;
- our ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain;
- our ability to obtain and maintain intellectual property protection for Twirla and our product candidates;
- the success and timing of our clinical trials or other studies, including post-marketing studies for Twirla;
- development of unexpected safety or efficacy concerns related to Twirla;
- our ability to continue to develop and maintain successful sales and marketing capabilities, including our ability to maintain an effective sales force or failure to build-out and implement an effective health care compliance program;
- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q. You should also read carefully the factors described in the "Risk Factors" included in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the Securities and Exchange Commission on March 28, 2024 to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, any such inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard any of these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we

believe these industry publications and third-party research, surveys, and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements.

Twirla® is one of our trademarks used in this Form 10-Q. This Form 10-Q also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Form 10-Q may appear without the ® symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Agile Therapeutics, Inc.
Part I — Financial Information

ITEM 1. Financial Statements

Agile Therapeutics, Inc.
Balance Sheets
(Unaudited)
(in thousands, except par value and share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 2,615	$ 2,557
Accounts receivable, net	4,813	3,392
Inventory, net	3,748	2,738
Prepaid expenses and other current assets	811	843
Total current assets	11,987	9,530
Property and equipment, net	50	75
Right of use asset	335	412
Other non-current assets	238	238
Total assets	$ 12,610	$ 10,255
Liabilities and stockholders' deficit		
Current liabilities:		
Long-term debt, current portion	$ —	$ 1,515
Notes payable, current portion	—	191
Accounts payable	12,620	9,574
Accrued expenses	8,443	9,131
Lease liability, current portion	378	366
Total current liabilities	21,441	20,777
Lease liabilities, long-term	—	100
Warrant liability	1,493	5,696
Total liabilities	22,934	26,573
Commitments and contingencies (Note 9)		
Stockholders' deficit		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at March 31, 2024 and no shares issued and outstanding at December 31, 2023	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized, 6,856,229 and 2,963,657 issued and outstanding at March 31, 2024 and December 31, 2023, respectively	5	4
Additional paid-in capital	411,555	406,846
Accumulated deficit	(421,884)	(423,168)
Total stockholders' deficit	(10,324)	(16,318)
Total liabilities and stockholders' deficit	$ 12,610	$ 10,255

See accompanying notes to unaudited financial statements.

Agile Therapeutics, Inc.
Statements of Operations and Comprehensive Income (Loss)
(Unaudited)
(in thousands, except per share and share data)

	Three Months Ended March 31,	
	2024	2023
Revenues, net	$ 5,716	$ 3,813
Cost of product revenues	1,680	2,003
Gross profit	4,036	1,810
Operating expenses:		
Research and development	$ 495	$ 763
Selling and marketing	3,682	4,670
General and administrative	2,616	3,085
Total operating expenses	6,793	8,518
Loss from operations	(2,757)	(6,708)
Other income (expense)		
Interest income	23	33
Interest expense	(185)	(402)
Unrealized gain on warrant liability	4,203	1,687
Total other income (expense), net	4,041	1,318
Income (loss) before benefit from income taxes	1,284	(5,390)
Benefit from income taxes	—	—
Net income (loss) and comprehensive income (loss)	$ 1,284	$ (5,390)
Net income (loss) per share (basic and diluted)	$ 0.28	$ (5.91)
Weighted-average common shares (basic and diluted)	4,631,902	912,044

See accompanying notes to unaudited financial statements.

Agile Therapeutics, Inc.
Statements of Changes in Stockholders' Deficit
(Unaudited)
(in thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Number of Shares	Amount	Number of Shares	Amount				
Balance December 31, 2023	—	$ —	2,963,657	$ 4	$ 406,846	$ —	$ (423,168)	$ (16,318)
Share-based compensation - stock options and RSUs	—	—	—	—	333	—	—	333
Issuance of common stock in connection with the exercise of common stock warrants, net of expenses	—	—	3,892,572	1	4,376	—	—	4,377
Net income	—	—	—	—	—	—	1,284	1,284
Balance March 31, 2024	—	$ —	6,856,229	$ 5	$ 411,555	$ —	$ (421,884)	$ (10,324)

See accompanying notes to unaudited financial statements.

On April 10, 2023, the Company effectuated a one-for-fifty reverse stock split of its outstanding shares of common stock (the "Reverse Stock Split"). The Reverse Stock Split reduces the Company's shares of outstanding common stock, stock options, RSU's, and warrants to buy shares of the Company's common stock. Fractional shares of common stock that would have otherwise resulted from the Reverse Stock Split were rounded down to the nearest whole share, and cash in lieu of payments were made to stockholders. All share and per share data for all periods presented in the accompanying financial statements and the related disclosures have been adjusted retrospectively to reflect the Reverse Stock Split. The number of authorized shares of common stock and the par value per share remains unchanged.

Agile Therapeutics, Inc.
Statements of Changes in Stockholders' Deficit
(Unaudited)
(in thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Number of Shares	Amount	Number of Shares	Amount				
Balance December 31, 2022	—	$ —	859,402	$ —	$ 403,157	$ —	$ (408,702)	$ (5,545)
Share-based compensation - stock options and RSUs	—	—	—	—	498	—	—	498
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	72,699	—	1,003	—	—	1,003
Net loss	—	—	—	—	—	—	(5,390)	(5,390)
Balance March 31, 2023	—	$ —	932,101	$ —	$ 404,658	$ —	$ (414,092)	$ (9,434)

See accompanying notes to unaudited financial statements.

Agile Therapeutics, Inc.
Statements of Cash Flows
(Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net income (loss)	$ 1,284	$ (5,390)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	26	26
Amortization	77	67
Noncash stock-based compensation	333	498
Noncash amortization of deferred financing costs	135	307
Unrealized gain on warrants	(4,203)	(1,687)
Changes in operating assets and liabilities:		
Accounts receivable	(1,421)	254
Inventory	(1,010)	(879)
Prepaid expenses and other assets	32	260
Accounts payable and accrued expenses	2,358	5,026
Lease liability	(87)	(77)
Net cash used in operating activities	(2,476)	(1,595)
Cash flows from investing activities:		
Acquisition of property and equipment	—	—
Net cash (used in) provided by investing activities	—	—
Cash flows from financing activities:		
Proceeds from At-the-Market sales of common stock, net of offering costs	—	1,003
Proceeds from the exercise of common stock warrants, net of offering costs	4,376	
Repayments of debt	(1,650)	(225)
Repayments of note payable	(191)	—
Net cash provided by financing activities	2,535	778
Net increase (decrease) in cash and cash equivalents	59	(817)
Cash and cash equivalents, beginning of period	2,556	5,246
Cash and cash equivalents, end of period	$ 2,615	$ 4,429
Supplemental cash flow information		
Interest paid	$ 50	$ 94

See *accompanying notes to unaudited financial statements*.

Agile Therapeutics, Inc.
Notes to Financial Statements
March 31, 2024
(amounts in tables in thousands, except share and per share data)

1. Organization and Description of Business

Nature of Operations

Agile Therapeutics, Inc. ("Agile" or the "Company") was incorporated in Delaware on December 22, 1997. Agile is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. The Company's activities since inception have consisted principally of raising capital, performing research and development, including development of the Company's lead product, Twirla®, and more recently commercializing Twirla. The Company is headquartered in Princeton, New Jersey.

The Company's sole approved product, Twirla, is a once-weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA, in February 2020 and was commercially launched in early December 2020. Substantially all of the Company's resources are currently dedicated to commercializing Twirla in the United States. The Company has generated minimal product revenue to date and is subject to a number of risks similar to those of other early stage commercial companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the need to obtain additional capital necessary to fund the development of its products, reliance on a consistent supply chain both for Twirla and in general, macroeconomic factors such as inflation, competition from larger companies, and compliance with FDA and other government regulations. If the Company does not continue to successfully commercialize Twirla, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of March 31, 2024, the Company had an accumulated deficit of approximately $421.9 million. The Company expects to continue to incur significant operating expenses for the foreseeable future in connection with its ongoing activities, as the Company:

- maintains a sales and marketing infrastructure and contract manufacturing arrangement to support the continued commercialization of Twirla in the United States;
- continues to commercialize Twirla and seek increased uptake of Twirla in the United States;
- continues to evaluate additional line extensions for Twirla and initiates development of potential product candidates in addition to Twirla;
- maintains, leverages, and expands the Company's intellectual property portfolio; and
- maintains operational, financial, and management information systems and personnel, including personnel to support the Company's product development and future commercialization efforts.

