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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2022

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 4,542,110 shares of the registrant's common stock, $0.0001 par value, outstanding as of May 9, 2022.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended March 31, 2022

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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®, the development of our other potential product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, 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 trial 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 successfully enhance the commercialization and increase the uptake for Twirla, our only approved product;
- the rate and degree of market acceptance of Twirla by physicians, patients, 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;
- the effects of the ongoing COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as the effects of the COVID-19 pandemic on our potential customer base;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- 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.

- 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 successfully complete a 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 come into compliance with the listing requirements of the Nasdaq Capital Market;

- 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, 2021 filed with the Securities and Exchange Commission on March 30, 2022 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)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 3,743	$ 19,143
Accounts receivable, net	1,665	1,533
Income taxes receivable	4,675	—
Inventory, net	2,693	966
Prepaid expenses and other current assets	1,576	2,283
Total current assets	14,352	23,925
Property and equipment, net	12,047	12,447
Right of use asset	888	949
Other non-current assets	2,012	2,012
Total assets	$ 29,299	$ 39,333
Liabilities and stockholders' equity		
Current liabilities:		
Long-term debt, current portion	$ 12,252	$ 16,833
Accounts payable	9,537	8,707
Accrued expenses	3,828	3,563
Lease liability, current portion	231	175
Total current liabilities	25,848	29,278
Lease liabilities, long-term	708	784
Long-term debt	—	—
Total liabilities	26,556	30,062
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $.0001 par value, 10,000,000 shares authorized, 4,850 issued and 2,425 outstanding at March 31, 2022 and no shares issued and outstanding at December 31, 2021	887	—
Common stock, $.0001 par value, 300,000,000 shares authorized, 3,365,422 and 3,034,901 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	400,742	396,388
Accumulated deficit	(398,886)	(387,117)
Total stockholders' equity	2,743	9,271
Total liabilities and stockholders' equity	$ 29,299	$ 39,333

See accompanying notes to unaudited financial statements.

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

	Three Months Ended March 31,	
	2022	2021
Revenues, net	$ 1,761	$ 116
Cost of product revenues	1,527	1,161
Gross profit (loss)	234	(1,045)
Operating expenses:		
Research and development	$ 1,257	$ 2,123
Selling and marketing	10,553	9,253
General and administrative	3,997	3,801
Total operating expenses	15,807	15,177
Loss from operations	(15,573)	(16,222)
Other income (expense)		
Interest income	1	16
Interest expense	(872)	(922)
Total other income (expense), net	(871)	(906)
Loss before benefit from income taxes	(16,444)	(17,128)
Benefit from income taxes	4,675	—
Net loss	$ (11,769)	$ (17,128)
Net loss per share (basic and diluted)	$ (3.78)	$ (8.00)
Weighted-average common shares (basic and diluted)	3,115,211	2,190,650
Comprehensive loss:		
Net loss	$ (11,769)	$ (17,128)
Other comprehensive income:		
Unrealized loss on marketable securities	—	(3)
Comprehensive loss	$ (11,769)	$ (17,131)

See accompanying notes to unaudited financial statements.

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount				
Balance December 31, 2021	—	$ —	3,034,901	$ —	$ 396,388	$ —	$ (387,117)	$ 9,271
Share-based compensation - stock options and RSUs	—	—	—	—	764	—	—	764
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	25,623	—	348	—	—	348
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 8)	4,850	4,850	—	—	—	—	—	4,850
Registered direct financing costs, inclusive of warrants		(965)			244			(721)
Conversion of series A convertible preferred stock	(2,425)	(897)	303,125	—	897			—
Vesting of RSUs	—	—	1,773	—	—	—	—	—
Warrants issued in connection with registered direct offering	—	(2,101)	—	—	2,101	—	—	—
Net loss	—	—	—	—	—	—	(11,769)	(11,769)
Balance March 31, 2022	2,425	$ 887	3,365,422	$ —	$ 400,742	$ —	$ (398,886)	$ 2,743

See accompanying notes to unaudited financial statements.

On April 26, 2022, the Company effectuated a one-for-forty 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 our 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
(Unaudited)
(in thousands, except share data)

	Common Stock		Additional	Accumulated		Total
	Number of Shares	Amount	Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2020	2,189,094	$ —	$ 361,548	$ 3	$ (312,223)	$ 49,328
Share-based compensation - stock options and RSUs	—	—	742	—	—	742
Issuance of common stock pursuant to at-the market stock sales, net of expenses	13,023	—	960	—	—	960
Issuance of common stock upon exercise of stock options	3,160	—	75	—	—	75
Vesting of RSUs	1,316	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	1,080	—	—	1,080
Unrealized net gain on marketable securities	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(17,128)	(17,128)
Balance March 31, 2021	2,206,593	$ —	$ 364,405	$ —	$ (329,351)	$ 35,054

See accompanying notes to unaudited financial statements.

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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (11,769)	$ (17,128)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	527	513
Amortization	61	33
Noncash stock-based compensation	764	742
Noncash interest	419	437
Changes in operating assets and liabilities:		
Accounts receivable	(132)	543
Income taxes receivable	(4,675)	—
Inventory	(1,727)	(1,590)
Prepaid expenses and other assets	707	421
Accounts payable and accrued expenses	1,095	1,393
Lease liability	(21)	(32)
Net cash used in operating activities	(14,751)	(14,668)
Cash flows from investing activities:		
Sales and maturities of marketable securities	—	16,256
Acquisition of property and equipment	(126)	(71)
Net cash (used in) provided by investing activities	(126)	16,185
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	348	409
Repayment of long-term debt	(5,000)	—
Proceeds from exercise of stock options	—	75
Net cash (used in) provided by financing activities	(523)	484
Net increase (decrease) in cash and cash equivalents	(15,400)	2,001
Cash and cash equivalents, beginning of period	19,143	14,463
Cash and cash equivalents, end of period	$ 3,743	$ 16,464
Supplemental disclosure of noncash financing activities		
Warrants issued in connection with long-term debt	$ —	$ 1,080
Warrants issued in connection with preferred stock ofering	2,101	—
Conversion of Series A preferred stock into common stock	897	—
Supplemental cash flow information		
Interest paid	$ 452	$ 588

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®, also known as AG200-15, 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 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 potential need to obtain additional capital necessary to fund the development of its products, competition from larger companies and compliance with FDA and other government regulations. If the Company does not successfully commercialize any product candidates, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of March 31, 2022, the Company had an accumulated deficit of approximately $399 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 to support the continued commercialization of Twirla in the United States;
- continues to evaluate additional line extensions for Twirla and initiates development of potential product candidates in addition to Twirla;
- maintains, leverages and expands the Company's intellectual property portfolio; and
- maintains operational, financial and management information systems and personnel, including personnel to support the Company's product development and future commercialization efforts.

