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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 June 30, 2021

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.)

101 Poor Farm Road
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 92,999,964 shares of the registrant's common stock, $0.0001 par value, outstanding as of July 23, 2021.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2021

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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 ability to successfully commercialize 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 product candidates 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;
- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- our ability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of Twirla and our potential product candidates 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 their 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 conduct a small post-marketing commitment, or PMC, study to assess the residual drug content of Twirla after use;
- our ability to maintain regulatory approval of Twirla and our ability to obtain regulatory approval of our potential product candidates, 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;
- our plans to develop our other potential product candidates;
- development of unexpected safety or efficacy concerns related to Twirla;
- our ability to continue to develop and maintain successful sales and marketing capabilities, including our ability to maintain an effective sales force or failure to build-out and implement an effective health care compliance program;
- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q. You should also read carefully the factors described in the “Risk Factors” included in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the Securities and Exchange Commission on March 1, 2021 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 26,118	$ 14,463
Marketable securities	4,999	40,008
Accounts receivable, net	1,167	865
Inventory	3,462	—
Prepaid expenses and other current assets	1,202	1,449
Total current assets	36,948	56,785
Property and equipment, net	13,363	14,243
Right of use asset	72	138
Other non-current assets	1,896	1,896
Total assets	$ 52,279	$ 73,062
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,410	$ 3,867
Accrued expenses	5,153	3,348
Lease liability, current portion	72	138
Total current liabilities	11,635	7,353
Long-term debt	16,035	16,381
Total liabilities	27,670	23,734
Commitments and contingencies (Note 12)		
Stockholders' equity		
Common stock, $.0001 par value, 150,000,000 shares authorized, 92,928,205 and 87,563,753 issued and outstanding at June 30, 2021 and December 31, 2020, respectively	9	9
Additional paid-in capital	371,588	361,539
Accumulated other comprehensive income	—	3
Accumulated deficit	(346,988)	(312,223)
Total stockholders' equity	24,609	49,328
Total liabilities and stockholders' equity	$ 52,279	$ 73,062

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues, net	$ 1,185	$ —	$ 1,301	$ —
Cost of product revenues	1,145	—	2,306	—
Gross profit (loss)	40	—	(1,005)	—
Operating expenses:				
Research and development	$ 862	$ 3,661	$ 2,975	$ 6,825
Selling and marketing	11,714	3,150	20,877	4,892
General and administrative	4,115	3,228	8,016	5,939
Total operating expenses	16,691	10,039	31,868	17,656
Loss from operations	(16,651)	(10,039)	(32,873)	(17,656)
Other income (expense)				
Interest income	7	115	23	247
Interest expense	(993)	(902)	(1,915)	(1,300)
Total other income (expense), net	(986)	(787)	(1,892)	(1,053)
Loss before benefit from income taxes	(17,637)	(10,826)	(34,765)	(18,709)
Benefit from income taxes	—	—	—	—
Net loss	$ (17,637)	$ (10,826)	$ (34,765)	$ (18,709)
Net loss per share (basic and diluted)	$ (0.20)	$ (0.12)	$ (0.39)	$ (0.23)
Weighted-average common shares (basic and diluted)	88,693,968	87,221,441	88,162,929	81,936,815
Comprehensive loss:				
Net loss	$ (17,637)	$ (10,826)	$ (34,765)	$ (18,709)
Other comprehensive income:				
Unrealized loss on marketable securities	—	10	(3)	10
Comprehensive loss	$ (17,637)	$ (10,816)	$ (34,768)	$ (18,699)

See accompanying notes to unaudited financial statements.

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	87,563,753	$ 9	$ 361,539	$ 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	520,937	—	960	—	—	960
Issuance of common stock upon exercise of stock options	126,400	—	75	—	—	75
Vesting of RSUs	52,651	—	—	—	—	—
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	88,263,741	$ 9	$ 364,396	$ —	$ (329,351)	$ 35,054
Share-based compensation - stock options and RSUs	—	—	843	—	—	843
Issuance of common stock pursuant to at-the market stock sales, net of expenses	4,593,034	—	6,349	—	—	6,349
Vesting of RSUs	71,430	—	—	—	—	—
Unrealized net gain on marketable securities	—	—	—	—	—	—
Net loss	—	—	—	—	(17,637)	(17,637)
Balance June 30, 2021	92,928,205	$ 9	$ 371,588	$ —	$ (346,988)	$ 24,609

See accompanying notes to unaudited financial statements.