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 8), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

Going Concern

As of March 31, 2024, the Company had cash and cash equivalents of $2.6 million and a $9.5 million working capital deficit. The Company's current liquidity is sufficient to fund operations into June 2024. The Company closely monitors its cash and cash equivalents and will need to raise additional funds to meet its projected operating requirements, including the continued commercialization of Twirla, and exploring the advancement of its existing pipeline and its possible expansion through business development activities.

The Company has generated losses since inception, used substantial cash in operations, has a working capital deficit as of March 31, 2024, and anticipates it will continue to incur net losses for the foreseeable future. The Company's future success depends on its ability to obtain additional capital and/or implement various strategic alternatives, and there can be no assurance that any financing can be realized by the Company, or if realized, what the terms of any such financing may be, or that any amount that the Company is able to raise will be adequate. Based upon the foregoing, management has concluded that there is substantial doubt about the Company's ability to

continue as a going concern through the 12 months following the date on which this Quarterly Report on Form 10-Q is filed.

The Company continues to analyze various alternatives, including refinancing alternatives, potential asset sales and mergers and acquisitions. The Company's future success depends on its ability to raise additional capital as discussed above. The Company cannot be certain that these initiatives, or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current stockholders will experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company then may be unable to continue the commercialization of Twirla, and may also be required to cut operating costs, and forego future development and other opportunities.

The unaudited financial statements as of March 31, 2024 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to obtain additional capital, reduce expenditures and/or execute on its business plan and successfully commercialize Twirla. The unaudited financial statements as of March 31, 2024 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for Quarterly Reports on Form 10-Q. Accordingly, certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP has been condensed or omitted pursuant to such rules and regulations. These interim financial statements should be read in conjunction with the audited financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC on March 28, 2024.

In the opinion of management, the unaudited interim financial statements reflect all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods presented. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of the operating results for the full fiscal year or any future period.

The accompanying unaudited financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. If the Company encounters unforeseen factors that impact the Company's current business plan or its ability to generate revenue from the commercialization of Twirla, the Company believes it has the ability to revise its commercial plans, including curtailing sales and marketing spending, to allow it to continue to fund its operations.

2. Summary of Significant Accounting Policies

The Company's complete listing of significant accounting policies is described in Note 2 to the Company's audited financial statements as of December 31, 2023 included in its Annual Report on Form 10-K filed with the SEC on March 28, 2024.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
March 31, 2024
(amounts in tables in thousands, except share and per share data)

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, revenue recognition, inventory reserves, the accounting for common stock warrants, stock-based compensation, and accounting for research and development costs. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Risks and Uncertainties

While Twirla has been approved by the FDA, other potential product candidates developed by the Company will require approval from the FDA prior to commercial sales. There can be no assurance that the Company's other product candidates will receive the required approval. If the Company is denied approval or such approval is delayed, or is unable to obtain the necessary financing to complete development and approval, there could be a material adverse impact on the Company's financial condition and results of operations.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. Cash and cash equivalents include money market funds that invest primarily in commercial paper and U.S. government and U.S. government agency obligations.

The Company maintains balances with financial institutions in excess of the Federal Deposit Insurance Corporation limit.

Accounts Receivable and Allowances

Accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The accounts receivable are recorded at the invoice amount, less prompt pay and other discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses represents the Company's estimate of losses over the life of the receivables. The Company evaluates forward-looking economic factors and uses professional judgment to determine the allowance for credit losses. The credit loss reserves are reviewed and adjusted periodically. Credit loss reserves were not material as of March 31, 2024 and December 31, 2023, respectively.

Accounts receivable are aged based on the contractual payment terms. When the collectability of an invoice is no longer probable, the Company will create a reserve for that specific receivable. If a receivable is determined to be uncollectible, it is charged against the general credit loss reserve or the reserve for the specific receivable, if one exists.

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash and cash equivalents (see Note 3) and the Company's warrant liability (see Note 3) are carried at fair value. The warrant liability is measured at fair value in accordance with ASC 815.

Other financial instruments, including accounts receivable, accounts payable and accrued liabilities, are carried at cost, which approximates fair value given their short-term nature.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
March 31, 2024
(amounts in tables in thousands, except share and per share data)

Inventory

Inventory is valued utilizing the weighted average costing method. The Company records an inventory reserve for losses associated with dated, expired, excess or obsolete items. This reserve is based on management's current knowledge with respect to inventory levels, planned production and sales volume assumptions. As of March 31, 2024 and December 31, 2023, inventory reserves approximated $1.4 million and $1.4 million, respectively.

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe the carrying values of any long-lived assets are impaired as of March 31, 2024.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expense consists primarily of costs related to personnel, including salaries and other personnel-related expenses, expenses related to manufacturing, clinical trial expenses, consulting fees, and support services used in drug development. All research and development costs are charged to operations as incurred in accordance with ASC 730, *Research and Development*.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

Advertising Costs

The Company has elected to expense advertising costs when incurred. Advertising costs totaled zero for each of the three months ended March 31, 2024 and 2023, respectively.

Deferred Financing Costs

Costs directly attributable to the Company's senior secured term loan (see Note 7) are deferred and reported as a reduction of the related term loan. These costs represent legal fees and other costs related to the term loan and are being amortized utilizing the straight-line method over the term of the loan. Amortization of deferred financing costs charged to interest expense was approximately $23,000 and $53,000 for the three months ended March 31, 2024 and 2023, respectively.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to credit risk consist principally of cash, cash equivalents, and accounts receivable. The Company invests its cash and cash equivalents in interest-bearing accounts in United States financial institutions, the balances of which exceed federally insured limits. The Company mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity, and have a high credit quality. The Company has not recognized any losses from credit risks on such accounts. The Company has no financial instruments with off balance sheet risk of accounting loss.

Major customers of the Company are defined as those constituting greater than 10% of its total revenue. In the three months ended March 31, 2024, the Company had sales to six customers that individually accounted for more than 10% of its total revenue. These customers had sales of $1.1 million, $0.9 million, $0.9 million, $0.8 million, $0.8 million, and $0.8 million, respectively, which represented 94% of total revenues in the three months ended March 31, 2024. Accounts receivable related to these six customers totaled 96% of the Company's total accounts receivable as of March 31, 2024. In the three months ended March 31, 2023, the Company had sales to four customers that individually accounted for more than 10% of its total revenue. These customers had sales of $1.1

million, $0.9 million, $0.8 million and $0.8 million, respectively, which represented 92% of total revenues in the three months ended March 31, 2023.

Revenue Recognition

The Company recognizes revenue from the sale of its product, Twirla, in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

In accordance with ASC 606, the Company recognizes revenue at the point in time when its performance obligation is satisfied by transferring control of the promised goods or services to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The Company's customers are located in the United States and consist primarily of wholesale distributors. Accounts receivable due to the Company from contracts with its customers are stated separately in the balance sheet, net of various allowances as described later in this section and in the Accounts Receivable and Allowance policy.

The amount of revenue recognized by the Company is equal to the amount of consideration that is expected to be received from the sale of product to its customers. Revenue is only recognized when it is probable that a significant reversal will not occur in future periods. To determine whether a significant reversal will occur in future periods, the Company assesses both the likelihood and magnitude of any such potential reversal of revenue.

Twirla is sold to customers at the wholesale acquisition cost ("WAC"). However, the Company records product revenue, net of reserves for applicable variable consideration. These types of variable consideration items reduce revenue and include the following:

- Distribution services fees;
- Prompt pay and other discounts;
- Product returns;
- Chargebacks;
- Rebates; and
- Co-payment assistance.

An estimate for each variable consideration item is made and is recorded in conjunction with the revenue being recognized. Generally, if the estimated amount is payable to a customer, it is recorded as a reduction to accounts receivable. If the estimated amount is payable to an entity other than a customer, it is recorded as a current liability. An estimated amount of variable consideration may differ from the actual amount. At each balance sheet date, these provisions are analyzed, and adjustments are made if necessary. Any adjustments made to these provisions would affect net product revenue and earnings in the current period.

In accordance with ASC 606, the Company must make judgments to determine the estimate for certain variable consideration. For example, the Company must estimate the percentage of end-users that will obtain the product through public insurance such as Medicaid or through private commercial insurance. To determine these estimates, the Company relied on quantitative and qualitative data from various internal and external sources to estimate its variable consideration.

The specific considerations that the Company uses in estimating these amounts related to variable considerations are as follows:

Distribution services fees – The Company pays distribution service fees primarily to its wholesale distributors. These fees are a contractually fixed percentage of WAC and are calculated at the time of sale based on the purchase amount. The Company records these fees as contra accounts receivable on the balance sheet.