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

Going Concern

As of March 31, 2022, the Company had cash and cash equivalents of $3.7 million and a working capital deficit of $11.5 million. On April 8, 2022, we received $4.7 million through the sale of net operating losses through the State of New Jersey's Technology Business Tax Certificate Transfer Program. The Company's current liquidity is sufficient to fund operations only through May of 2022. The Company closely monitors its cash and cash equivalents and intends raise money through an at-the-market facility ("ATM") and explore all other means available to raise capital to meet its projected operating requirements, including the continued commercialization of Twirla, 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 at March 31, 2022 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 strategic 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 March 31, 2022 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to obtain additional capital, reduce expenditures and/or execute on its business plan and successfully commercialize Twirla. The unaudited financial statements as of March 31, 2022 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 reporting 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, 2021 as filed with the SEC on March 30, 2022.

In the opinion of management, the unaudited interim financial statements reflect all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods presented. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the operating results for the full fiscal year or any future period. Certain expense classifications have been made to prior periods to conform with current reporting. Specifically, $90,000 of general and administrative expenses were reclassified to selling and marketing expenses, and $10,000 of general and administrative expenses were reclassified to research and development expenses, for the three months ending March 31, 2021.

The accompanying 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 COVID-19 pandemic or other factors impact the Company's current business plan or its ability to generate revenue from the launch 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, 2021 included in its Annual Report on Form 10-K filed with the SEC.

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 U.S. Food and Drug Administration, or 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 current public health threats could adversely affect our ongoing or planned business operations. In particular, the ongoing COVID-19 pandemic has 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. In many cases COVID-19 restrictions have recently eased, but re-implementation of such 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 its business in the manner and on the timeline presently planned could be materially and adversely impacted. It is unknown how long these conditions will last and what the complete effect will be on us. While to date we have been able to continue to execute our overall business plan, some of our business activities slowed and took longer to complete as we adjusted to the challenges of operating in a largely remote setting with our employees. While we have acclimated to a hybrid work model with our employees, another shut down necessitating work in a completely remote environment could result in delays to our business activities and commercialization plan. Overall, we recognize the challenges of commercializing a new product in a pandemic, and we will continue to closely monitor events as they develop and plan for alternative and mitigating measures that we can implement 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 March 31, 2022 and December 31, 2021, respectively.

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 are carried at fair value (see Note 3).

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.

The Company's third-party manufacturer, Corium, completed the validation of the commercial manufacturing process for Twirla in the fourth quarter of 2020. The costs associated with validation batches were expensed as research and development expenses during the period the costs were incurred. The Company used this validation product for commercial supplies and samples of Twirla into May 2021. Since the Company did not capitalize any validation product, all sales of this validation product had no associated product cost. During the three months ended March 31, 2021, units sold with no associated product cost were approximately 750. Had such inventory been valued at acquisition cost, it would have resulted in an immaterial increase to cost of goods sold and a corresponding decrease to gross profit.

Property and Equipment

Property and equipment, consisting of manufacturing equipment, office equipment and computer equipment, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets.

Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are charged to earnings in the period in which costs are incurred. Improvements and additions are capitalized in accordance with Company policy.

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe the carrying values of any long-lived assets are impaired as of March 31, 2022.

Research and Development Expenses

Research and development expenses consist 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 product 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 $3.3 million and $3.1 million for the three months ended March 31, 2022 and 2021, 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 a 1% facility fee paid directly to the lender, legal fees and other costs related to the term loan and are being amortized over the term of the loan. Amortization of deferred financing costs charged to interest expense was $73,000 and $69,000 for each of the three months ended March 31, 2022 and 2021, respectively.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash, cash equivalents, marketable securities and accounts receivable. The Company invests its cash, cash equivalents and marketable securities in debt instruments and interest-bearing accounts in United States financial institutions, the balances of which exceed federally insured limits. The Company has not recognized any losses from credit risks on such accounts. 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 no financial instruments with off balance sheet risk of accounting loss.

Major customers of the Company are defined as those constituting greater than 10% of its total revenue. In the three months ended March 31, 2022, the Company had sales to three customers that individually accounted for more than 10% of its total revenue. These customers had sales of $0.6 million, $0.5 million, and $0.5 million, respectively,which represented 90% of total revenues in the quarter. Accounts receivable related to these three customers comprised 36%, 36%, and 24%, respectively, as of March 31, 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 relies on industry standard data and trend analysis as historical sales data for Twirla are not yet available based on the December 2020 launch date. Once historical data becomes available, the Company will incorporate Twirla specific data into its estimates of variable consideration.

The Company uses the following specific considerations to estimate variable consideration.

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 March 31, 2022 was made based on industry-standard data and trend analysis. As time passes and historical data becomes available, the Company will use historical sales and return data to estimate future product returns.

Chargebacks – Certain government entities and indirect customers (for example group purchasing organizations and 340B covered entities) will be able to purchase the product at a price discounted below WAC. The difference between the price paid by the government or other indirect purchaser and the price paid by the wholesale distributor 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 Company is currently in the process of finalizing these agreements with Medicaid and Tricare. 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 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 on the balance sheet.