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, 2019	69,810,305	$ 7	$ 306,108	$ —	$ (260,370)	$ 45,745
Share-based compensation - stock options and RSUs	—	—	621	—	—	621
Issuance of common stock in public offering, net of expenses	17,250,000	2	48,433	—	—	48,435
Issuance of common stock upon exercise of stock options	152,907	—	119	—	—	119
Warrants issued in connection with long-term debt	—	—	3,570	—	—	3,570
Net loss	—	—	—	—	(7,883)	(7,883)
Balance March 31, 2020	87,213,212	$ 9	$ 358,851	$ —	$ (268,253)	$ 90,607
Share-based compensation - stock options and RSUs	—	—	839	—	—	839
Issuance of common stock upon exercise of stock options	84,393	—	166	—	—	166
Unrealized net gain on marketable securities	—	—	—	10	—	10
Net loss	—	—	—	—	(10,826)	(10,826)
Balance June 30, 2020	87,297,605	$ 9	$ 359,856	$ 10	$ (279,079)	$ 80,796

See accompanying notes to unaudited financial statements.

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

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (34,765)	$ (18,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,029	8
Amortization	67	82
Noncash stock-based compensation	1,585	1,460
Noncash interest	864	447
Changes in operating assets and liabilities:		
Accounts receivable	(302)	—
Inventory	(3,462)	—
Prepaid expenses and other assets	552	(686)
Accounts payable and accrued expenses	4,494	2,839
Lease liability	(66)	(90)
Net cash used in operating activities	(30,004)	(14,649)
Cash flows from investing activities:		
Purchases of marketable securities	—	(47,822)
Sales and maturities of marketable securities	34,729	—
Acquisition of property and equipment	(149)	(222)
Net cash provided by (used in) investing activities	34,580	(48,044)
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offering, net of offering costs	—	48,434
Proceeds from At-the-Market sales of common stock, net of offering costs	7,004	—
Proceeds from issuance of long-term debt	—	20,000
Debt financing costs paid	—	(1,059)
Proceeds from exercise of stock options	75	285
Net cash provided by financing activities	7,079	67,660
Net increase in cash and cash equivalents	11,655	4,967
Cash and cash equivalents, beginning of period	14,463	34,479
Cash and cash equivalents, end of period	$ 26,118	$ 39,446
Supplemental disclosure of noncash financing activities		
Warrants issued in connection with long-term debt	$ 1,080	$ 3,570
Supplemental cash flow information		
Interest paid	$ 1,182	$ 896

1. *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. 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 June 30, 2021, the Company had an accumulated deficit of approximately $347 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
- adds 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 9), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

Going Concern

As of June 30, 2021, the Company had cash, cash equivalents and marketable securities of $31.1 million. The Company closely monitors its cash, cash equivalents and marketable securities and will need to raise additional funds to meet its projected operating requirements, including the continued commercialization of Twirla, and exploring the advancement of its existing pipeline and its possible expansion through business development activities.

The Company has generated losses since inception, used substantial cash in operations and anticipates it will continue to incur net losses for the foreseeable future. The Company's future success depends on its ability to obtain additional capital and/or implement various strategic alternatives, and there can be no assurance that any financing can be realized by the Company, or if realized, what the terms of any such financing may be, or that any amount that the Company is able to raise will be adequate. Based upon the foregoing, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern through the 12 months following the date on which this Quarterly Report on Form 10-Q is filed.

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

The unaudited financial statements as of June 30, 2021 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 June 30, 2021 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, 2020 as filed with the SEC on March 1, 2021.

In the opinion of management, the unaudited interim financial statements reflect all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods presented. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the operating results for the full fiscal year or any future period. Certain reclassifications have been made to prior periods to conform with current reporting. On the statement of operations, the Company has separated the presentation of selling and marketing expenses from total general and administrative expenses. To conform prior year amounts to the current period presentation, $3.2 million and $4.9 million was reclassified from general and administrative expenses to selling and marketing expenses for the three and six months ended June 30, 2020, respectively.