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Prompt pay and other discounts – The Company incentivizes its customers to pay their invoices on time through prompt pay discounts. These discounts are an industry standard practice and the Company offers a prompt pay discount to each wholesale distributor customer. The specific prompt pay terms vary by customer and are contractually fixed. Prompt pay discounts are typically taken by the Company's customers, so an estimate of the discount is recorded at the time of sale based on the WAC. Prompt pay discount estimates are recorded as contra accounts receivable on the balance sheet.

The Company may also give other discounts to its customers to incentivize purchases and promote customer loyalty. The terms of such discounts may vary by customer. These discounts reduce gross product revenue at the time the revenue is recorded.

Product returns – Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than twelve months. Twirla was commercially launched in December 2020, an estimate for product returns as of March 31, 2024 was made based on: (i) data provided to the Company by its distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by third-parties including a third-party data provider which collects and publishes prescription data (iv) expired returns credits issued to date, and (v) the estimated remaining shelf life of Twirla previously shipped and currently being shipped to distributors. Estimated product returns are recorded as accrued expenses on the balance sheet.

Chargebacks – Certain covered entities and government entities will be able to purchase the product at a price discounted below WAC. The difference between the government or covered entity purchase price and the wholesale distributor purchase price of WAC will be charged back to the Company. The Company estimates the amount in chargebacks based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra accounts receivable on the balance sheet.

Rebates – The Company is subject to mandatory and negotiated discount obligations under the Medicaid and VA/DOD programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates are typically invoiced in arrears. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as accrued expenses on the balance sheet.

Co-payment assistance – The Company offers a co-payment assistance program to commercially insured patients whose insurance requires a co-payment to be made when filling their prescription. This is a voluntary program that is intended to provide financial assistance to patients meeting certain eligibility requirements. The Company estimates the amount of co-payment assistance based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Co-payment assistance estimates are recorded as accrued expenses on the balance sheet.

Provisions for the revenue reserves described above totaled $8.7 million and $4.5 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, reserves on the balance sheet associated with variable consideration were $11.1 million.

Warrants

The Company accounts for its warrants to purchase common stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*.

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In connection with entering into a senior secured term loan facility in February 2020 (the "Perceptive Credit Agreement"), the Company issued warrants to purchase 700 shares of its common stock to the lender, Perceptive Credit Holdings III, L.P. ("Perceptive"). In connection with an amendment to that facility in February 2021, the Company issued warrants to purchase 225 shares of the Company's common stock (collectively, the "Perceptive Warrants"). The Perceptive Warrants qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. In March 2023, in connection with the Waiver and Sixth Amendment to the Perceptive Credit Agreement, the Company amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants. In October 2023, in connection with the Seventh Amendment to the Perceptive Credit Agreement, the Company reset the strike price of the Perceptive Warrants. See Notes 7 and 8 for additional information.

In connection with an underwritten public offering completed in October 2021, the Company issued warrants to purchase 6,660 shares of its common stock. These warrants are classified as liabilities and were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statements of Operations and Comprehensive Income (Loss) each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 7 and 8 for additional information.

In connection with a registered direct offering completed in March 2022, the Company issued warrants to purchase 24,856 shares of its common stock. These warrants are classified as liabilities and were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Income (Loss) each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 7 and 8 for additional information.

In connection with a letter agreement and waiver entered into with an investor on April 2022, the Company issued warrants to purchase 4,243 shares of common stock. These warrants are classified as liabilities and were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Income (Loss) each reporting period. See Note 8 for additional information.

In connection with a public offering completed in July 2022, the Company issued warrants to purchase 1,093,333 shares of its common stock, of which 433,333 warrants expired unexercised in July 2023. In February 2024, 100,000 of these warrants were exercised (see Note 9). These warrants are classified as liabilities and were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Income (Loss) each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants.

In connection with a public offering completed in May 2023, the Company issued warrants to purchase 3,792,572 shares of its common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Income (Loss) each reporting period. These warrants were exercised in February 2024 (see Note 9). This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants.

On December 3, 2023, the Company entered into a Warrant Amendment and Additional Issuance Agreement ("Warrant Amendment and Additional Issuance Agreement") relating to the amendment of warrants to purchase shares of common stock that were issued in transactions on March 14, 2022, April 25, 2022, and May 25, 2023 (collectively, the "Warrants"). Collectively, the Warrants represent the right to purchase approximately 3.8 million shares of common stock. See Note 8 for additional information.

In connection with a warrant exercise agreement with a certain holder of its common stock warrants completed in February 2024, the Company issued new unregistered warrants to purchase up to 7,785,144 shares of common stock. These warrants are classified as liabilities and were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Income (Loss) each reporting period. See Note 8 for additional information.

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Income Taxes

The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, *Income Taxes*. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carryforwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no uncertain tax positions as of March 31, 2024 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company elects to account for forfeitures when they occur. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

The Company also awards restricted stock units (“RSUs”) to employees and its board of directors. RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net income (loss) per share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding plus the effect of dilutive potential common shares outstanding during the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net income (loss) per share calculation, common stock warrants, unvested RSUs and stock options are considered to be potentially dilutive securities but are excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive, and therefore, basic and diluted net income (loss) per share were the same for all periods presented.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net income (loss) per share for the three months ended March 31, 2024 and 2023, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	March 31,	
	2024	2023
Common stock warrants	9,676,830	1,130,024
Unvested restricted stock units	152,017	129
Common stock options	42,934	7,889
Total	9,871,781	1,138,042

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Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its consolidated financial statements or disclosures.

The Company did not adopt any new accounting pronouncements during the three months ended March 31, 2024 that had a material effect on its financial statements.

3. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures*, describes the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets consist of cash and cash equivalents. The Company has no Level 1 liabilities.

- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities. The Company has no Level 2 assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market data and which require internal development of assumptions about how market participants price the fair value of the assets or liabilities. The Company has no Level 3 assets. Level 3 liabilities consist of warrant liability.

The following table sets forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of March 31, 2024 and December 31, 2023 (in thousands):

	Level 1	Level 2	Level 3
March 31, 2024			
Assets:			
Cash and cash equivalents	$ 2,615	$ —	$ —
Total assets at fair value	$ 2,615	$ —	$ —
Liabilities:			
Warrant Liability	$ —	$ —	$ 1,493
Total assets at fair value	$ —	$ —	$ 1,493

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	Level 1	Level 2	Level 3
December 31, 2023			
Assets:			
Cash and cash equivalents	$ 2,557	$ —	$ —
Total assets at fair value	$ 2,557	$ —	$ —
Liabilities:			
Warrant Liability	$ —	$ —	$ 5,696
Total assets at fair value	$ —	$ —	$ 5,696

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of March 31, 2024 include (i) volatility 86.08% - 130.70%, (ii) risk-free interest rate 4.21% - 5.03%, (iii) strike price for the common warrants of $1.00, $1.56, $2.09, $3.69, $4.94, $45.00 and $1,700.00, (iv) fair value of common stock $0.34 and (v) expected life 0.65 – 5.18 years. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2023 include (i) volatility 101.5% - 126.0%, (ii) risk-free interest rate 3.8% - 4.0%, (iii) strike price for the common warrants $3.69, $45.00 and $1,700, (iv) fair value of common stock $1.95 and (v) expected life 2.8 - 4.4 years.

The following is a roll forward of the fair value of Level 3 warrants:

Beginning balance at December 31, 2023	$ 5,696
Warrants issued	3,888
Warrants exercised	(3,480)
Change in fair value	(4,611)
Ending Balance March 31, 2024	$ 1,493

There were no transfers between Level 1, 2 or 3 during the three months ended March 31, 2024 or 2023.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Prepaid insurance	$ 180	$ 441
Other	631	402
Total prepaid expenses and other current assets	$ 811	$ 843

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Gross to net accruals	$ 6,825	$ 6,492
Accrued compensation	908	832
Accrued professional fees and other	710	1,807
Total accrued liabilities	$ 8,443	$ 9,131

6. Leases

The Company has no finance leases and one operating lease for its corporate headquarters in Princeton, NJ. The current lease commenced on December 1, 2021 and terminates on March 31, 2025. The lease provides the Company with an option to extend the lease for an additional five years. Under the terms of the lease, the Company pays base annual rent subject to a fixed dollar amount increase each year, a fixed monthly charge for electricity, and other

normal operating expenses such as taxes, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. The lease does not require variable lease payments, residual value guarantees, or restrictive covenants.