Provisions for the revenue reserves described above totaled $1.2 million and $0 for the three months ending March 31, 2022 and March 31, 2021, respectively. As of March 31, 2022, reserves on the balance sheet associated with variable consideration were $1.5 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 Company issued warrants to purchase 35,000 shares of its common stock. In connection with an amendment to that facility in February 2021, the Company issued a warrant to purchase 11,250 shares of the Company's common stock. These warrant instruments qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. See Note 7 for additional information.

In connection with an underwritten public offering completed in October 2021, the Company issued warrants to purchase 333,333 shares of its common stock. This offering also triggered an adjustment to the exercise price of the existing warrants mentioned above, 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 1,242,813 shares of its common stock. This offering also triggered an adjustment to the exercise price of the existing warrants mentioned above, 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.

Income Taxes

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

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions which prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no uncertain tax positions as of March 31, 2022 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 months ended March 31, 2022 and 2021, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	March 31,	
	2022	2021
Common stock warrants	1,622,396	46,250
Unvested restricted stock units	6,559	4,452
Common stock options	306,007	254,010
Total	1,934,962	304,712

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). This guidance simplifies the accounting for income taxes by, among other things, reducing complexity in the interim-period accounting for year-to-date loss limitations and changes in tax laws. The Company adopted ASU 2019-12 effective January 1, 2021. The adoption of this standard did not have a material impact on its financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). The guidance is effective for the Company on January 1, 2022. The adoption of this standard did not have a material impact on its financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying 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. Level 2 assets consist of marketable securities. The Company has no Level 2 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 or liabilities.

The following table sets forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of March 31, 2022 and December 31, 2021 (in thousands):

	Level 1	Level 2	Level 3
March 31, 2022			
Assets:			
Cash and cash equivalents	$ 3,743	$ —	$ —
Total assets at fair value	$ 3,743	$ —	$ —

	Level 1	Level 2	Level 3
December 31, 2021			
Assets:			
Cash and cash equivalents	$ 19,143	$ —	$ —
Marketable securities	—	—	—
Total assets at fair value	$ 19,143	$ —	$ —

There were no transfers between Level 1, 2 or 3 during 2022 or 2021.

4. Prepaid Expenses and Other Current Assets

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

	March 31, 2022	December 31, 2021
Prepaid insurance	$ 608	$ 775
Other	968	1,508
Total prepaid expenses and other current assets	$ 1,576	$ 2,283

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Accrued compensation	$ 1,968	$ 2,086
Accrued professional fees and other	1,860	1,477
Total accrued liabilities	$ 3,828	$ 3,563

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 $38,000 for the three months ended March 31, 2022 and 2021, respectively. Operating cash flows used for operating leases during the 3 months ended March 31, 2022 and 2021 were $21,000 and $32,000 respectively. As of March 31, 2022, the weighted-average remaining lease term was 3.0 years and the weighted average discount rate was 11.8%.

Future minimum lease payments under non-cancellable leases as of March 31, 2022 were as follows (in thousands):

2022	$	228
2023		390
2024		398
2025		101
Total	$	1,117
Less: Interest		(178)
Present value of lease liability	$	939

7. Credit Agreement and Guaranty

On February 10, 2020 (the “Closing Date”), the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party (“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. Another $15.0 million tranche was to be available to the Company based on the achievement of a revenue milestone by December 31, 2021. We did not achieve that milestone and that tranche is no longer available to us. On February 26, 2021 the Perceptive Credit Agreement was amended (“Amended Perceptive Credit Agreement”) by creating a fourth tranche of $10.0 million that will be available based on the achievement of a revenue milestone. We currently do not believe we will achieve the milestone for the fourth tranche of $10.0 million. On January 7, 2022, the Company and Perceptive entered into a second amendment to the Amended Perceptive Credit Agreement (the “Second Amendment”). The Second Amendment waives the Company’s obligations to comply with certain financial covenants relating to minimum revenue requirements through September 30, 2022 and to file financial statements along with its Annual Report on Form 10-K that are not subject to any “going concern” qualification. The effectiveness of the Second Amendment is conditioned upon the satisfaction of certain conditions, including the Company raising additional capital and prepaying a portion of its outstanding debt. On January 7, 2022, the Company prepaid $5.0 million of the outstanding debt, and in accordance with the terms of the Second Amendment, no prepayment premium was due. On March 10, 2022, the Company and Perceptive entered into a third amendment to the Perceptive Credit Agreement, as amended (the “Third Amendment”). The Third Amendment waived the Company’s obligations to (1) comply with certain financial covenants relating to minimum revenue requirements through September 30, 2022, conditioned upon the satisfaction of certain conditions, including the Company raising additional capital and prepaying a portion of its outstanding debt by April 30, 2022 and (2) file financial statements along with its Annual Report on Form 10-K for the fiscal year ended December 31, 2021 that are not subject to any “going concern” qualification.

The facility will mature on February 10, 2024 ("Maturity Date"). The Company is scheduled to make interest-only payments on the loans under the Amended Perceptive Credit Agreement until February 10, 2023. Thereafter, the Company is required to make monthly principal payments in an amount equal to 1.50% of the principal amount of the outstanding loans until February 10, 2024, at which time all remaining principal amount outstanding is due.

Borrowings under the Third Amendment 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 the Closing Date and at March 31, 2022 was 11.75%. Upon the occurrence and during the continuance of any event of default under the Third Amendment, 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 4.0% if such prepayment occurs after February 10, 2022 and on or prior to February 10, 2023; and 2.0% if such prepayment occurs after February 10, 2023 and prior to the Maturity Date.

All of the Company's obligations under the Third Amendment 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 Third Amendment 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 Amended 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 Amended 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 Amended Perceptive Credit Agreement. In addition, the Company must (i) at all times prior 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 December 31, 2022, report revenues for the trailing 12-month period that exceed the amounts set forth in the Amended Perceptive Credit Agreement, which range from $53.0 million for the fiscal quarter ending December 31, 2022 to $87.1 million for the fiscal quarter ending December 31, 2023.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 35,000 shares of the Company's common stock (together, the "2020 Perceptive Warrants"). The first warrant is exercisable for 17,500 shares of common stock at an exercise price of $149.60 per share. The second warrant is exercisable for 17,500 shares of common stock at an exercise price of $186.80 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Amended Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 11,250 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 $114.80 per share. The 2021 Perceptive Warrant expires on February 26, 2028. 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 as a result of the exercise.