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. Based on the Company's current business plan and ability to commercialize Twirla, the Company believes that its cash, cash equivalents and marketable securities as of June 30, 2021 will be sufficient to meet its projected operating requirements through the end of 2021. 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, 2020 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, the accounting for common stock warrants, stock-based compensation, income taxes, and accounting for research and development costs. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Risks and Uncertainties

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

It should be noted that current public health threats could adversely affect the Company's 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 effect of these orders, government imposed quarantines and measures the Company has taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt the Company's business and could delay the Company's commercialization timeline. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if the Company or any of the third parties with whom it engages, including personnel at third-party manufacturing facilities and other third parties with whom the Company conducts business, were to experience shutdowns or other business disruptions, the Company's ability to conduct its business in the manner and on the timeline presently planned could be materially and adversely impacted. It is unknown how long these conditions will last and what the complete effect will be on the Company. While to date we have been able to continue to execute our overall business plan, some of our business activities have been slowed and taken longer to complete and we continue to adjust to the challenges of operating in a largely remote setting with our employees. We have only recently launched our commercial activities for Twirla and begun engaging with healthcare providers to promote Twirla. We expect that, as we broaden our sales detailing activities, in some instances our sales force may encounter challenges engaging with healthcare providers during this on-going pandemic. Although many areas of the United States have begun to re-open access to offices and other commercial facilities, there continue to be areas where restrictions remain in place, which may have the potential to affect our ability to conduct our business. Further, new variants, some of which could be resistant to existing vaccines, may lead to new shutdowns or business disruptions in the future. The Company will continue to closely monitor events as they develop and evaluate alternative, mitigating measures it 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.

Marketable Securities

The Company invests a portion of its excess cash balances in marketable securities, including U.S. government agency securities, and highly rated corporate bonds. The Company classifies all of its marketable securities as current assets on the balance sheet because they are available-for-sale and available to fund current operations.

Marketable securities are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity, until such gains and losses are realized. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is reclassified from accumulated other comprehensive income (loss) to the statements of operations. Realized gains and losses are determined on the specific identification method and are included in other income.

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, as Twirla was commercially launched in December 2020 and historical data is not yet available. The credit loss reserves are reviewed and adjusted periodically. Credit loss reserves were not material as of June 30, 2021.

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, cash equivalents, and marketable securities 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. Management does not believe the Company's inventory is subject to significant risk of obsolescence in the near term.

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 and six months ended June 30, 2021, units sold with no associated product cost were approximately 2,000 and 3,000, respectively. 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, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Currently, all fixed assets pertain to production equipment at the Company's third-party manufacturing partner and have an estimated useful life of 7 years.

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 June 30, 2021.

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 $3.0 million and $0 for the three months ended June 30, 2021 and 2020, respectively, and totaled $6.1 million and $0 for the six months ended June 30, 2021 and 2020, respectively.

Deferred Financing Costs

Costs directly attributable to the Company's senior secured term loan (see Note 8) 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 $69,000 for each of the three months ended June 30, 2021 and 2020, and was $139,000 and $92,000 for the six months ended June 30, 2021 and 2020, 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 June 30, 2021, the Company had sales to three customers that individually accounted for more than 10% of its total revenue. These customers had sales of $0.5 million, $0.4 million, and $0.3 million, respectively, which represented 96% of total revenues in the quarter. Accounts receivable related to these three customers comprised 41%, 27%, and 30%, respectively, as of June 30, 2021.

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 June 30, 2021 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 $345,000 and $348,000 for the three- and six-months ending June 30, 2021, respectively. As of June 30, 2021, reserves on the balance sheet associated with variable consideration were $0.3 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 1,400,000 shares of its common stock. In connection with an amendment to that facility in February 2021, the Company issued a warrant to purchase 450,000 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 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 June 30, 2021 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 June 30, 2021 and 2020, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	June 30,	
	2021	2020
Common stock warrants	1,850,000	1,400,000
Unvested restricted stock units	253,697	159,795
Common stock options	10,352,326	8,503,254
Total	12,456,023	10,063,049

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 Company is currently evaluating the impact of adopting this standard and does not expect the guidance to 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 June 30, 2021 and December 31, 2020.

	Level 1	Level 2	Level 3
June 30, 2021			
Assets:			
Cash and cash equivalents	$ 26,118	$ —	$ —
Marketable securities	—	4,999	—
Total assets at fair value	$ 26,118	$ 4,999	$ —

	Level 1	Level 2	Level 3
December 31, 2020			
Assets:			
Cash and cash equivalents	$ 14,463	$ —	$ —
Marketable securities	—	40,008	—
Total assets at fair value	$ 14,463	$ 40,008	$ —

There were no transfers between Level 1, 2 or 3 during 2021 or 2020.

