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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 September 30, 2023

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:

Title of each class	**Trading Symbol**	**Name of exchange on which registered:**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

There were 2,511,657 shares of the registrant's common stock, $0.0001 par value, outstanding as of November 7, 2023.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2023

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 ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla®, including the level of reimbursement available from third-party payors, the development of our other potential product candidates, the attractiveness of our business to potential investors or business partners, 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, our results of operations, financial condition, liquidity, prospects, growth and 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 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.

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 come into compliance with the listing requirements of the Nasdaq Capital Market;
- 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 implicating 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 or limiting access to prescription contraceptives;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- 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 required for 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, 2022 filed with the Securities and Exchange Commission on March 23, 2023 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. In addition, with respect to all of 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.

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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,873	$ 5,246
Accounts receivable, net	3,521	3,377
Inventory, net	2,411	1,332
Prepaid expenses and other current assets	1,259	1,403
Total current assets	10,064	11,358
Property and equipment, net	101	177
Right of use asset	486	695
Other non-current assets	238	2,012
Total assets	$ 10,889	$ 14,242
Liabilities and stockholders' deficit		
Current liabilities:		
Long-term debt, current portion	$ 1,589	$ 1,426
Notes payable, current portion	379	—
Accounts payable	6,879	7,734
Accrued expenses	8,338	3,908
Lease liability, current portion	353	319
Total current liabilities	17,538	13,387
Lease liabilities, long-term	196	466
Warrant liability	5,566	5,934
Total liabilities	23,300	19,787
Commitments and contingencies (Note 10)		
Stockholders' deficit		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at September 30, 2023 and no shares issued and outstanding at December 31, 2022	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized, 2,277,657 and 859,402 issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	406,288	403,157
Accumulated deficit	(418,699)	(408,702)
Total stockholders' deficit	(12,411)	(5,545)
Total liabilities and stockholders' deficit	$ 10,889	$ 14,242

See accompanying notes to unaudited financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues, net	$ 6,662	$ 3,002	$ 15,979	$ 6,888
Cost of product revenues	2,477	1,425	6,787	5,183
Gross profit	4,185	1,577	9,192	1,705
Operating expenses:				
Research and development	$ 705	$ 788	$ 2,171	$ 2,901
Selling and marketing	4,800	5,560	14,040	23,523
General and administrative	2,680	2,815	8,813	9,837
Loss on disposition of assets	—	11,122	—	11,122
Total operating expenses	8,185	20,285	25,024	47,383
Loss from operations	(4,000)	(18,708)	(15,832)	(45,678)
Other income (expense)				
Interest income	13	46	61	50
Interest expense	(341)	(1,004)	(1,114)	(2,699)
Unrealized gain on warrant liability	3,529	13,736	6,890	22,171
Total other income, net	3,201	12,778	5,837	19,522
Loss before benefit from income taxes	(799)	(5,930)	(9,995)	(26,156)
Benefit from income taxes	—	—	—	4,675
Net loss and comprehensive loss	$ (799)	$ (5,930)	$ (9,995)	$ (21,481)
Net loss per share (basic and diluted)	$ (0.27)	$ (8.01)	$ (5.30)	$ (71.61)
Weighted-average common shares (basic and diluted)	2,950,136	739,957	1,884,793	299,970

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	Accumulated		Total
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Stockholders' Deficit
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	—	—	—	—	—	—	(5,389)	(5,389)
Balance March 31, 2023	—	$ —	932,101	$ —	$ 404,658	$ —	$ (414,091)	$ (9,433)
Share-based compensation - stock options and RSUs	—	—	—	—	482	—	—	482
Fractional shares retired as a result of reverse split	—	—	—	—	(13)	—	—	(13)
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	105,342	—	652	—	—	652
Issuance of common stock in public offering, net of offering costs	—	—	95,000	—	—	—	—	—
Exercise of pre-funded warrants	—	—	508,286	—	—	—	—	—
Vesting of RSUs	—	—	76	—	—	—	—	—
Net loss	—	—	—	—	—	—	(3,809)	(3,809)
Balance June 30, 2023	—	$ —	1,640,805	$ —	$ 405,779	$ —	$ (417,900)	$ (12,121)
Share-based compensation - stock options and RSUs	—	—	—	—	439	—	—	439
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	29,842	—	70	—	—	70
Exercise of pre-funded warrants	—	—	607,000	—	—	—	—	—
Vesting of RSUs	—	—	10	—	—	—	—	—
Net loss	—	—	—	—	—	—	(799)	(799)
Balance September 30, 2023	—	—	2,277,657	$ —	$ 406,288	$ —	$ (418,699)	$ (12,411)

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' Equity (Deficit)
(Unaudited)
(in thousands, except share data)

	Preferred Stock		Common Stock		Additional	Accumulated		Total
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Stockholders' Deficit
Balance December 31, 2021	—	$ —	60,698	$ —	$ 387,205	$ —	$ (383,290)	$ 3,915
Share-based compensation - stock options and RSUs	—	—	—	—	764	—	—	764
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	512	—	348	—	—	348
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 8)	4,850	—	—	—	—	—	—	—
Conversion of series A convertible preferred stock		—	6,063	—	—	—	—	—
Vesting of RSUs	(2,425)	—	35	—	—	—	—	—
Net loss	—	—	—	—	—	—	(10,385)	(10,385)
Balance March 31, 2022	2,425	—	67,308	$ —	$ 388,317	$ —	$ (393,675)	$ (5,358)
Share-based compensation - stock options and RSUs	—	$ —	—	—	669	—	—	669
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	173,750	—	12,226	—	—	12,226
Conversion of series B convertible preferred stock	(2,425)	—	6,062	—	—	—	—	—
Vesting of RSUs	—	—	82	—	—	—	—	—
Unrealized net gain on marketable securities	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(5,168)	(5,168)
Balance June 30, 2022	—	$ —	$ 247,202	$ —	$ 401,212	$ —	$ (398,843)	$ 2,369
Share-based compensation - stock options and RSUs	—	—	—	—	536	—	—	536
Issuance of common stock pursuant to a public offering, net of expenses	—	—	533,333	—	—	—	—	—
Net loss	—	—	—	—	—	—	(5,930)	(5,930)
Balance September 30, 2022	—	$ —	$ 780,535	$ —	$ 401,748	$ —	$ (404,773)	$ (3,025)

See accompanying notes to unaudited financial statements.

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

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (9,995)	$ (21,481)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	77	1,255
Amortization	209	188
Loss on disposition of assets	—	11,122
Noncash stock-based compensation	1,418	1,969
Noncash amortization of deferred financing costs	838	1,635
Unrealized gain on warrants	(6,890)	(22,171)
Changes in operating assets and liabilities:		
Accounts receivable	(144)	(2,178)
Inventory	(1,079)	(831)
Prepaid expenses and other assets	2,480	(1,551)
Accounts payable and accrued expenses	3,572	(2,213)
Lease liability	(235)	(132)
Net cash used in operating activities	(9,749)	(34,388)
Cash flows from investing activities:		
Acquisition of property and equipment	—	(133)
Net cash used in investing activities	—	(133)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock in registered direct offering, net of offering costs	—	4,129
Proceeds from At-the-Market sales of common stock, net of offering costs	1,725	12,573
Proceeds from the issuance of common stock in public offering, net of offering costs	6,509	21,971
Repayments of long-term debt	(675)	(17,150)
Repayments of note payable	(184)	—
Net cash provided by financing activities	7,375	21,523
Net decrease in cash and cash equivalents	(2,374)	(12,998)
Cash and cash equivalents, beginning of period	5,246	19,143
Cash and cash equivalents, end of period	$ 2,873	$ 6,145
Supplemental disclosure of noncash financing activities		
Warrants issued in connection with preferred stock financing	$ —	$ 2,101
Conversion of Series A preferred stock into common stock	—	897
Conversion of Series B preferred stock into common stock	—	887
Supplemental cash flow information		
Interest paid	$ 276	$ 1,078

See *accompanying notes to unaudited financial statements*.

