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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from to

Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

There were 40,614,527 shares of the registrant's common stock, $0.0001 par value, outstanding as of November 4, 2022.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2022

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- our ability to successfully maintain and enhance the commercialization and increase the uptake for Twirla, our only approved product;
- the rate and degree of market acceptance of Twirla by physicians, patients, clinics, institutions, third-party payors and others in the healthcare community;
- our ability to obtain adequate coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- the size and growth of the markets for Twirla and our ability to serve those markets;
- the effects of the ongoing COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as the effects of the COVID-19 pandemic on our potential customer base;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- The growth in demand for Twirla and our ability to manage the levels of Twirla inventory, which could result in our having to write off inventory and our inability to meet the minimum requirements under our supply agreement with Corium.

- our ability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of Twirla or other materials required for a clinical trial or other tests and studies;

- the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla;

- the performance and financial condition of Corium or any of the suppliers;

- our ability to design and successfully complete a post-marketing long-term, prospective observational safety study comparing risks for venous thromboembolism, or VTE, and arterial thromboembolism, or ATE, in new users of Twirla to new users of oral combined hormonal contraceptives, or CHCs, and new users of Xulane in U.S. women of reproductive age using CHCs and successfully complete a post-marketing commitment, or PMC, to assess the residual drug content of Twirla after use;

- our ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain;

- our ability to obtain and maintain intellectual property protection for Twirla and our product candidates;

- the success and timing of our clinical trials or other studies, including post-marketing studies for Twirla;

- development of unexpected safety or efficacy concerns related to Twirla;

- our ability to continue to develop and maintain successful sales and marketing capabilities, including our ability to maintain an effective sales force or failure to build-out and implement an effective health care compliance program;

- our ability to come into compliance with the listing requirements of the Nasdaq Capital Market;

- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and

- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q. You should also read carefully the factors described in the “Risk Factors” included in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission on March 30, 2022 to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, any such inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard any of these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

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

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

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

Agile Therapeutics, Inc.
Part I — Financial Information

ITEM 1. Financial Statements

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 6,145	$ 19,143
Accounts receivable, net	3,711	1,533
Inventory, net	1,797	966
Prepaid expenses and other current assets	3,834	2,283
Total current assets	15,487	23,925
Property and equipment, net	203	12,447
Right of use asset	761	949
Other non-current assets	2,012	2,012
Total assets	$ 18,463	$ 39,333
Liabilities and stockholders' equity		
Current liabilities:		
Long-term debt, current portion	$ 1,318	$ 16,833
Accounts payable	4,906	8,707
Accrued expenses	5,152	3,563
Lease liability, current portion	277	175
Total current liabilities	11,653	29,278
Lease liabilities, long-term	550	784
Long-term debt	—	—
Total liabilities	12,203	30,062
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at September 30, 2022 and no shares issued and outstanding at December 31, 2021	—	—
Common stock, $.0001 par value, 300,000,000 shares authorized, 39,026,823 and 3,034,901 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	4	—
Additional paid-in capital	437,027	396,388
Accumulated deficit	(430,771)	(387,117)
Total stockholders' equity	6,260	9,271
Total liabilities and stockholders' equity	$ 18,463	$ 39,333

See accompanying notes to unaudited financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues, net	$ 3,002	$ 1,287	$ 6,888	$ 2,587
Cost of product revenues	1,425	2,711	5,183	5,017
Gross profit (loss)	1,577	(1,424)	1,705	(2,430)
Operating expenses:				
Research and development	$ 788	$ 1,593	$ 2,901	$ 4,568
Selling and marketing	5,560	9,386	23,523	30,263
General and administrative	2,815	3,371	9,837	11,386
Loss on disposition of assets	11,122	—	11,122	—
Total operating expenses	20,285	14,350	47,383	46,217
Loss from operations	(18,708)	(15,774)	(45,678)	(48,647)
Other income (expense)				
Interest income	46	1	50	24
Interest expense	(1,004)	(999)	(2,699)	(2,914)
Total other income (expense), net	(958)	(998)	(2,649)	(2,890)
Loss before benefit from income taxes	(19,666)	(16,772)	(48,327)	(51,537)
Benefit from income taxes	—	—	4,675	—
Net loss	$ (19,666)	$ (16,772)	$ (43,652)	$ (51,537)
Net loss per share (basic and diluted)	$ (0.53)	$ 7.20	$ (2.91)	$ (22.80)
Weighted-average common shares (basic and diluted)	36,997,836	2,343,930	14,998,534	2,251,205
Comprehensive loss:				
Net loss	$ (19,666)	$ (16,772)	$ (43,652)	$ (51,537)
Other comprehensive income:				
Unrealized loss on marketable securities	—	—	—	(3)
Comprehensive loss	$ (19,666)	$ (16,772)	$ (43,652)	$ (51,540)

See accompanying notes to unaudited financial statements.