4. Marketable Securities

The following is a summary of marketable securities, classified as available-for-sale:

		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
June 30, 2021				
U.S. government obligations (maturing in one year or less)	$ 3,000	$ —	$ —	$ 3,000
Corporate debt securities (maturing in one year or less)	1,999	—	—	1,999
Total marketable securities	$ 4,999	$ —	$ —	$ 4,999

The Company holds investment-grade marketable securities. There were no continuous unrealized loss positions in excess of twelve months as of June 30, 2021. There was no accrued interest income at June 30, 2021.

5**. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following:

	June 30, 2021	December 31, 2020
Prepaid insurance	$ 259	$ 680
Other	943	769
Total prepaid expenses and other current assets	$ 1,202	$ 1,449

6**. Accrued Liabilities**

Accrued liabilities consist of the following:

	June 30, 2021	December 31, 2020
Accrued compensation	$ 1,397	$ 1,697
Accrued professional fees and other	3,756	1,651
Total accrued liabilities	$ 5,153	$ 3,348

7**. Leases**

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The Company adopted ASU No. 2016-02 on January 1, 2019.

The Company has no finance leases and one operating lease for office space in Princeton, NJ. Operating lease expense was $38,000 and $75,000 for the three and six months ended June 30, 2021, respectively.

Operating cash flows used for operating leases during the three and six months ended June 30, 2021 were $34,000 and $66,000, respectively. As of June 30, 2021, the weighted-average remaining lease term was 0.50 years and the weighted average discount rate was 15.2%.

Future minimum lease payments under non-cancellable leases as of June 30, 2021 were as follows:

2021	$ 75
Total	$ 75
Less: Interest	(3)
Present value of lease liability	$ 72

8**. 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 will be available to the Company based on the achievement of certain revenue milestones. On February 26, 2021 the Perceptive Credit Agreement was amended (“Amended Perceptive Credit Agreement”) to increase the total amount available to the Company to $45.0 million by creating a fourth tranche of $10.0 million that will be available based on the achievement of a revenue milestone.

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.

Borrowings under the Amended Perceptive Credit Agreement will accrue interest at an annual rate equal to the London Interbank Offered Rate for one-month deposits ("LIBOR") plus 10.25%, provided that LIBOR shall not be less than 1.5%. The rate of interest in effect as of the Closing Date and at June 30, 2021 was 11.75%. Upon the occurrence and during the continuance of any event of default under the Amended Perceptive Credit Agreement, the interest rate automatically increases by 3.0% per annum.

The Company may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment fee of 8.0% if such prepayment occurs after February 10, 2021 and on or prior to February 10, 2022; 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 February 10, 2024.

All of the Company's obligations under the Amended Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's tangible and intangible assets, including intellectual property.

The Amended Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restrict or limit the ability of the Company to, among other things and subject to certain exceptions contained in the 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 June 30, 2021, report revenues for the trailing 12-month period that exceed the amounts set forth in the Amended Perceptive Credit Agreement, which range from $3.8 million for the fiscal quarter ending June 30, 2021 to $87.1 million for the fiscal quarter ending December 31, 2023. At June 30, 2021, the Company was in compliance with the cash balance covenant, but not in compliance with the revenue covenant. The Company obtained a written waiver from the lender with respect to the Company's failure to meet the revenue covenant for the three months ended June 30, 2021.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 1,400,000 shares of the Company's common stock (together, the "2020 Perceptive Warrants"). The first warrant is exercisable for 700,000 shares of common stock at an exercise price of $3.74 per share. The second warrant is exercisable for 700,000 shares of common stock at an exercise price of $4.67 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 450,000 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 $2.87 per share. The 2021 Perceptive Warrant expires on February 26, 2028. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections. The Perceptive Warrants 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.

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 $3.74 and $4.67 for the common stock warrants, (iv) fair value of common stock ($4.01) 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 $2.87 for the common stock warrant, (iv) fair value of common

stock ($2.87) 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).

	June 30, 2021
Notes payable	$ 20,000
Debt issuance costs	(689)
Warrant discount	(3,276)
Long-term debt	$ 16,035

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 $398,000 and $303,000 for the three months ended June 30, 2021 and 2020, respectively, and $734,000 and $404,000 for the six months ended June 30, 2021 and 2020, respectively.