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 September 30, 2023, the Company had an accumulated deficit of approximately $418.7 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 September 30, 2023, the Company had cash and cash equivalents of $2.9 million and a $7.5 million working capital deficit. The Company's current liquidity is sufficient to fund operations into December 2023. 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 September 30, 2023, 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, 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 September 30, 2023 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 September 30, 2023 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, 2022 as filed with the SEC on March 23, 2023.

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 and nine months ended September 30, 2023 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, 2022 included in its Annual Report on Form 10-K filed with the SEC on March 23, 2023.

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, costs of product revenues, 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.

It should be noted that the possibility of continued public health threats could adversely affect the Company's ongoing or planned business operations. For example, the coronavirus ("COVID-19") pandemic previously resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The most significant impacts to the Company's business were encountered by sales representatives promoting Twirla in the field, as some offices limited opportunities for face-to-face interactions with healthcare providers. Re-implementation of COVID-19 restrictions, if necessary in the future, may disrupt the Company's business and/or could adversely affect the Company's commercialization plans and results. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if the Company or any of the third parties with whom the Company engages, including personnel at third-party manufacturing facilities and other third parties with whom the Company conducts business, were to experience shutdowns or other business disruptions, the Company's ability to conduct its business in the manner and on the timeline presently planned could be materially and adversely impacted. Another shutdown necessitating work in a completely remote environment could result in delays to its business activities and commercialization plan. The Company will continue to closely monitor events as they develop, and plan for alternative and mitigating measures that can be implemented if needed.

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.

Trade Accounts Receivable and Allowances

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The trade 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 September 30, 2023 and December 31, 2022.

Trade 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.

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 September 30, 2023 and December 31, 2022, inventory reserves approximated $1.4 million and $0.6 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 September 30, 2023.

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 and $0.9 million for the three months ended September 30, 2023 and 2022, respectively, and totaled zero and $6.1 million for the nine months ended September 30, 2023 and 2022, 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 $44,000 and $146,000 for the three months ended September 30, 2023 and 2022, respectively and was approximately $146,000 and $284,000 for the nine months ended September 30, 2023 and 2022, 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 September 30, 2023, the Company had sales to five customers that individually accounted for more than 10% of its total revenue. These customers had sales of $1.7 million, $1.3 million, $1.1 million, $1.1 million, and $1.1 million, respectively, which represented 93% of total revenues in the three months ended September 30, 2023. In the nine months ended September 30, 2023, the Company had sales to five customers that

individually accounted for more than 10% of its total revenue. These customers had sales of $3.2 million, $3.2 million, $3.2 million, $3.0 million and $2.1 million, respectively, which represented 92% of total revenue for the nine months ended September 30, 2023. Accounts receivable related to these five customers comprised 36%, 26%, 18%, 15%, and 0%, of the Company's total accounts receivable, respectively, as of September 30, 2023. In the three months ended September 30, 2022, the Company had sales to three customers that individually accounted for more than 10% of its total revenue. These customers had sales of $0.7 million, $0.6 million, and $0.6 million, respectively, which represented 30% of total revenues in the three months ended September 30, 2022. In the nine months ended September 30, 2022, the Company had sales to three customers that individually accounted for more than 10% of its total revenue. These customers had sales of $1.9 million, $1.8 million and $1.7 million, respectively, which represented 33% of total revenue for the nine months ended September 30, 2022.

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. Trade accounts receivable due to the Company from contracts with its customers are stated separately in the balance sheet, net of various allowances as described in the Trade 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 significant 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 industry standard data and trend analysis since historical sales data was not available as Twirla was launched in December 2020. As historical data continues to become available, the Company will incorporate that data into its estimates of 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 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 trade accounts receivable on the balance sheet.

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 trade 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 and with limited historical sales data, an estimate for product returns as of September 30, 2023 was made based on industry standard data and trend analysis. Estimated product returns are recorded as other current liabilities in 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 trade accounts receivable on the balance sheet.

Rebates – The Company will be subject to mandatory discount obligations under the Medicaid and Tricare 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 for Medicaid and Tricare are typically invoiced in arrears. The Company estimates the amount in rebates 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. Rebate estimates are recorded as other current liabilities in 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 other current liabilities in accrued expenses on the balance sheet.

Provisions for the revenue reserves described above totaled $8.5 million and $3.2 million for the three months ended September 30, 2023 and 2022, respectively, and $19.3 million and $6.1 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, reserves on the balance sheet associated with variable consideration were $7.4 million.

Warrants

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

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, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statements of Operations and Comprehensive 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, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations 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, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations 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 533,333 warrants expired unexercised in July 2023. 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 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 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.

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 September 30, 2023 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 no less than 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 Loss Per Share

Basic net loss per share is calculated by dividing the net 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 loss per share is calculated by dividing the net 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 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 loss per share because their effect would be anti-dilutive, and therefore, basic and diluted net 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 loss per share for the three and nine months ended September 30, 2023 and 2022, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	September 30,	
	2023	2022
Common stock warrants	4,484,077	36,691
Unvested restricted stock units	135,037	142
Common stock options	43,510	5,778
Total	4,662,624	42,611

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 nine months ended September 30, 2023 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 September 30, 2023 and December 31, 2022 (in thousands):

	Level 1	Level 2	Level 3
September 30, 2023			
Assets:			
Cash and cash equivalents	$ 2,873	$ —	$ —
Total assets at fair value	$ 2,873	$ —	$ —
Liabilities:			
Warrant Liability	$ —	$ —	$ 5,566
Total assets at fair value	$ —	$ —	$ 5,566

	Level 1	Level 2	Level 3
December 31, 2022			
Assets:			
Cash and cash equivalents	$ 5,246	$ —	$ —
Total assets at fair value	$ 5,246	$ —	$ —
Liabilities:			
Warrant Liability	$ —	$ —	$ 5,934
Total assets at fair value	$ —	$ —	$ 5,934

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of September 30, 2023 include (i) volatility 86.06% - 123.42%, (ii) risk-free interest rate 4.62% - 5.46%, (iii) strike price for the common warrants of $3.69, $45.00 and $1,700.00, (iv) fair value of common stock $2.40 and (v) expected life 1.15 - 4.65 years. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2022 include (i) volatility 136.8% - 137.4%, (ii) risk-free interest rate 4.2% - 4.7%, (iii) strike price for the common warrants $45.00 and $1,700, (iv) strike price for the preferred warrants of $520.00, (v) fair value of common stock $11.50 and (vi) expected life 0.7 - 4.5 years.

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

Beginning balance at December 31, 2022	$ 5,934
Warrants issued	10,615
Change in fair value	(10,983)
Ending Balance September 30, 2023	$ 5,566

There were no transfers between Level 1, 2 or 3 during the nine months ended September 30, 2023 or 2022.

4. Prepaid Expenses and Other Current Assets

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

	September 30, 2023	December 31, 2022
Prepaid insurance	$ 697	$ 628
Other	562	775
Total prepaid expenses and other current assets	$ 1,259	$ 1,403

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Gross to net accruals	$ 3,933	$ 2,332
Accrued compensation	2,721	833
Accrued professional fees and other	1,684	743
Total accrued liabilities	$ 8,338	$ 3,908

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 and $90,000 for the three months ended September 30, 2023 and 2022, respectively. Operating lease expense was $267,000 and $271,000 for the nine months ended September 30, 2023 and 2022, respectively. Operating cash flows used for operating leases during the nine months ended September 30, 2023 and 2022 were approximately $235,000 and $132,000 respectively. As of September 30, 2023, the weighted average remaining lease term was 1.50 years, and the weighted average discount rate was 11.8%.