The lease does not provide an implicit rate, therefore the Company used its incremental borrowing rate as the discount rate when measuring the operating lease liability. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease.

Operating lease expense was $89,000 for each of the three months ended March 31, 2024 and 2023, respectively. Operating cash flows used for operating leases during the three months ended March 31, 2024 and 2023 were approximately $87,000 and $77,000 respectively. As of March 31, 2024, the weighted average remaining lease term was 1.0 years, and the weighted average discount rate was 11.8%.

Future minimum lease payments under non-cancellable leases as of March 31, 2024 were as follows (in thousands):

2024	$	298
2025		101
Total	$	399
Less: Interest		(21)
Present value of lease liability	$	378

7. Credit Agreement and Guaranty

On February 10, 2020, the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP ("Perceptive") for a senior secured term loan credit facility of up to $35.0 million (the "Perceptive Credit Agreement"). A first tranche of $5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15.0 million was funded as a result of the approval of Twirla by the FDA. On January 7, 2022, the Company prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 8, 2022, the Company prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 25, 2022, the Company entered into a fifth amendment to the Perceptive Credit Agreement, as amended (the "Fifth Amendment"). Pursuant to the Fifth Amendment, Perceptive agreed to release its security interest in certain assets being transferred from the Company to Corium in connection with an amendment to the Company's Manufacturing and Commercialization Agreement with Corium and waive the Company's obligations to comply with certain financial covenants through the end of 2022. In exchange, the Company agreed to prepay $7.0 million of outstanding principal which was paid on July 25, 2022. On March 21, 2023, the Company and Perceptive entered into a sixth amendment to the Perceptive Credit Agreement (the "Sixth Amendment"). The Sixth Amendment waived the Company's obligations to (1) comply with certain financial covenants relating to minimum revenue requirements and minimum liquidity through June 30, 2023, and (2) file financial statements along with its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 that are not subject to any "going concern" qualification. On October 30, 2023, the Company and Perceptive entered into a seventh amendment to the Perceptive Credit Agreement (the "Seventh Amendment"). The Seventh Amendment: (1) amended the Company's obligations to comply with certain financial covenants relating to minimum revenue requirements, (2) amended and waived the Company's obligations to comply with certain financial covenants relating to minimum liquidity through December 31, 2023, and (3) required the Company to make principal payments on its outstanding loan balance of $150,000 per month beginning on December 1, 2023.

The facility was scheduled to mature on February 10, 2024 ("Maturity Date") but was extended to March 11, 2024. On March 11, 2024, the Company paid off the remainder of the principal balance of $1.35 million and has no borrowings outstanding under the Perceptive Credit Agreement as of March 31, 2024. The Perceptive Credit Agreement terminated upon repayment of the remaining balance.

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Borrowings under the Perceptive Credit Agreement accrued interest at an annual rate equal to the Secured Overnight Financing Rate for one-month deposits ("SOFR") plus 10.25%.

All of the Company's obligations under the Perceptive Credit Agreement were secured by a first-priority lien and security interest in substantially all of the Company's tangible and intangible assets, including intellectual property. The Perceptive Credit Agreement contained certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restricted or limited the ability of the Company to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's business activities; make certain investments or restricted payments (each as defined in the Perceptive Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting the Company's ability to make loan repayments under the Perceptive Credit Agreement. In addition, as amended by the Seventh Amendment, the Company must (i) at all times for the period from June 30, 2023 to October 31, 2023 maintain a minimum cash balance of $0.5 million for the period from November 1, 2023 to December 31, 2023 maintain a minimum cash balance of $1.0 million, and after December 31, 2023 to the Maturity Date maintain a minimum cash balance of $3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending September 30, 2023, report net revenues for the trailing 12-month period that are not less than $5.0 million. Pursuant to the Seventh Amendment, the Company received a waiver of certain financial covenants through December 31, 2023.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 700 shares of the Company's common stock (together, the "2020 Perceptive Warrants"). The first warrant is exercisable for 350 shares of common stock at an exercise price of $7,480 per share. The second warrant is exercisable for 350 shares of common stock at an exercise price of $9,340 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 225 shares of the Company's common stock (the "2021 Perceptive Warrant" and, together with the 2020 Perceptive Warrants, the "Perceptive Warrants") at an exercise price of $5,740 per share. The 2021 Perceptive Warrant expires on February 26, 2028. In connection with the Sixth Amendment, the Company amended the Perceptive Warrants to reset the exercise price to $10.50 per warrant. In connection with the Seventh Amendment, the Company further amended the Perceptive Warrants to reset the exercise price to $1.82 per warrant. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections and are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of the Company's common stock because of the exercise.

The Company allocated the proceeds of $20.0 million in accordance with ASC 470 based on the relative fair values of the debt and the Perceptive Warrants. The relative fair value of the Perceptive Warrants of approximately $3.6 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in the preparation of the option pricing model for valuing the Perceptive Warrants issued include (i) volatility (70.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 7-year life), (iii) strike prices of $7,480 and $9,340 for the common stock warrants, (iv) fair value of common stock ($8,020) and (v) expected life (7 years). The fair value of the 2021 Perceptive Warrants of approximately $1.1 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in preparing the option pricing model for valuing the 2021 Perceptive Warrants issued include (i) volatility (103.5%), (ii) risk free interest rate of 1.15% (estimated using treasury bonds with a 7-year life), (iii) strike price of $5,740 for the common stock warrant, (iv) fair value of common stock ($5,740) and (v) expected life (7 years). The fair value of the warrants as well as the debt issue costs incurred in connection with the entry into the Perceptive Credit Agreement, including a facility fee of 1% of the total amount of loans available under the facility, are presented as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet as detailed below (in thousands).

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	March 31, 2024	December 31, 2023
Long-term debt	$ —	$ 1,650
Debt issuance costs	—	(23)
Warrant discount	—	(112)
Total debt	$ —	$ 1,515
Less, current portion	—	1,515
Long-term debt, less current portion	$ —	$ —

The fair value of the warrants and the debt issue costs were amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of zero and $307,000 for the three months ended March 31, 2024 and 2023, respectively.

8. Stockholders' Deficit

On January 7, 2022, the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 150,000,000 shares to 300,000,000 shares.

Reverse Stock Split

On April 10, 2023, the Company filed with the Secretary of State of the State of Delaware a certificate of amendment, or the Certificate of Amendment, to the Company's Amended and Restated Certificate of Incorporation, which became effective on April 10, 2023. The Certificate of Amendment implemented a 1-for-50 reverse stock split of the Company's common stock. On the effective date of April 10, 2023, the number of the Company's issued and outstanding shares of common stock was decreased from 46,605,134 to 932,101, and the par value remained unchanged. No fractional shares were issued as a result of the reverse stock split. Stockholders who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The reverse stock split affected all shares of the Company's common stock outstanding immediately prior to the effective date of the reverse stock split, as well as the number of shares of common stock available for issuance under the Company's equity incentive plans. In addition, the reverse stock split effected a reduction in the number of shares of common stock issuable upon the exercise of stock options, restricted stock units, or warrants outstanding.

Shelf Registration Statement

On October 2, 2020, the Company filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of $200.0 million (the "2020 Shelf Registration Statement"). On October 14, 2020, the 2020 Shelf Registration Statement was declared effective by the SEC. In the future, the Company may periodically offer one or more of these securities in amounts, prices, and terms to be announced when and if the securities are offered. At the time any of the securities covered by the 2020 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering. The 2020 Shelf Registration Statement expired on October 13, 2023.

Public Offerings

In May 2023, the Company completed a best efforts public offering of an aggregate of 95,000 shares of common stock and 1,801,286 pre-funded warrants in lieu of shares of common stock and warrants to purchase a total of 3,792,572 shares of common stock at combined public offering price of $3.9551 per share. Proceeds from the public offering, net of underwriting discounts, commissions, and offering expenses were approximately $6.5 million. All of the pre-funded warrants had been exercised prior to December 31, 2023. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. The Company also issued to certain designees of H.C. Wainwright warrants to purchase up to 94,814 shares of commons stock with an exercise price of $4.9439 per share.