9**. Stockholders' Equity**

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 February 2020, the Company completed a public offering of 17,250,000 shares of its common stock at a price of $3.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $48.4 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 six months ended June 30, 2021, the Company issued and sold 5,113,971 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $7.4 million, of which $7.0 million was received by June 30, 2021.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of goods sold	$ 75	$ —	$ 135	$ —
Research and development	121	139	228	337
Selling and marketing	43	26	78	43
General and administrative	604	674	1,144	1,080
Total	$ 843	$ 839	$ 1,585	$ 1,460

10. Accumulated Other Comprehensive Income

The change in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the six months ended June 30, 2021 is summarized below (in thousands):

	Unrealized Gain on Marketable Securities
Balance December 31, 2020	$ 3
Other comprehensive income	(3)
Balance June 30, 2021	$ —

No amounts were classified out of accumulated other comprehensive income during the six months ended June 30, 2021.

11. Income Taxes

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") which includes numerous modifications to income tax provisions, including a limitation on business interest expense and net operating loss provisions and the acceleration of alternative minimum tax credits. Given the Company's history of losses, the CARES Act did not have a material impact on its income tax provision.

12. 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 $10.9 million. This amount does not represent all of the Company's anticipated purchases in the future, but instead represents only purchases that are the subject of contractually obligated minimum purchases. The minimum commitments disclosed are determined based on non-cancelable minimum spend in 2021 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

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 June 30, 2021, the Company has not recorded a provision for any contingent losses.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the "SEC") on March 1, 2021. 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 have remained steadfast in our commitment to innovate 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 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 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 approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient, non-daily 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 2021, we plan to continue implementing our commercialization plan for Twirla, 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 ensure a successful launch in the United States, including maintaining a sales and marketing team and implementing a healthcare compliance program;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- Expand access to Twirla through multiple business channels including third-party payor contracts, retail and specialty pharmacies, telemedicine and government contracting;
- Maintain and manage the supply chain for Twirla to support commercialization of Twirla across the United States;
- Evaluate the advancement of our existing pipeline and its possible expansion through business development activities; and
- Complete and submit the proposed protocols for the two FDA required post-marketing commitment studies.

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 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 effect of these orders, government imposed quarantines and measures we have taken, such as implementing work-at-home policies, may negatively impact productivity, 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. During the pandemic, some of our business activities have been slowed and taken longer to complete and we continue to adjust to the challenges of operating in a largely remote setting with our employees. We launched our commercial activities for Twirla and began engaging with healthcare providers to promote Twirla in December 2020. In some instances our sales force has encountered challenges engaging with healthcare providers during this on-going pandemic. Although many areas of the United States have begun to re-open access to offices and other commercial facilities, there continue to be areas where restrictions remain in place, which may have the potential to affect our ability to conduct our business. Further, new

variants, some of which could be resistant to existing vaccines, may lead to new shutdowns or business disruptions in the future. Overall, we recognize the challenges of launching 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. We incurred research and development expenses of $13.5 million, $9.9 million and $9.8 million during the years ended December 31, 2020, 2019 and 2018, respectively. We incurred research and development expenses of $0.9 million and $3.7 million for the three months ended June 30, 2021 and 2020, respectively. We incurred research and development expenses of $3.0 million and $6.8 million for the six months ended June 30, 2021 and 2020, respectively. 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 studies, which include both our post marketing requirement and post marketing commitment to the FDA, and evaluate the development of our pipeline, our operating expenses have substantially shifted towards ongoing 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 June 30, 2021, and December 31, 2020, we had $31.1 million and $54.5 million in cash, cash equivalents and marketable securities, 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”), which was amended in February 2021 (“Amended Perceptive Credit Agreement”) to add a fourth tranche of $10.0 million, which is subject to the same interest rate and 1% fee payable upon the drawing of a tranche as set forth in the Amended 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 $25.0 million will be available in two separate tranches upon the achievement of certain revenue milestones. The facility will be interest only until the third anniversary of the closing date.

In February 2020, we completed a public offering of 17,250,000 shares of our common stock at a price of $3.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $48.4 million.

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 six months ended June 30, 2021, we issued and sold a total of 5,113,971 shares of common stock under the 2021 ATM Agreement resulting in net proceeds of approximately $7.4 million, $7.0 million of which was received by June 30, 2021.

Moving forward, we plan to monitor our cash, cash equivalents and marketable securities 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, we believe we may have the potential to access additional capital through the Amended Perceptive Agreement, the 2021 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 $51.9 million, $18.6 million and $19.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. Our net loss was $17.6 million and $10.8 million for the three months ended June 30, 2021 and 2020, respectively. Our net loss was $34.8 million and $18.7 million for the six months ended June 30, 2021 and 2020, respectively. We expect to incur significant operating expenses for the foreseeable future as we continue to commercialize Twirla, advance our other potential product candidates and expand our research and development programs.