Future minimum lease payments under non-cancellable leases as of September 30, 2023 were as follows (in thousands):

2023	$ 98
2024	397
2025	101
Total	$ 596
Less: Interest	(47)
Present value of lease liability	$ 549

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. The other tranches of debt under the Perceptive Credit Agreement are no longer available to the Company. 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 under the Perceptive Credit Agreement using the proceeds of recent sales under the Company's ATM program with H.C. Wainwright & Co., LLC (see Note 8). Such payment was made 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) amends the Company's obligations to comply with certain financial covenants relating to minimum revenue requirements, (2) amends and waives the Company's obligations to comply with certain financial covenants relating to minimum liquidity through December 31, 2023, and (3) requires the Company to make principal payments on its outstanding loan balance of $150,000 per month beginning on December 1, 2023.

The facility will mature on February 10, 2024 ("Maturity Date"). Pursuant to the Perceptive Credit Agreement, beginning August 31, 2022, the Company began making monthly principal payments in an amount equal to $75,000. Beginning on December 1, 2023 and pursuant to the Seventh Amendment, the Company will begin making monthly payments of $150,000 until the Maturity Date, at which time all remaining principal amount outstanding is due.

Borrowings under the Perceptive Credit Agreement will accrue interest at an annual rate equal to the London Interbank Offered Rate for one-month deposits ("LIBOR") plus 10.25%, provided that LIBOR shall not be less than 1.5%. The rate of interest in effect as of September 30, 2023 was 15.58%. Upon the occurrence and during the continuance of any event of default under the Perceptive Credit Agreement, the interest rate automatically increases by 3.0% per annum.

The Company may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment premium of 2.0%.

All of the Company's obligations under the Perceptive Credit Agreement are 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 contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restrict or limit 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 has 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.

As a result of the public offering of the Company's common stock completed in October 2021 (see Note 8), the antidilution provision of the Perceptive Warrants was triggered, resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of $9,340 per share were reduced to $7,080 per share, warrants to purchase 350 shares of common stock that had an exercise price of $7,480 per share were reduced to $5,760 per share, and warrants to purchase 225 shares of common stock that had an exercise price of $5,740 per share were reduced to $4,540 per share.

As a result of the registered direct offering completed in March 2022 (see Note 8), the anti-dilution provision of the Perceptive Warrants was again triggered resulting in a further reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an adjusted exercise price of $7,080 per share were reduced to $5,276 per share, warrants to purchase 350 shares of common stock that had an adjusted exercise price of $5,760 per share were reduced to $4,330.50 per share, and warrants to purchase 225 shares of common stock that had an adjusted exercise price of $4,540 per share were reduced to $3,456.50 per share.

As a result of the public offering of the Company's common stock completed in July 2022 (see Note 8), the antidilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of $5,276 per share were reduced to $745 per share, warrants to purchase 350 shares of common stock that had an exercise price of $4,330.50 per share were reduced to $618.50 per share, and warrants to purchase 225 shares of common stock that had an exercise price of $3,456.50 per share were reduced to $501.50 per share.

As a result of the public offering of the Company's common stock completed in May 2023 (see Note 8), the antidilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of $745 per share were reduced to $3.69 per share, warrants to purchase 350 shares of common stock that had an exercise price of $618.50 per share were reduced to $3.69 per share, and warrants to purchase 225 shares of common stock that had an exercise price of $501.50 per share were reduced to $3.69 per share.

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).

	September 30, 2023	December 31, 2022
Notes payable	$ 1,950	$ 2,625
Debt issuance costs	(63)	(209)
Warrant discount	(298)	(990)
Total debt	$ 1,589	$ 1,426
Less, current portion	1,589	1,426
Long-term debt, less current portion	$ —	$ —

The fair value of the warrants and the debt issue costs are being 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 $252,000 and $838,000 for the three months ended September 30, 2023 and 2022, respectively. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of $838,000 and $1,635,000 for the nine months ended September 30, 2023 and 2022, 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.

Public Offerings

In October 2021, the Company completed a public offering of 13,333 shares of its common stock and warrants to purchase 6,660 shares of its common stock at a combined price of $1,700 per share of common stock and one-half of a warrant to purchase one share of common stock. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $21.1 million.

In July 2022, the Company completed a best efforts public offering (the "2022 Offering") in which the Company 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 at a combined price of $45.00 per share of common stock and warrants. 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 2022 Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the 2022 Offering. The Company also issued to certain designees of H.C. Wainwright warrants to purchase up to 26,666 shares of common stock with an exercise price of $56.25 per share.

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. Through September 30, 2023 at total of 1,115,286 pre-funded warrants have been exercised and 686,000 pre-funded warrants remain available for exercise as of September 30, 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.

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

In March 2021, the Company entered into a common stock sales agreement (the "Sales Agreement") under which the Company may sell up to an aggregate of $50.0 million in gross proceeds through the sale of shares of common stock from time to time in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the Sales Agreement. During the year ended December 31, 2021, the Company issued and sold 3,457 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $9.3 million.

On January 10, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering an at-the-market offering program (the "2022 ATM") the Company entered into for the sale of up to $50.0 million of shares of its common stock. The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the Sales Agreement. During the three months ended March 31, 2022, the Company issued and sold 512 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $0.3 million. On April 26, 2022, the Company terminated the 2022 ATM.

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 nine months ended September 30, 2023, the Company issued and sold 207,883 shares for net proceeds of approximately $1.7 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.

Registered Direct Offering

On March 14, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering a direct offering (the "2022 Preferred Stock Offering") of 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 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 2022 Preferred Stock Offering are convertible into an aggregate of 12,125 shares of common stock. The Series A Warrants have an exercise price of $520.00 per share, will become 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 $520.00 per share, will become exercisable six months following the date of issuance, and will expire one and one-half years following the initial exercise date. Proceeds from the 2022 Preferred Stock Offering, net of the placement agent's fees and offering expenses were approximately $4.1 million. A portion of the placement agent's fees included warrants to purchase 606 shares of the common stock of the Company at a strike price of $500.00 per share. The warrants become exercisable six months following the date of issuance and will expire 5 years following the commencement of sales in the 2022 Preferred Stock Offering.

On March 15, 2022, 2,425 shares of the Series A Preferred Stock were converted into 6,025 shares of the Company's common stock. On April 4, 2022, 2,425 shares of the Series B Preferred Stock were converted into 6,025 shares of the Company's common stock.

On April 25, 2022, the Company entered into a letter agreement and waiver (the "Letter Agreement") with Armistice Capital Master Fund Ltd. ("Armistice"), pursuant to which Armistice consented to the Company entering into and effecting an at-the-market ("ATM") offering facility. On March 14, 2022, the Company entered into the 2022 Preferred Stock Offering with Armistice, under which agreement, the Company was restricted from entering into and effecting an ATM offering facility until the 180-day anniversary of the Closing Date. Pursuant to the Letter Agreement, the Company issued to Armistice a new common stock purchase warrant ("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. The Series A Warrants have an exercise price of $520.00 per share and will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The New Warrant is exercisable 6 months after the date of the Letter Agreement.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of goods sold	$ 12	$ 29	$ 69	$ 104
Research and development	94	90	261	284
Selling and marketing	10	40	73	120
General and administrative	323	377	1,015	1,461
Total	$ 439	$ 536	$ 1,418	$ 1,969

9. Income Taxes

Sale of New Jersey Net Operating Losses

The Company has participated in the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program") sponsored by The New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused NOLs and unused research and development credits to sell these tax benefits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The Program is administered by The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation. The Company had previously reached the maximum lifetime benefit of $15.0 million under the historical Program; however, in January 2021 the Program was amended to extend the maximum lifetime benefit to $20.0 million. The Company received final approval in March 2022 for $4.7 million of additional cash benefit that was received in April 2022.