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In December 2023, the Company entered into a Warrant Amendment and Additional Issuance Agreement relating to the amendment of warrants to purchase shares of common stock that were issued in transactions on March 14, 2022, April 25, 2022, and May 25, 2023. Collectively, the Warrants represent the right to purchase approximately 3.8 million shares of common stock. Under the terms of the Warrant Amendment and Additional Issuance Agreement, the holder agreed to revise provisions related to the use of a Black-Scholes model to value the Warrants in the event of a change of control transaction. The holder also agreed to revise provisions related to the cashless exercise of the Warrants. In exchange for the holder's agreement to amend the Warrants, the Company agreed to issue an additional new warrant (the "New Warrant") to purchase 1,005,560 shares of common stock. The New Warrant has an exercise price of $2.09 per share of common stock. The New Warrant is exercisable six months after issuance and will expire five years from the date that the New Warrant is initially exercisable. The exercise price of the New Warrant is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrant.

February 2024 Warrant Exercise

As previously reported, the Company issued warrants on July 6, 2022 and May 25, 2023, each of which were amended on December 3, 2023 (collectively the "Warrants") to a certain investor, collectively representing the right to purchase up to an aggregate of 3,892,572 shares of the common stock, par value $0.0001 per share, of the Company ("Common Stock"), at an exercise price of $3.69 per share. On February 22, 2024, the Company entered into a warrant exercise agreement (the "Exercise Agreement") with this certain holder of its Warrants (the "Exercising Holder") wherein the Exercising Holder agreed to exercise the Warrants for cash, at an exercise price reduced by the Company to $1.25 per share (the "Warrant Exercise"). The gross proceeds from the Warrant Exercise were approximately $4.8 million. In consideration for the Warrant Exercise, the Company issued new unregistered warrants to purchase shares of Common Stock (the "New Warrants"). The New Warrants are exercisable for an aggregate of up to 7,785,144 shares of Common Stock, at an exercise price of $1.00 per share and will be immediately exercisable upon issuance. 3,992,572 of the New Warrants will have a term of five years from the issuance date and 3,792,572 of the New Warrants will have a term of eighteen months from the issuance date. The exercise price of the New Warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrants. H.C. Wainwright & Co., LLC acted as placement agent and financial advisor in connection with the transaction and received a cash fee of 7.0% of the gross proceeds resulting from the Warrant Exercise, a management fee of 1.0% of the gross proceeds resulting from the Warrant Exercise and warrants (the "Placement Agent Warrants") to purchase 194,629 of shares of Common Stock which is equal to 5.0% of the number of Warrants exercised at an exercise price of $1.5625.

The Company has accounted for the warrants as liabilities, while the pre-funded warrants are classified as a component of permanent equity within additional paid-in capital because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. The Company also determined that the pre-funded warrants should be included in the determination of basic earnings per share in accordance with ASC 260, *Earnings per Share*.

ATM Sales Agreement

On April 27, 2022, the Company entered into a new at-the-market offering program (the "April 2022 ATM Agreement") with H.C. Wainwright LLC and Co. (the "Sales Agent") under which the Company is authorized to sell up to an aggregate of $12.8 million in gross proceeds through the sale of shares of common stock from time to time. The Company agreed to pay a commission of up to 3.0% of the gross proceeds of any common stock sold under the April 2022 ATM Agreement. Through September 30, 2022, the Company issued and sold a total of 173,750 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately $12.2 million. On August 22, 2022, the Company increased the April 2022 ATM ("August 2022 ATM"). As increased, the Company was eligible to offer and sell, from time to time through the Sales Agent, shares of its common stock having an aggregate offering price of up to $75.0 million. During the year ended December 31, 2022, the Company issued and sold 78,852 shares of common stock under the August 2022 ATM resulting in net proceeds of approximately $0.9 million. During the three months

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ended March 31, 2023, the Company issued and sold 72,698 shares for net proceeds of approximately $1.0 million. On April 12, 2023, the Company filed a prospectus supplement to its registration statement on Form S-3 for the August 2022 ATM verifying that it is now eligible to sell up to $4.5 million worth of shares through its ATM.

Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Cost of product revenues	$ 20	$ 29
Research and development	73	87
Selling and marketing	12	31
General and administrative	228	351
Total	$ 333	$ 498

Agile Therapeutics, Inc.
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9. Commitments and Contingencies

The Company has several firm purchase commitments, primarily related to the manufacture and supply of Twirla and the supply of a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services. Future firm purchase commitments under these agreements, the last of which ends in 2033, as well as the Company's operating lease (see Note 6) total $212.9 million. This amount does not represent all of the Company's anticipated purchases in the future, but instead represents only purchases that are the subject of contractually obligated minimum purchases. The minimum commitments disclosed are determined based on non-cancelable minimum spend in 2024 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

In April 2020, the Company entered into a manufacturing and commercialization agreement with Corium (the "Corium Agreement"). Under the Corium Agreement, the Company has a requirement to order quarterly minimum volumes of approximately $5.6 million of product. In the event that the Company does not order the minimum volume, the Company is required to pay an additional fee equal to twenty-five percent (25%) per unit of the transfer price for all units ordered in that quarter. The Company did not meet the minimum volume order in the first or second quarter of 2022, and has, therefore, paid the additional 25% per unit fee as a penalty for all units ordered during the period. Based on then-current demand expectations for Twirla, the Company did not expect to meet the minimum volume order for the balance of 2022 and would be subject to the additional fee on future purchases. On July 25, 2022 the Company and Corium entered into Amendment No. 1 to the Corium Agreement (the "Amendment") which was designed to restructure the contract minimums applicable to the purchase of manufactured Twirla and other services provided by Corium, transfer equipment ownership to Corium to support the manufacture of Twirla and extend the term of the Corium Agreement. Pursuant to the Amendment, the parties agreed to adjust the process for the Company providing Corium certain binding and non-binding forecasts required under the Corium Agreement. Additionally, Corium agreed not to enforce the original quantity minimums in the Corium Agreement, which were waived and replaced by new minimums based on Corium's revenue for product purchased by the Company, expiring raw materials, and other services billed by Corium to support batch production and release. The guaranteed minimum revenue requirement for 2024 and each year thereafter was $22.5 million. On May 13, 2024, the Company and Corium entered into Amendment No. 2 to the Corium Agreement (the 'Second Amendment"), which reset the guaranteed minimum revenue requirement for 2024 to $10.0 million. The transfer price for Twirla will be higher for the remainder of 2024 to support the lower guaranteed minimum revenue requirement. The guaranteed minimum revenue requirement for 2025 and beyond will return to $22.5 million per year. In the event that the Company does not meet the guaranteed minimum revenue requirements in any given year, the Company will be required to make additional payments to Corium for the shortfall. The Company agreed to make certain monthly supplemental payments to Corium through December 2023, which payments are eligible to be retroactively reduced based upon product orders placed by the Company during 2023 meeting certain designated thresholds. In connection with the supplemental payments, Corium will retain the proceeds for the sale of certain raw materials to which the Company would otherwise have economic right to offset such supplemental payments. Further, the Company agreed to reimburse Corium for any unused raw materials in the event the Company's actual product requirements are lower than initially forecasted. Pursuant to the Amendment, the term of the Corium Agreement was extended to December 31, 2033. Pursuant to the Amendment, the parties agreed to transfer ownership of certain manufacturing equipment used in the manufacture of Twirla from the Company to Corium under a Bill of Sale dated July 25, 2022.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred, and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company's operations or its financial position. As of March 31, 2024, the Company has not recorded a provision for any contingent losses.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the "SEC") on March 28, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Dollars in the text and in tabular format are presented in thousands, except per share data, or as otherwise indicated.

Overview

We are a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. We are committed to innovating in women's healthcare where there continues to be unmet needs – not only in contraception – but also in other meaningful women's health therapeutic areas. We are focused on our advancement as a commercial company and the growth of our first and only product, Twirla, a once-weekly prescription combination hormonal contraceptive patch.

Twirla, which was approved in February 2020 and launched in early December 2020, is a once-weekly prescription combination hormonal contraceptive patch. It exposes patients to an estrogen dose consistent with commonly prescribed combined hormonal contraceptives, or CHCs, and is lower than the estrogen dose found in other marketed contraceptive patches. We believe there is a market need for a contraceptive patch that is designed to deliver hormonal exposure equivalent to 30 mcg of estrogen and 120 mcg of progestin in a convenient once-weekly dosage form that may support compliance in a noninvasive fashion. Twirla leverages our proprietary transdermal patch technology called Skinfusion®. Skinfusion is designed to allow drug delivery through the skin while promoting patch adhesion and patient comfort and wearability, which may help support compliance.

We are focused on our advancement as a commercial company. During 2024, we plan to continue executing our commercialization plan for Twirla, with the goal of establishing a growing position in the hormonal contraceptive market.