Going Concern

As of June 30, 2021, we had cash, cash equivalents and marketable securities of $31.1 million. The Company closely monitors its cash, cash equivalents and marketable securities and will need to raise additional funds through debt issuance or the issuance and sale of its common stock to meet its projected operating requirements, including the continued commercialization of Twirla, the exploration and potential advancement of its existing pipeline and its possible expansion through business development activities.

Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. There can be no assurance that we can realize any financing, or if realized, what the terms of any such financing may be, or that any amount that the we are able to raise will be adequate. Based upon the foregoing, management has concluded that there is substantial doubt about our ability to continue as a going concern through the 12 months following the date on which this Quarterly Report on Form 10-Q is filed.

We continue to analyze various alternatives, including refinancing alternatives, potential asset sales and mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to obtain funds when needed or on acceptable terms, we then may be unable to 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 June 30, 2021 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 expect to incur 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.

Cost of Product Revenue

Costs of product revenue include direct and indirect costs related to the manufacturing of Twirla sold, including packaging services, freight, 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 approximately 2,000 units sold and 3,000 units sold in the three and six months ended June 30, 2021, respectively, as those units were validation inventory which was previously expensed as research and development expense in the fourth quarter of 2020.

Research and Development Expenses

Since our inception, we have 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 June 30, 2021 and 2020, our research and development expenses were approximately $0.9 million and $3.7 million, respectively. For the six months ended June 30, 2021 and 2020, our research and development expenses were approximately $3.0 million and $6.8 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended June 30, (In thousands)		Six months ended June 30, (In thousands)	
	2021	2020	2021	2020
Clinical development	$ 244	$ 451	$ 1,485	$ 628
Regulatory	(20)	105	138	334
Personnel related	531	368	1,195	860
Manufacturing—commercialization	(14)	2,598	(71)	4,666
Stock-based compensation	121	139	228	337
Total research and development expenses	$ 862	$ 3,661	$ 2,975	$ 6,825

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

Future research and development costs incurred for our potential product candidates and required post-marketing studies will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, access to additional capital, and significant and changing

government regulation. For the foreseeable future, we expect the current public health crisis to have a negative effect on the conduct of clinical trials. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration ("FDA") or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, coupled with an assessment of each product candidate's commercial potential. Substantially all of our resources are currently dedicated to 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 June 30, 2021 and 2020, our selling and marketing expenses totaled approximately $11.7 million and $3.2 million, respectively. For the six months ended June 30, 2021 and 2020, our selling and marketing expenses totaled approximately $20.9 million and $4.9 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 increase in the future as our commercialization efforts continue. These increases will likely include increased payroll and operating costs, including brand building, advocacy, market research and consulting, and the costs of maintaining our contract sales force.

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 June 30, 2021 and 2020, our general and administrative expenses totaled approximately $4.1 million and $3.2 million, respectively. For the six months ended June 30, 2021 and 2020, our general and administrative expenses totaled approximately $8.0 million and $5.9 million, respectively. We anticipate that our general and administrative expenses will increase in the future as our recently added administrative positions are maintained on a full-year basis. These increases will likely include legal and accounting services, stock registration and printing fees, addition of new personnel to support compliance and communication needs, increased insurance premiums, outside consultants and investor relations.

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 1, 2021.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

	Three months ended June 30,		
	2021	2020	Change
Revenues, net	$ 1,185	$ —	$ 1,185
Cost of product revenues	1,145	—	1,145
Gross profit	40	—	40
Operating expenses:			
Research and development	$ 862	$ 3,661	$ (2,799)
Selling and marketing	11,714	3,150	8,564
General and administrative	4,115	3,228	887
Total operating expenses	16,691	10,039	6,652
Loss from operations	$ (16,651)	$ (10,039)	(6,612)
Other income (expense)			
Interest income	7	115	(108)
Interest expense	(993)	(902)	(91)
Total other income (expense), net	(986)	(787)	(199)
Loss before benefit from income taxes	(17,637)	(10,826)	(6,811)
Benefit from income taxes	—	—	—
Net loss	$ (17,637)	$ (10,826)	$ (6,811)

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. Costs of product revenues totaled $1.1 million and consist of direct and indirect costs related to the manufacturing of Twirla sold, including packaging services, freight, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. During the three months ended June 30, 2021, approximately 24% of the product sold consisted of validation inventory which was previously expensed as research and development expense in the fourth quarter of 2020.