10. 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, total $230.1 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 2023 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") that is 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 will not enforce the original quantity minimums in the Corium Agreement, which are waived and replaced by new minimums that are 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 2023 is $7.0 million, and is $22.5 million for 2024 and each year thereafter. 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 September 30, 2023, 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 23, 2023. 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 2023, we plan to continue implementing our commercialization plan for Twirla, with the goal of establishing a growing position in the hormonal contraceptive market. In addition to growing Twirla, we also plan to continue pursuing opportunities to broaden our portfolio to address areas of unmet medical need in women's health.

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. We also expect to continue exploring possible expansion through business development activities, such as acquiring access to new products through in-licensing, co-promotion or other collaborative arrangements.

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 by growing our telemedicine presence through our 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.

It should be noted that the possibility of continued public health threats could adversely affect our ongoing or planned business operations. For example, the coronavirus ("COVID-19") pandemic previously resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The most significant impacts to our business were encountered by sales representatives promoting Twirla in the field, as some offices limited opportunities for face-to-face interactions with healthcare providers. Re-implementation of COVID-19 restrictions, if necessary in the future, may disrupt our business and/or could adversely affect our commercialization plans and results. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including personnel at third-party manufacturing facilities and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted. Another shutdown necessitating work in a completely remote environment could result in delays to our business activities and commercialization plan. We will continue to closely monitor events as they develop, and plan for alternative and mitigating measures that we can implement if needed.

Financial Overview

Since our inception in 1997 through 2022, we generated minimal revenue and have never been profitable. Through September 30, 2023, we had an accumulated deficit of $418.7 million. Our net loss was $0.8 million and $5.9 million for the three months ended September 30, 2023 and 2022, respectively and $10.0 million and $21.5 million for the nine months ended September 30, 2023 and 2022, respectively. 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 September 30, 2023, we had approximately $2.9 million in cash and cash equivalents.

Moving forward, 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 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. As of September 30, 2023, 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 business development opportunities to commercialize a second product, and to do so in a way that we believe would contribute to our ability to reduce our operating losses and reduce our time to achieving positive cash flow from operations.

Going Concern

As of September 30, 2023, we had cash and cash equivalents of $2.9 million. We closely monitor our cash and cash equivalents and expect that our current cash will support operations through December 2023.

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 September 30, 2023 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 September 30, 2023 and 2022, net sales totaled $6.7 million and $3.0 million, respectively, representing the sale of 74,424 units and 33,072 units, respectively. For the nine months ended

September 30, 2023 and 2022, net sales totaled $16.0 million and $6.9 million, respectively, representing the sale of 179,640 units and 71,442 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 September 30, 2023 and 2022, cost of product revenues totaled $2.5 million and $1.4 million, respectively. For the nine months ended September 30, 2023 and 2022, cost of product revenues totaled $6.8 million and $5.2 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 September 30, 2023 and 2022, our research and development expenses were approximately $0.7 million and $0.8 million, respectively. For the nine months ended September 30, 2023 and 2022, our research and development expenses were approximately $2.2 million and $2.9 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three Months Ended September 30, (In thousands)		Nine Months Ended September 30, (In thousands)	
	2023	2022	2023	2022
Clinical development	$ 29	$ 115	$ 108	$ 917
Regulatory	176	107	408	366
Personnel related	406	476	1,394	1,334
Stock-based compensation	94	90	261	284
Total research and development expenses	$ 705	$ 788	$ 2,171	$ 2,901

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 September 30, 2023 and 2022, our selling and marketing expenses totaled approximately $4.8 million and $5.6 million, respectively. For the nine months ended September 30, 2023 and 2022, our selling and marketing expenses totaled approximately $14.0 million and $23.5 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 September 30, 2023 and 2022, our general and administrative expenses totaled approximately $2.7 million and $2.8 million, respectively. For the nine months ended September 30, 2023 and 2022, our general and administrative expenses totaled approximately $8.8 million and $9.8 million, respectively. We anticipate that our general and administrative expenses will stabilize in the future.

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 23, 2023.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

	Three Months Ended September 30, (In thousands)		
	2023	2022	Change
Revenues, net	$ 6,662	$ 3,002	$ 3,660
Cost of product revenues	2,477	1,425	1,052
Gross profit	4,185	1,577	2,608
Operating expenses:			
Research and development	$ 705	$ 788	$ (83)
Selling and marketing	4,800	5,560	(760)
General and administrative	2,680	2,815	(135)
Loss on disposition of assets	—	11,122	(11,122)
Total operating expenses	8,185	20,285	(12,100)
Loss from operations	$ (4,000)	$ (18,708)	14,708
Other income (expense)			
Interest income	13	46	(33)
Interest expense	(341)	(1,004)	663
Unrealized gain on warrant liability	3,529	13,736	(10,207)
Total other income, net	3,201	12,778	(9,577)
Loss before benefit from income taxes	(799)	(5,930)	5,131
Benefit from income taxes	—	—	—
Net loss	$ (799)	$ (5,930)	$ 5,131

Revenues. Revenue, net increased by $3.7 million, or 122% from $3.0 million for the three months ended September 30, 2022 to $6.7 million for the three months ended September 30, 2023. Unit sales increased by 41,352 units, or 125%, from 33,072 units for the three months ended September 30, 2022, to 74,424 units for the three months ended September 30, 2023. 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 increased by $1.1 million, or 74% for the three months ended September 30, 2022 to $2.5 million for the three months ended September 30, 2023 and consists of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, 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 $0.1 million, or 11%, from $0.8 million for the three months ended September 30, 2022 to $0.7 million for the three months ended September 30, 2023. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022. This decrease primarily reflects a decrease in personnel costs and decreased consulting expenses.

Selling and marketing expenses. Selling and marketing expenses decreased by $0.8 million, or 14%, from $5.6 million for the three months ended September 30, 2022 to $4.8 million for the three months ended September 30, 2023. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the continued optimization of our contract sales force.

General and administrative expenses. General and administrative expense decreased by $0.1 million, or 5%, from $2.8 million for the three months ended September 30, 2022 to $2.7 million for the three months ended September 30, 2023.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an $11.1 million, one-time, non-cash charge during the three months ended September 30, 2022, which represented the loss on the transfer of fixed assets to Corium in connection with the amended Corium Agreement. There was no comparable expense during the three months ended September 30, 2023.

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

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 $0.7 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 due to the reduction in the principal amount outstanding on the loan.

Unrealized gain on warrant liability. Unrealized gain on warrant liability reflects the non-cash changes in the estimated fair value of the warrant liability.

Comparison of the Nine Months Ended September 30, 2023 and 2022

	Nine Months Ended September 30, (In thousands)		
	2023	2022	Change
Revenues, net	$ 15,979	$ 6,888	$ 9,091
Cost of product revenues	6,787	5,183	1,604
Gross profit	9,192	1,705	7,487
Operating expenses:			
Research and development	$ 2,171	$ 2,901	$ (730)
Selling and marketing	14,040	23,523	(9,483)
General and administrative	8,813	9,837	(1,024)
Loss on disposition of assets	—	11,122	(11,122)
Total operating expenses	25,024	47,383	(22,359)
Loss from operations	$ (15,832)	$ (45,678)	29,846
Other income (expense)			
Interest income	61	50	11
Interest expense	(1,114)	(2,699)	1,585
Unrealized gain on warrant liability	6,890	22,171	(15,281)
Total other income (expense), net	5,837	19,522	(13,685)
Loss before benefit from income taxes	(9,995)	(26,156)	16,161
Benefit from income taxes	—	4,675	(4,675)
Net loss	$ (9,995)	$ (21,481)	$ 11,486

Revenues. Revenue, net increased by $9.1 million or 132% from $6.9 million for the nine months ended September 30, 2022 to $16.0 million for the nine months ended September 30, 2023. Unit sales increased by 108,198 units, or 151%, from 71,442 units for the nine months ended September 30, 2022, to 179,640 units for the nine months ended September 30, 2023. 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 increased by $1.6 million or 31% from $5.2 million for the nine months ended September 30, 2022 to $6.8 million for the nine months ended September 30, 2023, and consists of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, 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 $0.7 million or 25% from $2.9 million for the nine months ended September 30, 2022 to $2.2 million for the nine months ended September 30, 2023. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses of $0.8 million for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022. This decrease reflects a reduction in spending related to our pipeline evaluation and development.