As a result of the public offering of the Company's common stock completed in October 2021 (see Note 8), the anti-dilution provision of the Perceptive Warrants was triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an exercise price of $186.80 per share were reduced to $153.20 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of $149.60 per share were reduced to $124.40 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of $114.80 per share were reduced to $97.20 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 17,500 shares of common stock that had an adjusted exercise price of $153.20 per share were reduced to $129.20 per share, warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of $124.40 per share were reduced to $104.80 per share, and warrants to purchase 11,250 shares of common stock that had an adjusted exercise price of $97.20 per share were reduced to $82.40 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 preparing 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 $149.60 and $186.80 for the common stock warrants, (iv) fair value of common stock ($160.40) 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 $114.80 for the common stock warrant, (iv) fair value of common stock ($114.80) 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).

	March 31, 2022	December 31, 2021
Notes payable	$ 15,000	$ 20,000
Debt issuance costs	(478)	(550)
Warrant discount	(2,270)	(2,617)
Total debt	$ 12,252	$ 16,833
Less, current portion	12,252	16,833
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 $412,000 and $335,000 for the three months ended March 31, 2022 and 2021, respectively.

8. Stockholders' Equity (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.

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 666,666 shares of its common stock and warrants to purchase 333,333 shares of its common stock at a combined price of $34.00 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.

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 172,879 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 25,623 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, the Company entered into a new at-the-market offering program with H.C. Wainwright and Co. ("April 2022 ATM"), please see footnote 11 below on Subsequent Events.

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 606,250 shares of the common stock of the Company and Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 606,250 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 $8.00 per share. The shares of preferred stock issued in the 2022 Preferred Stock Offering are convertible into an aggregate of 606,250 shares of common stock. The Series A Warrants have an exercise price of $10.40 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 $10.40 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's agents fees included warrants to purchase 30,313 shares of the common stock of the Company at a strike price of $10.00. 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.

The Company allocated the net proceeds of $4.1 million in accordance with ASC 470 based on the relative fair values of the preferred stock and the Series A Warrants and Series B Warrants (collectively, the "Warrants"). The relative fair value of the Warrants of approximately $2.1 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 preferred stock. The significant assumptions used in preparing the option pricing model for valuing the Warrants issued include (i) volatility of 111.9% for the Series A warrants and 69.7% for the Series B Warrants, (ii) risk free interest rate of 2.1% for the Series A Warrants and 1.6% for the Series B Warrants, (iii) strike price of $10.40, (iv) fair value of common stock ($9.48) and (v) expected life of 5.5 years for the Series A Warrants and 1.5 years for the Series B Warrants.

On March 15, 2022, 2,425 shares of the Series A Preferred Stock was converted into 303,125 shares of the Company's common stock.

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2022	2021
Cost of goods sold	$ 44	$ 60
Research and development	103	107
Selling and marketing	40	35
General and administrative	577	540
Total	$ 764	$ 742

9. Income Taxes

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 2030, total $3.4 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 2021 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

In April 2020, we entered into a manufacturing and commercialization agreement with Corium, Inc., which we refer to as 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 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 current demand expectations for Twirla, the Company does not expect to meet the minimum volume order for the balance of 2022 and would be subject to the additional fee on future purchases. The Company and Corium are actively negotiating the structure and application of the contract minimums for the years 2022 and beyond. Given the uncertainty of the outcome of the negotiations, the Company is not reasonably able to estimate the amount, if any, of additional fees to be paid to Corium.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company's operations or its financial position. As of March 31, 2022, the Company has not recorded a provision for any contingent losses.

11. Subsequent Events

On April 4, 2022, 2,425 shares of Series B Preferred Stock was converted into 303,125 shares of the Company's common stock.

On April 25, 2022, the Company entered into a letter agreement and waiver ("Letter Agreement") with the investor in the 2022 Preferred Stock Offering, pursuant to which the investor consented to the Company entering into and effecting an ATM offering facility. Pursuant to the purchase agreement for the 2022 Preferred Stock Offering, 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 the investor 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 212,188 shares of common stock, subject to adjustment thereunder. The Series A Warrants have an exercise price of $10.40 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 26, 2022, 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 26, 2022. The Certificate of Amendment implemented a 1-for-40 reverse stock split of the Company's common stock. On the effective date of April 26, 2022, the number of the Company's issued and outstanding shares of common stock was decreased from 146,741,862 to 3,668,546 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.

On April 27, 2022, the Company entered into the April 2022 ATM with H.C. Wainwright & Co., LLC (the "Sales Agent"), under which the Company may, from time to time in its sole discretion, issue and sell through or to the Sales Agent, acting as the Company's agent, up to $12,841,000 of shares of the Company's common stock (the "Placement Shares"). The Company will pay the Sales Agent a commission of up to 3.0% of the gross sales proceeds of any Placement Shares sold under the April 2022 ATM. As of May 9, 2022, we issued and sold a total of 873,564 shares of common stock under the April 2022 ATM Agreement resulting in net proceeds of approximately $1.9 million.

On May 11, 2022, the Company and Perceptive entered into a fourth amendment to the Credit Agreement and Guarantee dated February 10, 2020, as amended on February 26, 2021, January 7, 2022 and March 10, 2022, between us and Perceptive Credit Holdings III, LP, or Perceptive, which we may refer to as the Amended Perceptive Credit Agreement. The Amended Perceptive Credit Agreement waived our obligations to comply with certain financial covenants relating to minimum revenue requirements through September 30, 2022, conditioned upon the satisfaction of certain conditions, including us raising additional capital and prepaying a portion of our outstanding debt by May 31, 2022.

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 30, 2022. 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.