Research and development expenses. Research and development expenses decreased by $2.8 million, or 76%, from $3.7 million for the three months ended June 30, 2020 to $0.9 million for the three months ended June 30, 2021. This decrease in research and development expenses was primarily due to a decrease in manufacturing commercialization expenses of $2.6 million for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. This decrease reflects costs to conduct validation work for the commercial manufacturing of Twirla by Corium, our contract manufacturer, which was completed in 2020.

Selling and marketing expenses. Selling and marketing expenses increased by $8.6 million, or 272%, from $3.2 million for the three months ended June 30, 2020 to $11.7 million for the three months ended June 30, 2021. This overall increase in selling and marketing expenses is due to increases related to our commercialization activities such as our contract sales force, brand building, advocacy, market research and consulting.

General and administrative expenses. General and administrative expenses increased by $0.9 million, or 27%, from $3.2 million for the three months ended June 30, 2020 to $4.1 million for the three months ended June 30, 2021. This increase in general and administrative expense was primarily due to:

- an increase in salaries and wages of $0.3 million, due to increased headcount for the three months ended June 30, 2021; and

- an increase in professional fee expenses of $0.3 million primarily related to investor relations expenses and increased use of financial consultants.

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

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense increased by $0.1 million, from $0.9 million for the three months ended June 30, 2020 to $1.0 million for the three months ended June 30, 2021.

Comparison of the Six Months Ended June 30, 2021 and 2020

	Six Months Ended June 30,		
	2021	2020	Change
Revenues, net	$ 1,301	$ —	$ 1,301
Cost of product revenues	2,306	—	2,306
Gross profit	(1,005)	—	(1,005)
Operating expenses:			
Research and development	$ 2,975	$ 6,825	$ (3,850)
Selling and marketing	20,877	4,892	15,985
General and administrative	8,016	5,939	2,077
Total operating expenses	31,868	17,656	14,212
Loss from operations	$ (32,873)	$ (17,656)	(15,217)
Other income (expense)			
Interest income	23	247	(224)
Interest expense	(1,915)	(1,300)	(615)
Total other income (expense), net	(1,892)	(1,053)	(839)
Loss before benefit from income taxes	(34,765)	(18,709)	(16,056)
Benefit from income taxes	—	—	—
Net loss	$ (34,765)	$ (18,709)	$ (16,056)

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. Costs of product revenues totaled $2.3 million and consist of direct and indirect costs related to the manufacturing of Twirla sold, including packaging services, freight, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. During the six months ended June 30, 2021, approximately 29% of the product sold consisted of validation inventory which was previously expensed as research and development expense in the fourth quarter of 2020.

Research and development expenses. Research and development expenses decreased by $3.9 million, or 56%, from $6.8 million for the six months ended June 30, 2020 to $3.0 million for the six months ended June 30, 2021. This decrease in research and development expenses was primarily due to the following:

- a decrease in manufacturing commercialization expenses of $4.7 million for the six months ended June 30, 2021 as compared to the six months ended June 30, 2020. This decrease reflects costs to conduct validation work for the commercial manufacturing of Twirla by Corium, our contract manufacturer, which was completed in 2020; and

- an increase in clinical development expenses of $0.8 million for the six months ended June 30, 2021 as compared to the six months ended June 30, 2020. This increase reflects higher costs as we evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla and higher medical education costs for the six months ended June 30, 2021.

Selling and marketing expenses. Selling and marketing expenses increased by $16.0 million, or 327%, from $4.9 million for the six months ended June 30, 2020 to $20.9 million for the six months ended June 30, 2021. This overall increase in selling and marketing expenses is due to increases related to our commercialization activities such as our contract sales force, brand building, advocacy, market research and consulting.

General and administrative expenses. General and administrative expenses increased by $2.1 million, or 35%, from $5.9 million for the six months ended June 30, 2020 to $8.0 million for the six months ended June 30, 2021. This increase in general and administrative expense was primarily due to:

- an increase in salaries and wages of $0.9 million, due to increased headcount for the six months ended June 30, 2021;

- an increase in professional fee expenses of $0.8 million primarily related to investor relations expenses and increased use of financial consultants; and

- an increase in insurance expense of $0.3 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020.

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

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense increased by $0.6 million, from $1.3 million for the six months ended June 30, 2020 to $1.9 million for the six months ended June 30, 2021.