Selling and marketing expenses. Selling and marketing expenses decreased by $9.5 million, or 40%, from $23.5 million for the nine months ended September 30, 2022 to $14.0 million for the nine months ended September 30, 2023. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the optimization of our contract sales force.

General and administrative expenses. General and administrative expenses decreased by $1.0 million, or 10%, from $9.8 million for the nine months ended September 30, 2022 to $8.8 million for the nine months ended September 30, 2023. This decrease in general and administrative expense was primarily due to lower personnel-related costs due to lower headcount.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an $11.1 million, one-time, non-cash charge during the nine months ended September 30, 2022, which represented the loss on the transfer of fixed assets to Corium in connection with the amended Corium Agreement. There was no comparable expense during the nine months ended September 30, 2023.

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

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 $1.6 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 due to the reduction in the principal amount outstanding on the loan.

Unrealized gain on warrant liability. Unrealized gain on warrant liability reflects the non-cash changes in the estimated fair value of the warrant liability.

Benefit from income taxes. Benefit from income taxes represents $4.7 million received under the State of New Jersey's Technology Business Tax Certificate Transfer Program sponsored by The New Jersey Economic Development Authority during the nine months ended September 30, 2022.

Liquidity and Capital Resources

At September 30, 2023, we had cash and cash equivalents totaling $2.9 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:

	Nine Months Ended September 30, (In thousands)	
	2023	2022
Net cash used in operating activities	$ (9,748)	$ (34,388)
Net cash used in investing activities	—	(133)
Net cash provided by financing activities	7,375	21,523
Net decrease in cash and cash equivalents	$ (2,373)	$ (12,998)

Operating Activities

Net cash used in operating activities was $9.8 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of $9.3 million offset by a $6.9 million unrealized gain on warrants, non-cash stock-based compensation expense of $1.4 million, $1.1 million of other non-cash charges, primarily interest expense, and $3.9 million of positive working capital changes, primarily an increase in accounts payable and accrued expenses and a decrease in deposits. Net cash used in operating activities was $34.4 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of $43.6 million and negative working capital changes of $7.0 million, offset by non-cash stock-based compensation expense of $2.0 million, depreciation expense of $1.3 million, a $11.1 million non-cash loss on the disposition of fixed assets, and $1.8 million of other charges, primarily interest expense.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2023 was zero. Net cash used in investing activities for the nine months ended September 30, 2022 was $0.1 million and consisted of acquisitions of equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was $7.4 million, which consists of net proceeds of $6.5 million from a public offering of common stock and prefunded warrants, $1.7 million from the sale of 207,882 shares of our common stock through an at-the-market, or ATM, sales program partially offset by $0.7 million of principal payments on our debt. Net cash provided by financing activities for the nine months ended September 30, 2022 was $21.5 million, which consisted of net proceeds of $4.1 million from the sale of preferred stock in a registered offering, $22.0 million from the sale of 533,333 shares of common stock in a public offering and proceeds of $12.6 million from the sale of 174,263 shares of our common stock through an at-the-market, or ATM sales program, partially offset by a principal payment of short-term debt of $17.0 million.

Funding Requirements and Other Liquidity Matters

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. In addition, on October 2, 2020 we 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.

On January 10, 2022, we filed a prospectus supplement to our 2020 Shelf Registration Statement registering the 2022 ATM we entered into for the sale of up to $50.0 million of shares of our common stock. During the three months ended March 31, 2022, we sold and issued 512 shares of common stock resulting in net proceeds of $0.3 million. On April 26, 2022, we terminated the 2022 ATM Agreement.

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 we 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 $520.00 per share, will become 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 $520.00 per share, will become 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 $520.00 per share, will become exercisable six months after the date of the Letter Agreement, and will expire 5 years following the initial exercise date.

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 78,852 shares of common stock under the August 2022 ATM resulting in net proceeds to us of approximately $0.9 million. During the nine months ended September 30, 2023, we issued and sold 207,883 shares resulting in net proceeds of approximately $1.7 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 through our ATM.

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.

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

We believe we may have the potential to access additional capital through the August 2022 ATM, 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;
- 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 if 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 September 30, 2023, the minimum amount committed totals $230.1 million.

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 September 30, 2023, 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 18-month term totals $0.6 million as of September 30, 2023.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, financing, exchange rates or other factors. These market risks are principally limited to interest rate fluctuations.

We had cash and cash equivalents of $2.9 million and $5.2 million at September 30, 2023 and December 31, 2022, respectively, consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows are subject to fluctuations due to changes in interest rates. We do not believe that we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a 1% unfavorable change in interest rates would not have a material effect on interest expense for the nine months ended September 30, 2023.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the nine months ended September 30, 2023.

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 December 31, 2022, our chief executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective to ensure that the information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, due to the material weakness in our internal control over financial reporting described below.

Management has concluded that there is a material weakness in the review procedures related to complex securities including the determination of liability versus equity treatment of certain warrants. Management has concluded that there is a material weakness in the design and operating effectiveness of the Company's review procedures related to complex securities. The reviewer had insufficient resources supporting the assessment of the complex securities accounting model and the review procedures were not performed at a level of precision to prevent or detect a material misstatement on a timely basis in the normal course of the review. Based on this assessment, management believes that our internal control over financial reporting was not effective as of December 31, 2022.

Changes to Internal Control Over Financial Reporting

Effective August 16, 2023, we appointed a Senior Vice President, Chief Financial Officer and Treasurer of the Company, Other than the foregoing, there have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation Plan for Material Weakness

Management has actively initiated remediation efforts to address the material weakness. Specifically, we expanded and improved our review process for complex securities and related accounting standards. We plan to further improve this process by enhancing access to accounting literature and identification of third-party accounting professionals with whom to consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Part II: Other Information

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

The following risk factor should be considered in addition to our risk factors previously reported in our Annual Report on Form 10-K for the year ended December 31, 2022.

We are not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.

On March 27, 2023, we received a deficiency letter from Nasdaq notifying us that we are not in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires companies listed on the Nasdaq Capital Market to maintain stockholders' equity of at least $2,500,000 (the "Stockholders' Equity Requirement"). Our Annual Report on Form 10-K for the fourth quarter and year ended December 31, 2022 reported stockholders' equity of $(5,545,000), which is below the Stockholders' Equity Requirement for continued listing on the Nasdaq Capital Market. As of the date of this filing, the Company does not have a market value of listed securities of $35 million, or net income from continued operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, the alternative quantitative standards for continued listing on the Nasdaq Capital Market. In accordance with Nasdaq rules, we were provided 45 calendar days from the receipt of the Nasdaq notification, or until May 11, 2023, to submit a plan to regain compliance (the "Compliance Plan"). We submitted that plan on May 11, 2023.

On June 2, 2023, we received a letter (the "Extension Notice") from Nasdaq notifying us that we had been granted an additional 180-day period, or until September 25, 2023, to regain compliance with Nasdaq Listing Rule 5550(b)(1). On September 27, 2023, the Company received a notice from the Staff advising the Company that the Staff had determined that the Company did not meet the terms of the extension and that unless the Company requests an appeal, the Staff would proceed with delisting. The Company submitted a hearing request to the Nasdaq Hearings Panel (the "Panel"), on October 4, 2023. The request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires.

At the Panel hearing, the Company intends to present a plan to regain compliance with the Stockholders' Equity Requirement. In the interim, the Company's common stock will continue to trade on the Nasdaq Capital Market under the symbol "AGRX" at least pending the ultimate conclusion of the hearing process. Additionally, the Panel may review the Company's plan and grant an additional 180 days from the date of the notice, until March 25, 2024, for the Company to regain compliance with the Rule.