Our Strategy

Our near-term goal is to establish a growing franchise in the multi-billion dollar U.S. hormonal contraceptive market built on approval of Twirla in the United States. Our resources are currently focused on the commercialization of Twirla. In 2024, we plan to explore additional partnerships that could potentially increase the sales reach for Twirla, supplement growth, and further reduce operating expenses. We plan to explore all strategic opportunities, both internally and externally, that have the ability to maximize Twirla growth and increase shareholder value.

Our current priorities are as follows:

- Continue to manage our available cash and obtain financing to fund our business plan without delay;
- Continue to implement our commercialization plans for Twirla to increase uptake of Twirla in the United States, through targeted digital direct to customer advertising, should funding allow, growing our telemedicine presence through new partnerships and our existing partnership with Nurx®, and driving growth in the non-retail channel through our collaboration with Afaxys, which provides us access to some of the largest Planned Parenthood organizations in the country;
- Continue to expand access to Twirla through multiple business channels including retail and specialty pharmacies, telemedicine, government contracting, and non-retail channels, including public health centers, through our relationship with Afaxys;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;

- Maintain and manage the supply chain for Twirla to support increased commercialization of Twirla across the United States and working through as much existing and future inventory as possible prior to product becoming short-dated;
- Reduce our operating loss and continue to progress towards generating positive cash flows;
- Evaluate the advancement of our existing pipeline and its possible expansion through business development activities; and
- Continue to implement our obligations related to our post-marketing requirement study of Twirla.

Financial Overview

Since our inception in 1997, we have never been profitable. In 2021 and 2022, we generated minimal revenue from sales of Twirla. Through March 31, 2024, we had an accumulated deficit of $421.9 million. Our net income was $1.3 million and our net loss was $5.4 million for the three months ended March 31, 2024 and 2023, respectively. Our net income for the three months ended March 31, 2024 was due to the unrealized gain on our warrant liability which is a component of other income (expense) in our Statement of Operations and Comprehensive Income (Loss). Although we had net income in the first quarter 2024, we expect to continue to incur operating losses for the foreseeable future as we commercialize Twirla. We have financed our operations primarily through the public offerings of equity securities, convertible preferred stock, term loans and sale of our New Jersey net operating losses. As of March 31, 2024, we had approximately $2.6 million in cash and cash equivalents.

We plan to continue to monitor our cash and cash equivalents balances in an effort to ensure we have adequate liquidity to fund our operations. If we encounter unforeseen factors that impact our current business plan or our ability to generate revenue from the commercialization of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations using existing cash and cash equivalents.

As we continue to develop as a commercial company, we anticipate that our operating expenses will be primarily focused on commercialization activities for Twirla. We also expect a portion of our operating expenses in the future will be related to research and development as we design and conduct our long-term, prospective observational safety study for Twirla, which is a post marketing requirement from the FDA, and evaluate the development of our pipeline. We have significantly reduced our operating expenses through several measures, including optimizing our sales force, reorganizing our internal operations, reducing our advertising spend, and reorganizing our executive leadership team and general personnel. We are committed to continuing to explore ways to reduce expenses in a manner that allows us to simultaneously focus efforts and available resources on the commercialization, uptake and growth of Twirla. Our ability to reduce our operating loss and begin to generate positive cash flow from operations depends on the continued success in commercializing Twirla and maintaining discipline over our operating expenses. We continue to explore strategic opportunities that have the ability to maximize Twirla growth and increase shareholder value.

Going Concern

As of March 31, 2024, we had cash and cash equivalents of $2.6 million. We closely monitor our cash and cash equivalents and expect that our current cash will support operations through June 2024.

We have generated losses since inception, used substantial cash in operations, and anticipate we will continue to incur net losses for the foreseeable future. Our future success depends on our ability to obtain additional capital and/or implement various strategic alternatives, and there can be no assurance that any financing can be realized by us, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate. If we are unable to raise capital when needed or on acceptable terms, we then will be unable to continue the commercialization of Twirla, be required to cut operating costs, and forego future development and other opportunities. Based upon the foregoing, management has concluded that there is substantial doubt about our ability to continue as a going concern through the 12 months following the date on which this Quarterly Report on Form 10-Q is filed.

We continue to analyze various alternatives, including refinancing alternatives, potential asset sales, and mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through

selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to obtain funds when needed or on acceptable terms, we then may be unable to continue the commercialization of Twirla and may also be required to further cut operating costs, forego future development and other opportunities, and may need to seek bankruptcy protection.

The unaudited financial statements as of March 31, 2024 have been prepared under the assumption that we will continue as a going concern for the next 12 months. Our ability to continue as a going concern is dependent upon our uncertain ability to obtain additional capital, reduce expenditures, and/or execute on our business plan and continue the commercial growth of Twirla. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We do not own any manufacturing facilities and rely on our contract manufacturer, Corium, for all aspects of the manufacturing of Twirla. We will need to continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to be capable of supplying projected commercial quantities of Twirla. We have incurred significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing, distribution, medical affairs, and compliance functions. We will need to generate significant revenue to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

To date, we have generated minimal revenue from product sales. In the future, in addition to revenue from product sales, we may generate revenue from license fees, milestone payments or royalties from the sale of products developed using our intellectual property. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Twirla and any product candidates that we may advance in the future. If we fail to successfully commercialize Twirla, or any other product candidates we advance in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, could be adversely affected.

For the three months ended March 31, 2024 and 2023, net sales totaled $5.7 million and $3.8 million, respectively, representing the sale of 70,662 units and 43,446 units, respectively.

Cost of Product Revenues

Cost of product revenues include direct and indirect costs related to the manufacturing of Twirla sold, including packaging services, freight, obsolescence, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. We expect these relatively fixed costs to become less significant as a percentage of sales with anticipated volume increases.

For the three months ended March 31, 2024 and 2023, cost of product revenues totaled $1.7 million and $2.0 million, respectively.

Research and Development Expenses

Since our inception and through approval of Twirla by the FDA in February 2020, we focused our resources on our research and development activities. Research and development expenses consist primarily of costs incurred for the development of Twirla and other current and future potential product candidates, and include:

- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials and preclinical studies;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expenses;
- the cost of acquiring, developing, and manufacturing clinical trial materials, including the supply of our potential product candidates; and
- costs associated with research, development, and regulatory activities.

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our third-party vendors.

Historically, research and development activities were central to our business model and to date, our research and development expenses have been related primarily to the development of Twirla. 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. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Twirla. Our research and development expenses have reduced significantly over the past three years.

For the three months ended March 31, 2024 and 2023, our research and development expenses were approximately $0.5 million and $0.8 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three Months Ended March 31, (In thousands)	
	2024	2023
Clinical development	$ 32	$ 45
Regulatory	111	111
Personnel related	279	520
Stock-based compensation	73	87
Total research and development expenses	$ 495	$ 763

It is difficult to determine with any certainty the exact duration and completion costs of any of our future clinical trials of Twirla or our current and future potential product candidates we may advance. It is also difficult to determine if, when, or to what extent we will generate revenue from the commercialization and sale of Twirla or our potential product candidates that obtain regulatory approval.

Future research and development costs incurred for our potential product candidates and required post-marketing studies will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, access to additional capital, and significant and changing government regulation. For the foreseeable future, we expect the current public health crisis to have a negative effect on the conduct of clinical trials. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration (“FDA”) or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities, we could be required to expend significant additional financial resources and time

with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, coupled with an assessment of each product candidate's commercial potential. Substantially all of our resources are currently dedicated to continuing to commercialize Twirla.

Selling and Marketing Expenses

Selling and marketing expenses consist principally of the cost of salaries and related costs for personnel in sales and marketing, our contract sales force, brand building, advocacy, market research and consulting. Selling and marketing expenses are expensed as incurred.

For the three months ended March 31, 2024 and 2023, our selling and marketing expenses totaled approximately $3.7 million and $4.7 million, respectively. Since the commercial launch of Twirla in the United States, we have utilized a contract sales force. We anticipate that our selling and marketing expenses will continue to be significant as our commercialization efforts continue.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including payroll taxes and health insurance, stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, insurance and professional fees for legal, patent review, consulting, and accounting services. General and administrative expenses are expensed as incurred.