Liquidity and Capital Resources

At June 30, 2021, we had cash, cash equivalents and marketable securities totaling $31.1 million. We invest a portion of our cash equivalents and marketable securities 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:

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (30,004)	$ (14,649)
Net cash provided by (used in) investing activities	34,580	(48,044)
Net cash provided by financing activities	7,079	67,660
Net increase in cash and cash equivalents	$ 11,655	$ 4,967

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 $30.0 million for the six months ended June 30, 2021 and consisted primarily of a net loss of $34.8 million, offset by a net increase from operating assets and liabilities of $1.2 million, non-cash stock-based compensation expense of $1.6 million, depreciation expense of $1.0 million, and $0.9 million of other non-cash charges, primarily interest expense. Net cash used in operating activities was $14.6 million for the six months ended June 30, 2020 and consisted primarily of a net loss of $18.7 million, offset by non-cash stock-

based compensation expense of $1.5 million, $0.5 million of other non-cash charges, and a net increase from operating assets and liabilities of $2.1 million.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2021 was $34.6 million and primarily represents net sales and maturities of marketable securities. Cash used in investing activities for the six months ended June 30, 2020 primarily represents the purchase of marketable securities.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2021 was $7.1 million, which consists of net proceeds of $7.0 million from the sale of 5,113,971 shares of our common stock through an at-the-market, or ATM, sales program, and stock option proceeds of $0.1 million. Net cash provided by financing activities for the six months ended June 30, 2020 was $67.7 million which consists of net proceeds of $48.4 million received from the issuance of 17,250,000 shares of our common stock through a public offering, and proceeds of $20.0 million from the Perceptive term loan. These proceeds were partially offset by debt financing costs of $1.0 million.

Funding Requirements and Other Liquidity Matters

We plan to monitor our cash, cash equivalents and marketable securities 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. In March 2021, we entered into the 2021 ATM to sell common stock through the 2020 Shelf Registration Statement. We believe we may have the potential to access additional capital through the Amended Perceptive Agreement, the 2021 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
- add 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 (“the Commercialization Agreement”) with Corium, Inc. for the manufacture and supply of Twirla. Under the terms of the Commercialization Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Commercialization Agreement includes a fixed price per unit for two years depending on annual purchase volume and quarterly minimum purchase amounts. As of June 30, 2021, the amount committed for purchases through the third quarter of 2021 is $7.1 million.

In April 2020, we entered into a project agreement (the “Project Agreement”) with inVentiv Commercial Services, LLC (“inVentiv”) under which inVentiv 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 the Company in exchange for an up-front implementation fee and a fixed annual fee. The Project Agreement has an initial term of two years from August 24, 2020, the date of the first activity undertaken by inVentiv to detail Twirla (the "Deployment Date"), unless earlier extended upon the mutual written agreement of the parties. We may terminate the Project Agreement for any reason upon timely notice after the first anniversary of the Deployment Date; provided, however, that if we terminate the Project Agreement prior to the eighteen month anniversary of the Deployment Date, we will be obligated to pay inVentiv a termination fee, the amount of which varies depending on the date of termination. As of June 30, 2021, the minimum amount committed totals $3.8 million.

The following table summarizes our contractual obligations and commitments as of June 30, 2021 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(In thousands)		
Long-term Debt Obligations	$ 20,000	$ —	$ 20,000	$ —	$ —
Operating Lease Obligations	75	75	—	—	—
Purchase Obligations	10,914	10,914	—	—	—
Total	$ 30,989	$ 10,989	$ 20,000	$ —	$ —

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. On November 11, 2020, we entered into an extension for this location through December 31, 2021 and simultaneously reduced the amount of space we are leasing. We are currently seeking new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Shelf Registration Statement

On October 2, 2020, we filed 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 February 21, 2020, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering a public offering of 17,250,000 shares of common stock at a price of $3.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $48.4 million.

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 six months ended June 30, 2021, we sold 5,113,971 shares of our common stock under the at-the-market program resulting in net proceeds of approximately $7.4 million, of which $7.0 million was received by June 30, 2021.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

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, cash equivalents and marketable securities of $31.1 million and $54.5 million at June 30, 2021 and December 31, 2020, respectively, consisting primarily of funds in cash, money market accounts and corporate and government debt securities. 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 six months ended June 30, 2021.

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 six months ended June 30, 2021.

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 June 30, 2021 to our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2020.

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
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 June 30, 2021 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)

** 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: July 26, 2021

Agile Therapeutics, Inc.

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

Date: July 26, 2021

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

Exhibit 31.1

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

I, Alfred Altomari, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: July 26, 2021

/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: July 26, 2021

/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 June 30, 2021 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: July 26, 2021

/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 June 30, 2021 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: July 26, 2021

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