We intend to monitor our stockholders' equity and, if appropriate, consider further available options to regain compliance with the Stockholders' Equity Requirement. There can be no assurance that we will regain compliance or otherwise maintain compliance with any of the other listing requirements.

If our securities are delisted, it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair the liquidity of our common stock and could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

Item 5. Other Information

During the three months ended September 30, 2023, 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
10.1*	Employment Agreement, dated August 16, 2023, by and between Agile Therapeutics, Inc. and Scott Coiante (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K/A, file number 001-36464, filed August 22, 2023.)
10.2*	Transition and Separation Agreement, dated August 17, 2023, by and between Agile Therapeutics, Inc. and Jason Butch.
10.3	Seventh Amendment to Project Agreement, dated September 28, 2023, by and between Agile Therapeutics, Inc. and Syneos Health Commercial Services, LLC (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on September 28, 2023.)
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 September 30, 2023 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)

* Indicates management contract or compensatory plan or arrangement.

** 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: November 9, 2023

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

Date: November 9, 2023

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

Exhibit 10.2

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

TRANSITION AND SEPARATION AGREEMENT AND GENERAL RELEASE

This Transition and Separation Agreement and General Release (this "***Agreement***") agreed to by and between Agile Therapeutics, Inc. (the "***Company***") and **Jason Butch** ("***you***"), dated as of August 16, 2023, sets forth the terms of the transition of your role and your ultimate separation of employment with the Company. You and the Company are parties to this Agreement and are collectively referred to herein as the "***Parties***." If you understand and agree with these terms, please sign in the space provided below. If you and the Company sign below, this will be a legally binding document representing the entire agreement between you and the Company regarding the subjects it covers.

WHEREAS, you currently serve as the Chief Accounting Officer of the Company and your employment is currently governed by the terms of that certain employment offer letter agreement, by and between you and the Company, dated as of May 28, 2020 (the "***Employment Agreement***"), and that certain Change in Control Severance Agreement by and between you and the Company, dated as of August 14, 2020 (the "***CIC Agreement***"); and

WHEREAS, you and the Company have agreed to transition your role, as of June 23, 2023 (the "***Transition Date***"), and terminate your employment as of August 15, 2023 (the "***Expected Termination Date***"), in each case in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, for and in consideration of the premises and mutual promises and agreements contained herein, together with other good and valuable consideration, receipt and sufficiency of which is hereby acknowledged, it is mutually agreed as follows:

1. **Transition Period; Termination of Employment**.

(a) You and the Company agree that, during the period commencing on the Transition Date until the Termination Date (the "***Transition Period***"), you will use your best efforts to fulfill your duties and responsibilities as Chief Accounting Officer of the Company in accordance with this Agreement. During the Transition Period, as requested by the Company, you shall also use your best efforts to transition your role to your successor, as designated by the Company and perform such other duties as designated by the Company, consistent with your role and the transition of your role. During the Transition Period, you will continue to serve the Company faithfully, conscientiously and to the best of your ability.

(b) This Agreement will supersede and replace the Employment Agreement and the CIC Agreement, and following the effectiveness of this Agreement, in consideration for entering into this Agreement, the Employment Agreement and the CIC Agreement shall be of no further force or effect.

(c) Your last day of work with the Company is expected to be the Expected Termination Date; *provided* that you or the Company may provide 30 days advanced written notice to terminate your employment earlier than the Expected Termination Date (in which case the Consideration set forth in Section 3 will not become payable); *provided further* based on mutual agreement, you and the Company may extend the Transition Period beyond the Expected Termination Date; *provided further* that if the Company terminates your employment for Reasonable Cause (as defined in the CIC Agreement), such termination will be effective immediately. For the purposes of this Agreement, the "***Termination Date***" will be the date that your employment with the Company and its affiliates actually terminates. As of the Termination Date, any position or office you hold with the Company and its affiliates, including as an officer or director of the Company or any of its affiliates will end. The Company will have no obligation to hire or re-employ you in the future.

2. **Compensation during Transition Period**. The Company will continue to pay your base salary as in effect on the Transition Date, less applicable federal, state and local tax deductions, through the Termination Date, in accordance with the Company's normal payroll practices. Through the Termination Date, you shall also remain eligible to participate in the same broad-based employee benefit plans and programs as in effect on the Transition Date, subject to the terms and conditions of such employee benefit plans and programs.

3. **Consideration**. Contingent on (i) your signing and not revoking this Agreement, (ii) your continued compliance with the terms of this Agreement and the Covenant Agreement (as defined below), (iii) your continued employment in good standing through the Expected Termination Date and, if mutually agreed and applicable, a later Termination Date, and (iv) your signing and not revoking the Reaffirmation Agreement attached as Attachment [A] hereto and comply with its terms, you will be entitled to receive the following:

(a) the Company will continue to pay your base salary as in effect on the Termination Date, less applicable federal, state and local tax deductions, through the six (6)-month anniversary of the Termination Date, in accordance with the Company's normal payroll practices; *provided* that the first payment will be made on the first payroll date that is administratively practicable after the Effective Date (as defined below) (and within 60 days after the Termination Date) and will include unpaid installments for the period from the Termination Date to the first payment date; *provided, further*, that after the first payment, and further provided you are not in breach of this Agreement, in the event any periodic payments set forth in this Section 3(a) are late by more than 5 business days, the Company agrees (i) to pay a late fee in the amount of $500 for each and every late periodic payment and (ii) that if any agreed upon payments are not made, and a judgement is entered in respect of the unpaid amount, the amount due to you by the Company will be increased by a 10% penalty and reasonable costs and attorney fees reasonably incurred in seeking such judgement;

(b) provided you timely elect COBRA continuation medical coverage, the Company shall reimburse you, or directly pay to the plan administrator of the Company's fully insured group health plan, a portion of your premium, in an amount not to exceed the amount that the Company was paying on behalf of you and your eligible dependents prior

to the Effective Date, for the period starting on the Termination Date and ending on the six (6)-month anniversary of the Termination Date or such earlier date when you become eligible to participate in a subsequent employer's medical plan; *provided* that if you become eligible to participate in a subsequent employer's medical plan, you will notify the Company within five (5) days of such eligibility; and

(c) the vested portion of your options, as set forth in Attachment [B] will be exercisable until the 90th day following the Termination Date. Any such vested portion of your options that is not exercised on or before the 90th day following the Termination Date, shall be forfeited upon the expiration of the post-termination exercise period. The portion of your options that are not exercisable as of the Termination Date shall be forfeited on the Termination Date. The award agreements governing your stock options are hereby amended to reflect this change.

4. **Return of Company Property**. You agree that by the Termination Date or date as agreed to with the Company, you will return to the Company all Company property, including all papers, records, data, notes, drawings, files, documents, samples, devices, products, equipment, and other materials, including copies and in whatever form, relating to the business of the Company that you possess or created as a result of your employment with the Company, whether or not confidential, and all keys, equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones and pagers), access or credit cards, company identification, company vehicles and any other property owned by the Company in your possession or control and have left intact all electronic documents of the Company, including, but not limited to, those that you developed or helped to develop during your employment. You will be provided a computer for your personal that you may keep after the Termination Date. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company's name, including, but not limited to, credit cards, telephone charge cards, cellular phone and/or pager accounts and computer accounts. To the extent you have any Company information or material stored on any personal device, personal computer, personal email, hard drive, thumb drive, cloud or other electronic storage device, you agree to cooperate with the Company in permanently deleting such information from such devices, subject to any Company litigation preservation directive then in effect.