For the three months ended March 31, 2024 and 2023, our general and administrative expenses totaled approximately $2.6 million and $3.1 million, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and related disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

There have been no material changes to our critical accounting policies and estimates from the information discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K, as filed with the SEC on March 28, 2024.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

	Three Months Ended March 31, (In thousands)		
	2024	2023	Change
Revenues, net	$ 5,716	$ 3,813	$ 1,903
Cost of product revenues	1,680	2,003	(323)
Gross profit	4,036	1,810	2,226
Operating expenses:			
Research and development	$ 495	$ 763	$ (268)
Selling and marketing	3,682	4,670	(988)
General and administrative	2,616	3,085	(469)
Total operating expenses	6,793	8,518	(1,725)
Loss from operations	$ (2,757)	$ (6,708)	3,951
Other income (expense)			
Interest income	23	33	(10)
Interest expense	(185)	(402)	217
Unrealized gain on warrant liability	4,203	1,687	2,516
Total other income, net	4,041	1,318	2,723
Income (loss) before benefit from income taxes	1,284	(5,390)	6,674
Benefit from income taxes	—	—	—
Net income (loss)	$ 1,284	$ (5,390)	$ 6,674

Revenues. Revenue, net increased by $1.9 million, or 50% from $3.8 million for the three months ended March 31, 2023 to $5.7 million for the three months ended March 31, 2024. Unit sales increased by 27,216 units, or 63%, from 43,446 units for the three months ended March 31, 2023, to 70,662 units for the three months ended March 31, 2024. The decrease in the percentage of growth between dollars and units pertains to increased price discounts offered to the non-retail sales channel. Revenue, net consists of sales of Twirla and reflects the shipment of Twirla to specialty distributors, net of estimates for applicable variable consideration, which consist primarily of wholesale distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns, and co-pay assistance programs.

Cost of product revenues. Cost of product revenues decreased by $0.3 million, or 16% from $2.0 million for the three months ended March 31, 2023 to $1.7 million for the three months ended March 31, 2024. Cost of product revenues consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, obsolescence and allocations of overhead costs that are primarily fixed, such as salaries, benefits, and insurance.

Research and development expenses. Research and development expenses decreased by $0.3 million, or 35%, from $0.8 million for the three months ended March 31, 2023 to $0.5 million for the three months ended March 31, 2024. This decrease in research and development expenses was primarily due to a decrease in personnel costs.

Selling and marketing expenses. Selling and marketing expenses decreased by $1.0 million, or 21%, from $4.7 million for the three months ended March 31, 2023 to $3.7 million for the three months ended March 31, 2024. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives, the continued optimization of our contract sales force and a decrease in personnel costs.

General and administrative expenses. General and administrative expense decreased by $0.5 million, or 15%, from $3.1 million for the three months ended March 31, 2023 to $2.6 million for the three months ended March 31, 2024. This decrease in general and administrative expenses was primarily due to a decrease in personnel costs.

Interest income. Interest income comprises interest earned on cash and cash equivalents and marketable securities.

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense decreased by $0.2 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 due to the reduction in the principal amount outstanding on the loan.

Unrealized gain on warrant liability. The unrealized gain on warrant liability was $4.2 million and $1.7 million for the three months ended March 31, 2024 and 2023, respectively. Unrealized gain is attributable to the subsequent non-cash changes in the estimated fair value of the warrants issued in various public offerings and transactions between October 2021 and February 2024.

Liquidity and Capital Resources

At March 31, 2024, we had cash and cash equivalents totaling $2.6 million. We invest our cash equivalents in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

The following table sets forth the primary sources and uses of cash for the periods indicated:

	Three Months Ended March 31, (In thousands)	
	2024	2023
Net cash used in operating activities	$ (2,476)	$ (1,595)
Net cash (used in) provided by investing activities	—	—
Net cash provided by financing activities	2,535	778
Net (decrease) increase in cash and cash equivalents	$ 59	$ (817)

Operating Activities

Net cash used in operating activities was $2.5 million for the three months ended March 31, 2024 and consisted primarily of net income of $1.0 million adjusted for a $4.2 million unrealized gain on warrants, non-cash stock-based compensation expense of $0.3 million, $0.2 million of other non-cash charges, primarily interest expense, and $0.1 million of net working capital changes, primarily an increase in accounts payable and accrued expenses offset by an increase in inventory and accounts receivable. Net cash used in operating activities was $1.6 million for the three months ended March 31, 2023 and consisted primarily of a net loss of $5.4 million and $1.7 million unrealized gain on warrants, offset by non-cash stock-based compensation expense of $0.5 million, $0.4 million of other non-cash charges, primarily interest expense, and $4.6 million of positive working capital changes, primarily an increase in accounts payable and accrued expenses.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2024 and 2023 was zero.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 was $2.5 million, which consists of net proceeds of $4.4 million from the exercise of 3,892,572 common stock warrants partially offset by $1.8 million of principal payments on our debt, including notes payable. Net cash provided by financing activities for the three months ended March 31, 2023 was $0.8 million, which consisted of net proceeds of $1.0 million from the sale of 72,699 shares of our common stock through an at-the-market, or ATM sales program partially offset by $0.2 million of principal payments on our debt.

Funding Requirements and Other Liquidity Matters

Shelf Registration Statement, At-The-Market ("ATM") Offerings and Equity Offerings

We closely monitor our cash and cash equivalents balances, in an effort to ensure we have adequate liquidity to fund the operations of the Company. If unforeseen factors impact our current business plan or our ability to generate

revenue from the commercialization of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations.

ATM

On April 27, 2022, we entered into the April 2022 ATM Agreement under which we are authorized to sell up to an aggregate of $12.8 million in gross proceeds through the sale of shares of common stock from time to time in the April 2022 ATM. We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. Through September 30, 2022, we issued and sold a total of 173,750 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately $12.2 million. On August 22, 2022, we increased the April 2022 ATM ("August 2022 ATM"). As increased, we were eligible to offer and sell, from time to time through the Sales Agent, shares of our common stock having an aggregate offering price of up to $75.0 million. During the year ended December 31, 2022, we issued and sold 78,853 shares of common stock under the August 2022 ATM resulting in net proceeds to us of approximately $0.9 million. On April 12, 2023, we filed a prospectus supplement to our registration statement on Form S-3 for the August 2022 ATM verifying that we were then eligible to sell up to $4.5 million worth of shares of common stock. During the three months ended March 31, 2023, we issued and sold 72,699 shares of common stock resulting in net proceeds of approximately $1.0 million.

2022 Equity Offerings

On March 13, 2022, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with a single healthcare-focused institutional investor (the "Purchaser"), pursuant to which the Company issued, in a registered direct offering (the "2022 Preferred Stock Offering"), 2,425 shares of Series A convertible preferred stock (the "Series A Preferred Stock") and 2,425 shares of Series B convertible preferred stock (the "Series B Preferred Stock") and Series A warrants (the "Series A Warrants") to purchase up to an aggregate of 12,125 shares of the common stock of the Company (the "Common Stock") and Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 12,125 shares of Common Stock. Each share of Series A Preferred Stock and Series B Preferred Stock has a stated value of $1,000 per share and a conversion price of $400.00 per share. The shares of preferred stock issued in the offering are convertible into an aggregate of 12,125 shares of Common Stock. The Series A Warrants have an exercise price of $3.69 per share and became exercisable six months following the date of issuance and will expire 5 years following the initial exercise date. The Series B Warrants have an exercise price of $3.69 per share and became exercisable six months following the date of issuance and will expire one and one-half years following the initial exercise date. The Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties. The 2022 Preferred Stock Offering closed on March 14, 2022 and total net proceeds were approximately $4.3 million.

On April 25, 2022, we entered into a Letter Agreement with the Purchaser, pursuant to which the Purchasers consented to us entering into and effecting an ATM offering facility. Pursuant to the Letter Agreement, we issued to the Purchaser the New Warrant, on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 4,243 warrant shares, subject to adjustment thereunder. The Series A Warrants have an exercise price of $3.69 per share and became exercisable six months after the date of the Letter Agreement, and will expire 5 years following the initial exercise date.

On July 6, 2022, we completed a best-efforts public offering (the "Offering") in which we raised net proceeds of $22.0 million through the sale of 382,966 shares of common stock and 150,366 pre-funded warrants ("Series B pre-funded warrants") to purchase 150,366 shares of common stock. Both the sales of shares of common stock and pre-funded warrants were accompanied by Series A-1 and Series A-2 warrants (together the "Series A warrants") to purchase shares of common stock. The Series A-1 warrants are exercisable immediately and will expire five years from the date of issuance, and the Series A-2 warrants expired unexercised in August 2023. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. We also issued to certain designees of H.C. Wainwright warrants to purchase up to 26,666 shares of commons stock with an exercise price of $56.25 per share.