Our first and only product, Twirla, which was approved in February 2020 and launched in early December 2020, is a once-weekly prescription combination hormonal contraceptive patch. It delivers a dose of estrogen 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 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.

With the approval of Twirla we are now focused on our advancement as a commercial company. During 2022, we plan to continue implementing our commercialization plan for Twirla, with the goal of becoming a contraceptive market leader, and ultimately, 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 an initial franchise in the multi-billion dollar U.S. hormonal contraceptive market built on approval of Twirla in the U.S. Our resources are currently focused on the commercialization of Twirla. We also expect to explore 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 implement our commercialization plans for Twirla to increase uptake of Twirla in the United States, including increasing targeted digital direct to consumer advertising;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- Continue to expand access to Twirla through multiple business channels including third-party payor contracts, retail and specialty pharmacies, telemedicine and government contracting, and public health centers;
- Maintain and manage the supply chain for Twirla to support increased commercialization of Twirla across the United States and working through existing and future inventory prior to product becoming short-dated;
- Manage our available cash and obtain financing to fund our business plan without delay;
- 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
- Complete and submit the final study report for a post-marketing commitment study and continue to implement our obligations for the post-marketing requirement study.

It should be noted that current public health threats could adversely affect our ongoing or planned business operations. In particular, the ongoing COVID-19 pandemic has 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. In many cases COVID-19 restrictions have recently eased, but re-implementation of such 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. It is unknown how long these conditions will last and what the complete

effect will be on us. While to date we have been able to continue to execute our overall business plan, some of our business activities slowed and took longer to complete as we adjusted to the challenges of operating in a largely remote setting with our employees. While we have acclimated to a hybrid work model with our employees, another shut down necessitating work in a completely remote environment could result in delays to our business activities and commercialization plan. Overall, we recognize the challenges of commercializing a new product in a pandemic, 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, we have devoted substantial resources to developing and seeking regulatory approval for Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. While we anticipate that a portion of our operating expenses will continue to be related to research and development as we plan our post marketing long-term, prospective observational safety study, which is apost marketing requirement from the FDA, and evaluate the development of our pipeline, our operating expenses have substantially shifted towards commercialization activities for Twirla.

We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of March 31, 2022, and December 31, 2021, we had $3.7 million and $19.1 million in cash and cash equivalents, respectively.

In February 2020, we entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party (“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. Another $15.0 million tranche was to be available to us based on the achievement of a revenue milestone by December 31, 2021. We did not achieve that milestone and that tranche is no longer available to us. On February 26, 2021 the Perceptive Credit Agreement was amended (“Amended Perceptive Credit Agreement”) by creating a fourth tranche of $10.0 million that will be available based on the achievement of a revenue milestone. We currently do not believe we will achieve the milestone for the fourth tranche of $10.0 million. The facility will be interest only until the third anniversary of the closing date. The interest rate and 1% fee payable upon the drawing of a tranche set forth in the Perceptive Credit Agreement also applied to the fourth tranche created by the Amended Perceptive Credit Agreement. In addition, the Company received a covenant waiver pertaining to the existence of a “going concern” qualification in the accompanying opinion of the Company’s auditors in the Company’s Annual Report on Form 10-K, filed on March 1, 2021. In connection with the Amended Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 11,250 shares of the Company’s common stock with an exercise price of $114.80 per share.

On January 7, 2022, we entered into a second amendment to the Perceptive Credit Agreement (the “Second Amendment”). The Second Amendment waives our obligations to comply with certain financial covenants relating to minimum revenue requirements through September 30, 2022 and to file financial statements along with our Annual Report on Form 10-K that are not subject to any “going concern” qualification. The effectiveness of the Second Amendment is conditioned upon the satisfaction of certain conditions, including the Company raising additional capital and prepaying a portion of its outstanding debt. On March 10, 2022, we entered into a third amendment to the Perceptive Credit Agreement (the “Third Amendment”). The Third Amendment waived the Company’s obligations to (1) comply with certain financial covenants relating to minimum revenue requirements through September 30, 2022, conditioned upon the satisfaction of certain conditions, including the Company raising additional capital and prepaying a portion of its outstanding debt by April 30, 2022 and (2) file financial statements along with its Annual Report on Form 10-K for the fiscal year ended December 31, 2021 that are not subject to any “going concern” qualification.

In March 2021, we entered into a common stock sales agreement (the “2021 ATM Agreement”) under which we are authorized to 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). We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. During the year ended December 31, 2022, we issued and sold a total of 172,879 shares of common stock under the 2021 ATM Agreement resulting in net proceeds of approximately $9.3 million.

In October 2021, we completed a public offering of 666,666 shares of our common stock and warrants to purchase 333,333 shares of our common stock at a combined price of $34.00 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 January 2022, we entered into a common stock sales agreement (the “2022 ATM”) under which we are authorized to 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). We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. During the three months ended March 31, 2022 we issued and sold a total of 25,623 shares of common stock under the 2022 ATM resulting in net proceeds of approximately $0.3 million. On April 26, 2022, we terminated the 2022 ATM.

On March 13, 2022, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with a single healthcare-focused institutional investor (the “Purchaser”), pursuant to which the Company issued, in a registered direct offering (the “2022 Preferred Stock Offering”), 2,425 shares of Series A convertible preferred stock (the “Series A Preferred Stock”) and 2,425 shares of Series B convertible preferred stock (the “Series B Preferred Stock”) and Series A warrants (the “Series A Warrants”) to purchase up to an aggregate of 606,250 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 606,250 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 $8.00 per share. The shares of preferred stock issued in the offering are convertible into an aggregate of 606,250 shares of Common Stock. The Series A Warrants have an exercise price of $10.40 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 $10.40 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. Total gross proceeds from the 2022 Preferred Stock Offering, before deducting the placement agent's fees and other estimated offering expenses, are $4.9 million. The 2022 Preferred Stock Offering closed on March 14, 2022.