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount				
Balance December 31, 2021	—	$ —	3,034,901	$ —	$ 396,388	$ —	$ (387,117)	$ 9,271
Share-based compensation - stock options and RSUs	—	—	—	—	764	—	—	764
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	25,623	—	348	—	—	348
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 8)	4,850	4,850	—	—	—	—	—	4,850
Registered direct financing costs, inclusive of warrants		(965)			244	—	—	(721)
Conversion of series A convertible preferred stock	(2,425)	(897)	303,125	—	897	—	—	—
Vesting of RSUs	—	—	1,773	—	—	—	—	—
Warrants issued in connection with registered direct offering	—	(2,101)	—	—	2,101	—	—	—
Net loss	—	—	—	—	—	—	(11,769)	(11,769)
Balance March 31, 2022	2,425	$ 887	3,365,422	$ —	$ 400,742	$ —	$ (398,886)	$ 2,743
Share-based compensation - stock options and RSUs	—	—	—	—	669	—	—	669
Fractional shares retired as a result of reverse split	—	—	(10)	—	—	—	—	—
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	8,687,502	1	12,225	—	—	12,226
Conversion of series B convertible preferred stock	(2,425)	(887)	303,125	—	887	—	—	—
Vesting of RSUs	—	—	4,118	—	—	—	—	—
Net loss	—	—	—	—	—	—	(12,219)	(12,219)
Balance June 30, 2022	—	$ —	12,360,157	$ 1	$ 414,523	$ —	$ (411,105)	$ 3,419
Share-based compensation - stock options and RSUs	—	—	—	—	536	—	—	536
Issuance of common stock pursuant to a public offering, net of expenses	—	—	26,666,666	3	21,968	—	—	21,971
Net loss	—	—	—	—	—	—	(19,666)	(19,666)
Balance September 30, 2022	—	—	39,026,823	$ 4	$ 437,027	$ —	$ (430,771)	$ 6,260

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 Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount				
Balance December 31, 2020	2,189,094	$ —	$ 361,548	$ 3	$ (312,223)	$ 49,328
Share-based compensation - stock options and RSUs	—	—	742	—	—	742
Issuance of common stock pursuant to at-the market stock sales, net of expenses	13,023	—	960	—	—	960
Issuance of common stock upon exercise of stock options	3,160	—	75	—	—	75
Vesting of RSUs	1,316	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	1,080	—	—	1,080
Unrealized net gain on marketable securities	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(17,128)	(17,128)
Balance March 31, 2021	2,206,593	$ —	$ 364,405	$ —	$ (329,351)	$ 35,054
Share-based compensation - stock options and RSUs	—	—	843	—	—	843
Issuance of common stock pursuant to at-the market stock sales, net of expenses	114,826	—	6,349	—	—	6,349
Vesting of RSUs	1,786	—	—	—	—	—
Unrealized net gain on marketable securities	—	—	—	—	—	—
Net loss	—	—	—	—	(17,637)	(17,637)
Balance June 30, 2021	2,323,205	$ —	$ 371,597	$ —	$ (346,988)	$ 24,609
Share-based compensation - stock options and RSUs	—	—	887	—	—	887
Issuance of common stock pursuant to at-the market stock sales, net of expenses	45,030	—	1,956	—	—	1,956
Unrealized net gain on marketable securities	—	—	—	—	—	—
Net loss	—	—	—	—	(16,772)	(16,772)
Balance September 30, 2021	2,368,235	$ —	$ 374,440	$ —	$ (363,760)	$ 10,680

See accompanying notes to unaudited financial statements.