2023 Equity Offering

On May 25, 2023 we completed a best-efforts public offering (the "May 2023 Offering") in which we raised net proceeds of $6.5 million through the sale of 1,896,286 shares of common stock (or pre-funded warrants in lieu thereof). Both the sales of shares of common stock and pre-funded warrants were accompanied by Series C-1 and Series C-2 warrants (together the "Series C warrants") to purchase shares of common stock. The Series C-1 warrants are exercisable immediately and will expire five years from the date of issuance, and the Series C-2 warrants are exercisable immediately and will expire eighteen months from the date of issuance. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. We also issued to certain designees of H.C. Wainwright warrants to purchase up to 94,814 shares of commons stock with an exercise price of $4.9439 per share (the "Placement Agent Warrants"). The Placement Agent Warrants expire on the fifth anniversary from the date of the commencement of sales in the May 2023 Offering.

February 2024 Warrant Exercise

As previously reported, we issued warrants on July 6, 2022 and May 25, 2023, each of which were amended on December 3, 2023 (collectively the "Warrants") to a certain investor, collectively representing the right to purchase up to an aggregate of 3,892,572 shares of the common stock, par value $0.0001 per share, of the Company ("Common Stock"), at an exercise price of $3.69 per share. On February 22, 2024, we entered into a warrant exercise agreement (the "Exercise Agreement") with this certain holder of its Warrants (the "Exercising Holder") wherein the Exercising Holder agreed to exercise the Warrants for cash, at an exercise price reduced by the Company to $1.25 per share (the "Warrant Exercise"). The gross proceeds from the Warrant Exercise were approximately $4.8 million. In consideration for the Warrant Exercise, we issued new unregistered warrants to purchase shares of Common Stock (the "New Warrants"). The New Warrants are exercisable for an aggregate of up to 7,785,144 shares of Common Stock, at an exercise price of $1.00 per share and will be immediately exercisable upon issuance. 3,992,572 of the New Warrants will have a term of five years from the issuance date and 3,792,572 of the New Warrants will have a term of eighteen months from the issuance date. The exercise price of the New Warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrants. H.C. Wainwright & Co., LLC acted as placement agent and financial advisor in connection with the transaction and received a cash fee of 7.0% of the gross proceeds resulting from the Warrant Exercise, a management fee of 1.0% of the gross proceeds resulting from the Warrant Exercise and warrants (the "Placement Agent Warrants") to purchase 194,629 of shares of Common Stock which is equal to 5.0% of the number of Warrants exercised at an exercise price of $1.5625.

We believe we may have the potential to access additional capital through selling additional debt or equity securities or obtaining a line of credit or other loan as required.

We expect to continue to incur significant operating expenses for the foreseeable future in connection with our ongoing activities as we:

- maintain a sales and marketing infrastructure and contract manufacturing arrangement to support the continued commercialization of Twirla in the United States;
- continue to commercialize Twirla and seek increased uptake of Twirla in the United States;
- conduct the post-marketing requirements from the FDA that we are obligated to perform;
- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- maintain operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We may also need to raise additional funds if we need to change components of our commercial plan or we encounter any unforeseen events that affect our current business plan, or we may choose to raise additional funds to provide us with additional working capital. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms or are unable to enter into strategic collaborations, we then may be unable to successfully commercialize Twirla and may also be required

to further cut operating costs, forego future development and other opportunities or even terminate our operations, which may involve seeking bankruptcy protection. Because of the numerous risks and uncertainties associated with such developments, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the commercialization of Twirla. Our future capital requirements will depend on many factors, including:

- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for Twirla;
- the revenue received from commercial sales of Twirla;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

We do not have any committed external source of funds. Until such time, if ever, as we can generate substantial cash flows from product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

Contractual Obligations and Commitments

In April 2020, we entered into a Manufacturing and Commercialization Agreement (the 'Corium Agreement") with Corium Innovations, Inc. ("Corium") which replaced our previous development agreement. Pursuant to the Corium Agreement, Corium will manufacture and supply all of our product requirements for Twirla at certain specified rates. Under the terms of the Corium Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement included a quarterly minimum purchase commitment and a fixed price per unit for two years from December 2020, the date of the first commercial batch purchase order invoice, depending on annual purchase volume. During 2021, we did not meet all of our minimum quantity purchases from Corium, and as a result, paid penalties as required by our agreement with Corium. On July 25, 2022 we, along with Corium, amended the Corium Agreement to restructure the minimums applicable to the purchase of manufactured Twirla and to extend the term of the Corium Agreement until December 31, 2033. The Corium Agreement terminates automatically on December 31, 2033, but may be terminated for any reason upon the written mutual agreement of both parties; provided, however, that the parties must confer in good faith regarding possible mutual termination. In the event of such termination, we may still submit purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of March 31, 2024, the minimum amount committed totals $210.1 million for the 10-year period from 2024 through 2033. On May 13, 2024, we and Corium entered into Amendment No. 2 to the Corium Agreement (the 'Second Amendment"), which reset the guaranteed minimum revenue requirement for 2024 to $10.0 million. The transfer price for Twirla will be higher for the remainder of 2024 to support the lower guaranteed minimum revenue requirement. The guaranteed minimum revenue requirement for 2025 and beyond will return to $22.5 million per year.

In April 2020, we entered into a project agreement with inVentiv Commercial Services, LLC, or inVentiv, a Syneos Health Group Company, which we refer to as the Syneos Agreement, under our Master Services Agreement with inVentiv. Pursuant to the Syneos Agreement, inVentiv, through its affiliate Syneos Selling Solutions, will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services with respect to Twirla to us in exchange for an up-front implementation fee and a fixed monthly fee. Effective February 1, 2022, we entered into an amendment to the Syneos Agreement that extended the term until August 23, 2024. At that time, the Syneos Agreement will terminate automatically unless extended upon the mutual written agreement of the parties. We may terminate the Syneos Agreement for any reason upon timely written notice without incurring a termination fee. On September 28, 2023, we entered into the Seventh Amendment to the Syneos Agreement, pursuant to which we will pay Syneos a fixed weekly fee for the performance of Services (as defined in the Syneos Agreement) through August 23, 2024. As of March 31, 2024, the minimum amount committed totals $2.4 million.

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. The lease for this space commenced in December 2021, and the minimum payments over the remaining 12-month term totals $0.4 million as of March 31, 2024.

Recent Accounting Pronouncements

See Note 2 to our financial statements that discusses new accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

[Reserved]

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2024, our chief executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable level.

Changes to Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during the period covered by this Quarterly Report on Form 10-Q 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 currently subject to any material legal proceedings.

Item 1A. Risk Factors.

As of the date of this Quarterly Report on Form 10-Q, there are no material changes from the risk factors previously described in the "Risk Factors" included in Part I, Item 1A in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 5. Other Information

During the three months ended March 31, 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.

Item 6. Exhibits.

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

Exhibit Index

Exhibit Number	Description of Document
4.1	Form of New Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)
4.2	Form of New Warrant (Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)
4.3	Form of Placement Agent Warrant (Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)
10.1	Eighth Amendment to Credit Agreement and Guaranty, by and among Agile Therapeutics, Inc., the guarantors from time to party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of February 9, 2024 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 15, 2024.)
10.2	Form of Exercise Agreement (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)
31.1	Certification of the Registrant's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Registrant's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Registrant's Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Registrant's Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2024 formatted in Inline Extensible Business Reporting Language (XBRL): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders' Equity (Deficit), (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

** The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates them by reference.

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.

Agile Therapeutics, Inc.

Date: May 15, 2024

By: /s/ Alfred Altomari
Alfred Altomari
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2024

By: /s/ Scott M. Coiante
Scott M. Coiante
Sr. Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alfred Altomari, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Agile Therapeutics, 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 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;

5. The registrant's other certifying officer 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.

Date: May 15, 2024

/s/ Alfred Altomari
Alfred Altomari
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott M. Coiante, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Agile Therapeutics, 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 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;

5. The registrant's other certifying officer 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.

Date: May 15, 2024

/s/ Scott M. Coiante
Scott M. Coiante
Chief Financial Officer
Principal Financial Officer

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
AGILE THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, Alfred Altomari, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2024

/s/ Alfred Altomari
Alfred Altomari
Chief Executive Officer
Principal Executive Officer

Exhibit 32.2

STATEMENT OF CHIEF ACCOUNTING OFFICER OF
AGILE THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, Scott M. Coiante, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2024

/s/ Scott M. Coiante
Scott M. Coiante
Chief Financial Officer
Principal Financial Officer