On April 25, 2022, we entered into a letter agreement and waiver (“Letter Agreement”) with Armistice Capital Master Fund Ltd. (“Armistice”), pursuant to which Armistice consented to us entering into and effecting an at-the-market (“ATM”) offering facility. Pursuant to the Letter Agreement, we issued to Armisitice 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 212,188 warrant shares, subject to adjustment thereunder. The Series A Warrants have an exercise price of $10.40 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.

On April 27, 2022, we entered into a common stock sales agreement (the “April 2022 ATM Agreement”) under which we are authorized to sell up to an aggregate of $12,841,000 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) (“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. As of May 9, 2022, we issued and sold a total of 873,564 shares of common stock under the April 2022 ATM Agreement resulting in net proceeds of approximately $1.9 million.

Moving forward, we plan to monitor our cash and cash equivalents balances, in an effort to ensure we have adequate liquidity to fund our operations. If the COVID-19 pandemic or other factors impact our current business plan or our ability to generate revenue from the launch 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, we believe we may have the potential to access additional capital through the April 2022 ATM, selling additional debt or equity securities or obtaining a line of credit or other loan as required.

We have generated minimal revenue and have never been profitable for any year. Our net loss was $74.9 million, $51.9 million and $18.6 million for the years ended December 31, 2021, 2020 and 2019, respectively. Our net loss was $11.8 million and $17.1 million for the three months ended March 31, 2022 and 2021, respectively.

We expect to continue to incur significant operating losses for the foreseeable future as we commercialize Twirla. This includes commercially launching Twirla, advancing our other potential product candidates and expanding our research and development programs.

Going Concern

As of March 31, 2022, we had cash and cash equivalents of $3.7 million. On April 8, 2022, we received $4.7 million through the sale of net operating losses through the State of New Jersey's Technology Business Tax Certificate Transfer Program. We closely monitor our cash and cash equivalents and expect that our current cash will fund our planned through May 2022. We plan to raise additional funds through debt issuances or the issuance and sale of our common stock to meet our projected operating requirements, including the continued commercialization of Twirla, the exploration and potential advancement of our existing pipeline and our possible expansion through business development activities.

Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. Our ability to continue operations will depend on our ability to obtain additional capital, 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.

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 complete 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 financial statements as of March 31, 2022 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 successfully launch Twirla. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Financial Operations Overview

Revenue

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

regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, could be adversely affected.

For the three months ended March 31, 2022 and 2021, net sales totaled $1.8 million and $0.1 million, respectively, representing the sale of 16,818 units and 744 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. There was no direct cost of product revenue on 744 units sold in the three months ended March 31, 2021, as those units were validation inventory which was previously expensed as research and development expense in the fourth quarter of 2020.

For the three months ended March 31, 2022 and 2021, cost of product revenues totaled $1.5 million and $1.2 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.

Research and development activities are central to our business model and to date, our research and development expenses have 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.

For the three months ended March 31, 2022 and 2021, our research and development expenses were approximately $1.3 million and $2.1 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended March 31, (In thousands)	
	2022	2021
Clinical development	$ 448	$ 1,251
Regulatory	133	158
Personnel related	573	664
Manufacturing—commercialization	—	(57)
Stock-based compensation	103	107
Total research and development expenses	$ 1,257	$ 2,123

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 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 commercializing Twirla.

Selling and Marketing Expenses

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

For the three months ended March 31, 2022 and 2021, our selling and marketing expenses totaled approximately $10.6 million and $9.3 million, respectively. Our commercial launch of Twirla in the United States utilized a contract sales force. We anticipate that our selling and marketing expenses will continue to be significant as our commercialization efforts continue.

General and Administrative Expenses

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

For the three months ended March 31, 2022 and 2021, our general and administrative expenses totaled approximately $4.0 million and $3.8 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 30, 2022.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31, (In thousands)		
	2022	2021	Change
Revenues, net	$ 1,761	$ 116	$ 1,645
Cost of product revenues	1,527	1,161	366
Gross profit	234	(1,045)	1,279
Operating expenses:			
Research and development	$ 1,257	$ 2,123	$ (866)
Selling and marketing	10,553	9,253	1,300
General and administrative	3,997	3,801	196
Total operating expenses	15,807	15,177	630
Loss from operations	$ (15,573)	$ (16,222)	649
Other income (expense)			
Interest income	1	16	(15)
Interest expense	(872)	(922)	50
Total other income (expense), net	(871)	(906)	35
Loss before benefit from income taxes	(16,444)	(17,128)	684
Benefit from income taxes	4,675	—	4,675
Net loss	$ (11,769)	$ (17,128)	$ 5,359

Revenues. Revenue, net consists of sales of Twirla, which was approved by the FDA in February 2020 and launched in the US in December 2020, 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 totaled $1.5 million and consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance.

Research and development expenses. Research and development expenses decreased by $0.9 million, or 41%, from $2.1 million for the three months ended March 31, 2021 to $1.3 million for the three months ended March 31, 2022. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses of $0.8 million for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021. This decrease reflects a reduction in spending related to our pipeline evaluation and development.

Selling and marketing expenses. Selling and marketing expenses increased by $1.3 million, or 14%, from $9.3 million for the three months ended March 31, 2021 to $10.6 million for the three months ended March 31, 2022. This overall increase in selling and marketing expenses is due to increased spending on marketing initiatives and the launch of our first consumer commercial on connected TV in the first quarter of 2022.

General and administrative expenses. General and administrative expenses increased by $0.2 million, or 5%, from $3.8 million for the three months ended March 31, 2021 to $4.0 million for the three months ended March 31, 2022. This increase in general and administrative expense was primarily due to higher professional fees.

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 $50,000 for the three months ended March 31, 2022 compared to the three months ended March 31, 2021 due to the $5.0 million principal payment made during the three months ending March 31, 2022.

Benefit from income taxes. Benefit from income taxes reflects $4.7 million received under 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 has reached the maximum lifetime benefit $20.0 million.