5. **Mutual Release of Claims**. In exchange for the payments described in the Consideration clause and the Company's willingness to enter into this Agreement, you hereby waive all claims available under federal, state or local law against the Company and all of its divisions, subsidiaries, affiliates, related entities, and their predecessors, successors and affiliates, and all of their past and present directors, officers, employees, shareholders, benefit plans, insurers, attorneys and agents ("***Releasees***") of whatever nature, whether known or unknown, which exist or may exist on your behalf against Releasees, including but not limited to any and all claims arising out of your employment with the Company or the termination of that employment, including but not limited to all claims arising under the Americans with Disabilities Act, Title VII of the Civil Rights Act of 1991, the Employee Retirement Income Security Act, the Equal Pay Act, the Genetic Information Non-Discrimination Act, the Family and Medical Leave Act, Section 1981 of U.S.C, Title VII of the Civil Rights Act, the Age Discrimination in Employment Act (ADEA), the Older Workers Benefit Protection Act, the New Jersey Law Against Discrimination, the New Jersey Conscientious Employee Protection Act, the New Jersey State Wage and Hour

Law, the New Jersey Equal Pay Act, the New Jersey Family Leave Act, the New Jersey Constitution, the New Jersey Security and Financial Empowerment Act, New Jersey common law, as well as wrongful termination claims, breach of contract claims, discrimination claims, harassment claims, retaliation claims, whistleblower claims, defamation or other tort claims, contract claims, equitable claims, breach of fiduciary duty claims, public policy claims, statutory claims, personal injury claims, emotional distress claims, invasion of privacy claims, fraud claims, quantum meruit claims, and claims for attorneys' fees and costs (collectively, the "***Claims***"). You understand that the identification of specific statutes in this paragraph is for purposes of example only, and the omission of any specific statute or law shall not limit the scope of this general release in any manner,

Notwithstanding the foregoing, you are not waiving your right to vested benefits under the written terms of the Company's employee pension benefit plans, claims for unemployment or workers' compensation benefits, or claims that are not otherwise waivable under applicable law including without limitation your right to challenge the validity of the release under the ADEA.

You agree and represent that as of the Effective Date of this Agreement, you have not filed any claims, charges, or lawsuits against the Releasees in any court, tribunal, or agency.

In consideration for your promises in this Agreement, the Company agrees to release, waive, and forever discharge you from any and all claims, causes of action, damages, demands, and any other liability or claims that the Company has or had against you, except as provided in this Agreement.

The Company is not waiving, releasing or discharging any claims, any causes of action, or damages for conduct or behavior by you that is illegal, would constitute a criminal offense or are based on willful misconduct; your unauthorized use, publication, or disclosure of any Company confidential and proprietary information; your breach of any of your obligations under this Agreement; and any claims and causes of action that, as a matter of law, cannot be waived, released, and discharged.

6. **Medicare Disclaimer**. You represent that you are not a Medicare Beneficiary as of the time you enter into this Agreement.

7. **Limit on Disclosures. Y**ou shall not disclose or cause to be disclosed the terms of this Agreement to any person (other than your spouse or domestic/civil union partner, attorney and tax advisor), except pursuant to a lawful subpoena, **as set forth in the Reports to Government Entities** clause below or as otherwise permitted by law. This provision is not intended to restrict your legal right to discuss the terms and conditions of your employment. You represent and agree that you have not made any claims or allegations of sex discrimination, gender discrimination, retaliation, or sexual harassment against the Company.

8. **Confidential Information. "*Confidential Information*" means data, trade secrets, know-how, and other information relating to the Company's business and not generally available to the public, which was disclosed to you or with which you became familiar during your term of employment with the Company. Confidential Information includes information relating to the Company's business practices and prospective business interests, products, processes, equipment, manufacturing operations, marketing programs, research, product development, regulatory interactions with government agencies, clinical trial information and related data. Following the Termination Date, unless you receive the Company's written consent, you will not disclose, use, disseminate, lecture upon, or publish**

any part of the Company's Confidential Information, whether or not developed by you. Also, you will have the same obligations with respect to the secret or confidential information of any other company or individual, to which you gained access in connection with your employment with the Company.

9. **Reports to Government Entities. Nothing in this Agreement, including the Limit on Disclosures, Confidential Information or Release of Claims clauses hereof, restricts or prohibits you from initiating communications directly with,** responding **to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General (collectively, the "*Regulators*"), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. However, to the maximum extent permitted by law, you are waiving your right to receive any individual monetary relief from the Company or any others covered by the Release of Claims resulting from such claims or conduct, regardless of whether you or another party has filed them, and in the event you obtain such monetary relief the Company will be entitled to an offset for the payments made pursuant to this Agreement. This Agreement does not limit your right to receive an award from any Regulator that provides awards for providing information relating to a potential violation of law. You do not need the prior authorization of the Company to engage in conduct protected by this paragraph, and you do not need to notify the Company that you have engaged in such conduct**.

Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

10. **Non-Admission of Liability**. Nothing in this Agreement is an admission of any wrongdoing, liability or unlawful activity by you or by the Company.

11. **No Other Amounts Due**. You acknowledge that the Company has paid you all wages, salaries, bonuses, benefits and other amounts earned and accrued, less applicable deductions, and that the Company has no obligation to pay any additional amounts other than the payment(s) described in the Consideration clause of this Agreement. You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you.

12. **Non-Disparagement**. You agree that you shall not make, publish, post or otherwise disseminate any negative or disparaging statements or comments about the Company's business, technologies, market position, employment policies and practices, employees (past and present), operations, products or services, either as fact or opinion.

13. **Cooperation**. You agree that upon the Company's reasonable notice to you, you shall cooperate with the Company and its counsel (including, if necessary, preparation for and appearance at depositions, hearings, trials or other proceedings) with regard to matters that relate to or arise out of matters you have knowledge about or have been involved with during your employment with the Company. In the event that such cooperation is required, you will be reimbursed for any reasonable travel expenses incurred in connection therewith.

14. **Acknowledgement of Voluntariness and Time to Review and Revoke**. You acknowledge that:

- you read this Agreement and you understand it;
- you are signing this Agreement voluntarily in order to release your claims against the Company in exchange for consideration that is greater than you would otherwise have received;
- you are signing this Agreement after the date of your separation from the Company and you were offered at least 45 days to consider your choice to sign this Agreement;
- the Company advises you to consult with an attorney;
- you agree that changes to this Agreement before its execution, whether material or immaterial, do not restart your time to review this Agreement;
- you are not waiving any rights or claims under the Age Discrimination in Employment Act of 1967 (29 U.S.C. § 621 et seq.) that may arise after the date this Agreement is executed;
- you have received a listing of the ages and job titles of persons in the Decisional Unit, described in Attachment C, who are selected for termination and eligible for severance pay and benefits (Attachment C-1), and who are not selected for termination and not eligible for severance pay and benefits (Attachment C-2); and
- you know that you can revoke this Agreement within 7 days of signing it and that this Agreement does not become effective until that 7-day period has passed (the "***Effective Date***"). To be effective, your revocation under this paragraph must be emailed return receipt requested within the 7-day period to Jessica Gagliardi, Senior Director, Human Resources, jgagliardi@agiletherapeutics.com.

15. **Successors and Assigns**. It is expressly understood and agreed by the Parties that this Agreement and all of its terms shall be binding upon each Parties' representatives, heirs, executors, administrators, successors and assigns.

16. **Drafting**. The Parties agree that this Agreement shall be construed without regard to the drafter of the same and shall be construed as though each party to this Agreement participated equally in the preparation and drafting of this Agreement.

17. **Attorneys' Fees**. In the event that any party to this Agreement asserts a claim for breach of this Agreement or seeks to enforce its terms, the prevailing party in any such proceeding shall be entitled to recover costs and reasonable attorneys' fees.

18. **Execution of Additional Documents**. The Parties agree to execute such other, further, and different documents as reasonably may be required to effectuate this Agreement.

19. **Headings**. The headings in each paragraph herein are for convenience of reference only and shall be of no legal effect in the interpretation of the terms hereof.