Liquidity and Capital Resources

At March 31, 2022, we had cash and cash equivalents totaling $3.7 million. We invest our cash equivalents in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

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

	Three Months Ended March 31, (In thousands)	
	2022	2021
Net cash used in operating activities	$ (14,751)	$ (14,668)
Net cash (used in) provided by investing activities	(126)	16,185
Net cash (used in) provided by financing activities	(523)	484
Net (decrease) increase in cash and cash equivalents	$ (15,400)	$ 2,001

Operating Activities

We incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as Twirla was being developed. With the approval of Twirla early in 2020, our operating expenses shifted substantially to selling and marketing as we built out our commercial infrastructure. Net cash used in operating activities was $14.8 million for the three months ended March 31, 2022 and consisted primarily of a net loss of $11.8 million and a $4.7 million increase in income taxes receivable, offset by non-cash stock-based compensation expense of $0.8 million, depreciation expense of $0.5 million, and $0.5 million of other non-cash charges, primarily interest expense. Net cash used in operating activities was $14.7 million for the three months ended March 31, 2021 and consisted primarily of a net loss of $17.1 million, offset by non-cash stock-based compensation expense of $0.7 million, depreciation expense of $0.5 million, $0.5 million of other non-cash charges, primarily interest expense, and a net increase from operating assets and liabilities of $0.7 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 was $0.1 million and consisted of acquisitions of equipment. Net cash provided by investing activities for the three months ended March 31, 2021 was $16.2 million and primarily represents the net sales and maturities of marketable securities.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2022 was $$0.5 million, which consists of a principal payment of long-term debt of $5.0 million, offset by net proceeds of $4.1 million from the sale of preferred stock in a registered direct offering and proceeds of $0.3 million from the sale of 1,024,906 shares of our common stock through an at-the-market, or ATM, program. Net cash provided by financing activities for the three months ended March 31, 2021 was $0.5 million, which consists of net proceeds of $0.4 million from the slae of 207,593 shares of our common stock through an at-the-market, or ATM, sales program, and stock option proceeds of $0.1 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 the COVID-19 pandemic or other factors impact our current business plan or our ability to generate revenue from the launch 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. Prior to the 2020 Shelf Registration Statement, we had filed a universal shelf registration statement in November 2018 for the issuance of up to $100.0 million of securities, which we refer to as the 2018 Shelf Registration Statement, which was declared effective by the SEC on November 14, 2018.

On March 18, 2021, we filed a prospectus supplement to our 2020 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $50.0 million of shares of our common stock. During the year ended December 31, 2021, we sold 172,879 shares of our common stock under the at-the-market program resulting in net proceeds of approximately $9.3 million.

On October 8, 2021, we filed a prospectus supplement to our 2020 Shelf Registration Statement registering a public offering of 666,666 shares of common stock sold together with warrants to purchase up to 333,333 shares of our common stock at a combined offering price of $34.00 per share of common stock and one-half of a warrant to purchase one share of common stock. The warrants have an exercise price of $340.00 per share, are exercisable immediately, and will expire five years from the date of issuance. On October 13, 2021, we completed the offering and realized proceeds of approximately $21.1 million, net of underwriting discounts, commissions and offering expenses.

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 ending March 31, 2022, we sold and issued 25,623 shares of common stock resulting in net proceeds of $0.3 million. On April, 26, 2022, we terminated the 2022 ATM Agreement. On April, 26, 2022, we terminated the 2022 ATM.

On March 13, 2022, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with a single healthcare-focused institutional investor (the "Purchaser"), pursuant to which the Company issued, in a registered direct offering (the "2022 Preferred Stock Offering"), 2,425 shares of Series A convertible preferred stock (the "Series A Preferred Stock") and 2,425 shares of Series B convertible preferred stock (the "Series B Preferred Stock") and Series A warrants (the "Series A Warrants") to purchase up to an aggregate of 606,250 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 606,250 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 $8.00 per share. The shares of preferred stock issued in the offering are convertible into an aggregate of 606,250 shares of Common Stock. The Series A Warrants have an exercise price of $10.40 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 $10.40 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 $4.1 million.

On April 25, 2022, we entered into the Letter Agreement with the Purchaser, pursuant to which the Purchases consented to us entering into and effecting an ATM offering facility. Pursuant to the Letter Agreement, we issued to the Purchases the New Warrant, on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 212,188 warrant shares, subject to adjustment thereunder. The Series A Warrants have an exercise price of $10.40 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 $12,841,000 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. As of May 9, 2022 we issued and sold a total of 873,564 shares of common stock under the April 2022 ATM Agreement resulting in net proceeds of approximately $1.9 million.

We believe we may have the potential to access additional capital through the 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 to support the continued commercialization 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.

Contractual Obligations and Commitments

In April 2020, we entered into a manufacturing and commercialization agreement with Corium, Inc., which we refer to as the Corium Agreement, and 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 includes 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. The Corium Agreement terminates automatically after ten years, 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 effect purchase orders after the notice of termination is given and until the time any such termination becomes effective.

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. As of March 31, 2022, the minimum amount committed totals $3.4 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 36 month term totals $1.1 million as of March 31, 2022.

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 $3.7 million and $19.1 million at March 31, 2022 and December 31, 2021, 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 March 31, 2022.

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 three months ended March 31, 2022.

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.

Changes to Internal Control Over Financial Reporting

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, the Company's internal control over financial reporting.

Part II: Other Information

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

There have been no material changes during the quarter ended March 31, 2022 to our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2021.

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
3.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on January 7, 2022 (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022)
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on March 14, 2022 (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on March 14, 2022 (Incorporated by reference, Exhibit 3.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022).
4.1	Form of Series A Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022).
4.2	Form of Series B Warrant (Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022).
4.3	Form of Placement Agent Warrant (Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022).
10.1	Form of Securities Purchase Agreement, dated March 13, 2022, by and between Agile Therapeutics, Inc. and the purchaser signatory thereto (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022).
10.2	Waiver and Second Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of January 7, 2022 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022).
10.3	Waiver and Third Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of March 10, 2022 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 11, 2022)
10.4	Controlled Equity Offering℠ Sales Agreement dated January 10, 2022 by and among Agile Therapeutics, Inc. and Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022).
10.5*	FifthAmendment to Master Service Agreement, dated February 1, 2022, by and between the Registrant and inVentiv Commercial Services, LLC.

31.1	Certification of the Registrant's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Registrant's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Registrant's Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Registrant's Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 formatted in Inline Extensible Business Reporting Language (XBRL): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders' Equity, (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

** The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report 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.

Date: May 12, 2022

Agile Therapeutics, Inc.

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

Date: May 12, 2022

By: /s/ Dennis P. Reilly
Dennis P. Reilly
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

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 as private and confidential.

FIFTH AMENDMENT TO PROJECT AGREEMENT (DETAILING – FIELD TEAM)

This Fifth Amendment (the "Amendment") entered into as of the last date of signature herein and made effective as of February 1, 2022 (the "Amendment Effective Date") is made by and between Syneos Health Commercial Services, LLC, f/k/a inVentiv Commercial Services LLC, with an office at 500 Atrium Drive, Somerset, N.J. 08873 ("Syneos Health") and Agile Therapeutics, Inc. with an office located at 500 College Road East, Suite 310, Princeton, New Jersey 08540 (the "Client"). Syneos Health and Client may each be referred to herein as a "Party" and, collectively, as the "Parties."

W I T N E S S E T H:

WHEREAS, Syneos Health and Client are parties to a Project Agreement (Detailing – Field Team) made as of April 30, 2020, First Amendment to Project Agreement (Detailing – Field Team) dated June 1, 2020, Second Amendment to Project Agreement (Detailing – Field Team) dated January 1, 2021, Third Amendment to Project Agreement (Detailing – Field Team) dated July 1, 2021 and Fourth Amendment to Project Agreement dated September 1, 2021 (collectively, the "Agreement"); and

WHEREAS, Syneos Health and Client desire to amend the Agreement as set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, it is agreed as follows:

1. Except as provided in this Amendment, the terms and conditions set forth in the Agreement shall remain unaffected by execution of this Amendment. To the extent any provisions or terms set forth in this Amendment conflict with the terms set forth in the Agreement, the terms set forth in this Amendment shall govern and control. Terms not otherwise defined herein, shall have the meanings set forth in the Agreement.

2. All references to "RS Reps" and "regional sales representatives" are hereby deleted in their entirety and replaced with "EC Reps" and "engagement center representatives."

3. Section 3, "The Term," is hereby amended to extend the term until [***]. The period from [***]until [***]shall be referred to as "[***]" and the period from [***] until [***]shall be referred to as "[***]."

4. The Amended and Restated Exhibit A, the "Project Team" as defined in the first paragraph is hereby deleted and replaced with the below. Also, the table after the 2nd paragraph is hereby deleted in its entirety and replaced with the below table.

Syneos Health will provide Client with a field force that shall consist of up to [***] sales representatives (the "Representatives") and [***] engagement center representatives (the "EC Reps" and collectively with the Representatives, the "Syneos Health Sales Representatives" or "Sales Representatives"). The Sales Representatives shall detail the Client's Product by making calls pursuant to a Call Plan on Targets. The Sales Representatives will be managed by up to [***] regional sales managers (the "RSMs") who will also be Syneos Health employees. Syneos shall also provide [***]allocated at [***]alliance lead (the "Alliance Lead") and [***] sales trainer manager (the "STM"). The Sales Representatives, RSMs, Alliance Lead and STM may be referred to collectively herein as the "Project Team".

For purposes of clarity, the [***]and [***]outlined in Section I(a) and (b) of Exhibit F includes the headcount for the Project Team as set forth in the table below.

Position	**Headcount**	[***]
Project Team		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

5. The Amended and Restated Exhibit F, "[***]," is amended as follows:

(a) The table in Section I, "[***]," is hereby deleted in its entirety and replaced with the below table.

Position	**Headcount**	[***]
Project Team		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(b) The table in Section I(b), "[***]," paragraph (i) is hereby deleted in its entirety and replaced with the below table:

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(c) The second table in Section I(c)(i), "[***]," is hereby amended to include [***]and [***]as follows:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(d) The table in Section I(c)(ii), "[***]," is hereby amended to include [***]and [***]as follows:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(e) The table in Section I(d), "[***]," is hereby amended to include [***]and [***]as follows:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(f) The tables in Section I(e), "[***]," are hereby amended to include [***]and [***]as follows:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***]

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***]

(g) Section III, "[***]," the first line item is hereby deleted in its entirety and replace with the following:

- [***]

(h) Section IV(b), "[***]," is hereby amended to include the [***].

(i) Section IV (c), "[***]," is hereby amended to include [***].

(j) Section V, "[***]," the first sentence is hereby amended to include [***].

6. This Amendment may be executed simultaneously in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Execution and delivery of this Amendment by exchange of facsimile copies or via pdf file bearing the facsimile signature of a party hereto shall constitute a valid and binding execution and delivery of this Amendment by such party. Such facsimile copies and/or pdf versions shall constitute enforceable original documents.

7. The terms of this Amendment are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and may not be contradicted by evidence of any prior or contemporaneous agreement. The Parties further intend that this Amendment constitute the complete and exclusive statement of its terms and shall supersede any prior agreement with respect to the subject matter hereof.

WHEREFORE, the parties hereto have caused this Amendment to be executed by their duly authorized representatives.

AGILE THERAPEUTICS, INC.	**SYNEOS HEALTH COMMERCIAL**
/s/ Al Altomari	By: /s/ Todd Tomasoski
Name:	Name:
Title:	Title:
Date: 3/17/2022	Date: 3/21/2022

Exhibit 31.1

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

I, Alfred Altomari, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2022

/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, Dennis P. Reilly, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2022

/s/ Dennis P. Reilly
Dennis P. Reilly
Chief Financial Officer
Principal Financial Officer

Exhibit 32.1

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

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Alfred Altomari, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: May 12, 2022

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

Exhibit 32.2

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

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Dennis P. Reilly, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: May 12, 2022

/s/ Dennis P. Reilly
Dennis P. Reilly
Chief Financial Officer
Principal Financial Officer