20. **Integration**. This Agreement constitutes a single, integrated, written contract, expressing the entire agreement between the Parties. It supersedes all prior agreements between the Parties, including, but not limited to the Employment Agreement and the CIC Agreement, but does not supersede any agreement you have entered into that provides for a restriction on trade secrets, Confidential Information, competition with the Company or solicitation of the Company's current or prospective customers, employees, suppliers, vendors, consultants or contractors, including that certain Employee Non-Disclosure and Invention Assignment Agreement, dated May 29, 2020 (the "***Covenant Agreement***"), which remains effective and enforceable pursuant to the terms of the agreement applicable to such restriction. The Parties represent and warrant that they are not relying on any promises or representations that do not appear written herein. The Parties further understand and agree that this Agreement can be amended or modified only by a written agreement, signed by all of the Parties hereto.

21. **Severability**. If any provision in this Agreement is found to be unenforceable, it shall not affect the enforceability of the remaining provisions and the court shall enforce the remaining provisions to the extent permitted by law.

22. **Counterparts**. This Agreement may be executed in separate counterparts and each such counterpart shall be deemed an original with the same effect as if all Parties had signed the same document.

23. **Governing Law**. This Agreement shall be construed, performed, enforced and in all respects governed in accordance with the laws of the State of New Jersey, without giving effect to the principles of conflicts of law thereof.

24. **Authority to Enter Into Agreement**. Each party represents and warrants that, as of the date of the execution of this Agreement, he or it has the right and authority to execute this Agreement, and he or it has not sold, assigned, transferred, conveyed, or otherwise disposed of any claims or demands relating to any right surrendered by virtue of this Agreement. Each party further represents and warrants that he or it has had the opportunity to consult and has consulted legal counsel in connection with the execution of this Agreement. Each of the Parties and his or its signatory represents that the signatory is either a party or a business representative or assignee of, and is fully authorized to execute this Agreement on behalf of, the party for whom he or she signs.

25. **Application of Section 409A of the Internal Revenue Code**. This Agreement is intended to comply with section 409A of the Internal Revenue Code and the regulations issued thereunder ("***Section 409A***"), including the six-month delay for certain key employees if applicable, or an exemption. Severance benefits under this Agreement are intended to be exempt from Section 409A under the "short-term deferral" exception, to the maximum extent applicable, and then under the "separation pay" exception, to the maximum extent applicable. All payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" under Section 409A. For purposes of Section 409A, the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments and each payment shall be treated as a separate payment. With respect to payments that

are subject to Section 409A, in no event may you, directly or indirectly, designate the calendar year of a payment, and if a payment that is subject to execution of this Agreement could be made in more than one taxable year, based on timing of the execution of this Agreement, payment will be made in the later taxable year. Any reimbursements and in-kind benefits provided under this Agreement will be made or provided in accordance with the requirements of Section 409A. You will be solely responsible for any tax imposed under Section 409A and in no event will the Company have any liability with respect to any tax, interest or other penalty imposed under Section 409A.

[*Signature page follows*]

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

You acknowledge that you have fully read, understand, and voluntarily enter into this agreement, had a reasonable amount of time to consider the terms of this Agreement and you sign it with the intent to be legally bound**.**

Agile Therapeutics, Inc.

By: /s/ Al Altomari
Name: Al Altomari
Title: Chairperson and CEO

By signing below, you represent the following:

I HAVE READ THIS AGREEMENT. I HAVE BEEN ADVISED BY THE COMPANY TO CONSULT WITH AN ATTORNEY OF MY OWN CHOOSING DURING THE FORTY-FIVE (45)-DAY CONSIDERATION PERIOD. I SIGN THIS AGREEMENT FREELY AND VOLUNTARILY, WITHOUT DURESS OR COERCION.

/s/ Jason Butch

Jason Butch

August 17, 2023

Execution Date

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

Attachment A

REAFFIRMATION AGREEMENT

By signing below, Jason Butch, wishing to be legally bound, acknowledges and agrees to the following:

I have confirmed my understanding and agreement to the commitments set forth in the Transition and Separation Agreement and General Release (the "*Agreement*") to which this Reaffirmation Agreement is attached. This page represents my reaffirmation of the commitments and representations set forth in the Agreement as of the date hereof, written below, and I hereby agree that the general release of claims pursuant to Section 5 the Agreement will be extended to cover any Claims (as defined in the Agreement) arising from any act, omission or occurrence occurring up to and including the date hereof. Accordingly, you acknowledge that Section 14 of the Agreement is incorporated into this Reaffirmation Agreement as if set forth herein and applicable to the additional release of Claims set forth in the preceding sentence.

I ratify and reaffirm the commitments set forth in the Agreement and the release of Claims described in the Agreement as of the date hereof:

By: /s/ Jason Butch
Name: Jason Butch
Title: August 17, 2023

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

Attachment B

Option Summary

[***]

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

Attachment C

PROGRAM ELIGIBILITY FACTORS

The Company informs you that severance pay and other benefits are being offered to eligible employees in accordance with the following:

A. Group Covered/Decisional Unit. The decisional unit is U.S.-based employees employed with the Company (the "***Decisional Unit***") effective as of June 15, 2023. Effective June 15, 2023, the Decisional Unit is being downsized due to current operational needs and reorganization of the Company's finance operations. Employees in the Decisional Unit were selected for termination based on various factors, including position, function, redundancies, cost savings, and/or skill set.

B. Eligibility Factors. Employees selected for termination are eligible for a severance payment and benefits provided that the following conditions are met: (1) the employee is an active, non-temporary, full-time, or part-time Company employee on the United States payroll; (2) the employee's position was eliminated as a result of the job eliminations in the Decisional Unit, and (3) the employee signs and returns (and does not revoke, if applicable) the Transition and Separation Agreement and General Release ("***Agreement***") in the form provided to him or her and within the time permitted, and adheres to all terms and conditions set forth in the Agreement.

C. Applicable Time Limits. Eligible employees 40 years or older have forty-five (45) calendar days to review and consider the Agreement, including all attachments, with an attorney of their choosing, and must sign and return the Agreement within that time period. Eligible employees 40 years or older will have seven (7) days after he or she signs the Agreement to revoke the Agreement by notifying the Company in writing as set forth in the Agreement.

D. Job Title(s) and Age(s) of All Active Employees in the Decisional Unit Eligible for Severance Payments and Other Benefits.

See Attachment C-1.

E. Job Title(s) and Age(s) of All Active Employees in the Decisional Unit Not Eligible for Severance Payments and Other Benefits.

See Attachment C-2.

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

Attachment C-1

Job Title(s) and Age(s) (as of June 15, 2023) of All Active Employees in the Decisional Unit Eligible for Severance Payments and Other Benefits

Job Title	Age
VP, Chief Accounting Officer	[***]
Sr. Manager, FP&A	[***]

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats and private and confidential.

Attachment C-2

Job Title(s) and Age(s) (as of June 15, 2023) of All Active Employees in the Decisional Unit Not Eligible for Severance Payments and Other Benefits

Job Title	Age
SVP & Chief Corporate Planning & Supply Chain Officer	[***]
SVP & General Counsel	[***]
SVP & CMO	[***]
SVP, Chief Commercial Officer	[***]
VP, Policy, Advocacy & Access	[***]
Sr. Director, Marketing	[***]
Sr Product Manager	[***]
Director Business Systems	[***]
Paralegal	[***]
Senior Manager, Investor Relations	[***]
Sr Director Human Resources	[***]
VP, Legal & Chief Compliance Officer	[***]
Sr Director QA	[***]
Senior Accountant & Financial Analyst	[***]
Controller	[***]
Director Pharmacovigilance	[***]
Director Information Technology	[***]
Chairman & CEO	[***]

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: November 9, 2023

/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: November 9, 2023

/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 September 30, 2023 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: November 9, 2023

/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 September 30, 2023 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: November 9, 2023

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