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (43,652)	$ (51,537)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash inventory reserve	—	1,415
Depreciation	1,255	1,546
Amortization	188	102
Loss on disposition of assets	11,122	—
Noncash stock-based compensation	1,969	2,472
Noncash amortization of deferred financing costs	1,635	1,262
Changes in operating assets and liabilities:		
Accounts receivable	(2,178)	(444)
Inventory	(831)	(4,875)
Prepaid expenses and other assets	(1,551)	(885)
Accounts payable and accrued expenses	(2,213)	2,462
Lease liability	(132)	(102)
Net cash used in operating activities	(34,388)	(48,584)
Cash flows from investing activities:		
Sales and maturities of marketable securities	—	39,729
Acquisition of property and equipment	(133)	(214)
Net cash (used in) provided by investing activities	(133)	39,515
Cash flows from financing activities:		
Proceeds from issuance of preferred stock in registered direct offering, net of offering costs	4,129	—
Proceeds from issuance of common stock in public offering, net of offering costs	21,971	—
Proceeds from At-the-Market sales of common stock, net of offering costs	12,573	9,266
Repayments of long-term debt	(17,150)	—
Proceeds from exercise of stock options	—	75
Net cash provided by financing activities	21,523	9,341
Net (decrease) increase in cash and cash equivalents	(12,998)	272
Cash and cash equivalents, beginning of period	19,143	14,463
Cash and cash equivalents, end of period	$ 6,145	$ 14,735
Supplemental disclosure of noncash financing activities		
Warrants issued in connection with long-term debt	$ —	$ 1,080
Warrants issued in connection with preferred stock offering	2,101	—
Conversion of Series A preferred stock into common stock	897	—
Conversion of Series B preferred stock into common stock	887	—
Supplemental cash flow information		
Interest paid	$ 1,078	$ 1,782

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 prior to its approval as AG200-15, is a once-weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA, in February 2020 and was commercially launched in early December 2020. Substantially all of the Company's resources are currently dedicated to commercializing Twirla in the United States. The Company has generated minimal product revenue to date and is subject to a number of risks similar to those of other early stage companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the potential need to obtain additional capital necessary to fund the development of its products, reliance on a consistent supply chain both for Twirla and in general, macroeconomic factors such as inflation, competition from larger companies, and compliance with FDA and other government regulations. If the Company does not successfully commercialize Twirla, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of September 30, 2022, the Company had an accumulated deficit of approximately $431 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 commercialize Twirla and seek increased uptake of Twirla in the United States;
- works towards completing its post-marketing evaluations of Twirla agreed upon with the FDA upon Twirla's approval;
- continues to evaluate additional line extensions for Twirla and initiates development of potential product candidates in addition to Twirla;
- maintains, leverages and expands the Company's intellectual property portfolio; and
- maintains operational, financial and management information systems and personnel, including personnel to support the Company's product development and future commercialization efforts.

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

Going Concern

As of September 30, 2022, the Company had cash and cash equivalents of $6.1 million. We believe our current cash will support operations through December 31, 2022.

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. If the Company is unable to obtain funds when needed or on acceptable terms, the Company then will be unable to continue the commercialization of Twirla, and be required to

cut operating costs, and forego future development and other opportunities. Based upon the foregoing, management has concluded that there is substantial doubt about 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 unaudited financial statements as of September 30, 2022 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for reporting on Form 10-Q. Accordingly, certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP has been condensed or omitted pursuant to such rules and regulations. These interim financial statements should be read in conjunction with the audited financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 30, 2022.

In the opinion of management, the unaudited interim financial statements reflect all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods presented. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the operating results for the full fiscal year or any future period.

The accompanying unaudited financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. If the COVID-19 pandemic or other factors impact the Company's current business plan or its ability to generate revenue from the launch of Twirla, the Company believes it has the ability to revise its commercial plans, including curtailing sales and marketing spending, to allow it to continue to fund its operations.

2. Summary of Significant Accounting Policies

The Company's complete listing of significant accounting policies is described in Note 2 to the Company's audited financial statements as of December 31, 2021 included in its Annual Report on Form 10-K filed with the SEC on March 30, 2022.

Reverse Stock Split

On April 26, 2022, the Company effectuated a one-for-forty reverse stock split of its outstanding shares of common stock (the "Reverse Stock Split"). The Reverse Stock Split reduces the Company's shares of outstanding common stock, stock options, RSUs, and warrants to buy shares of our common stock. Fractional shares of common stock that would have otherwise resulted from the Reverse Stock Split were rounded down to the nearest whole share and cash in lieu of payments were made to stockholders. All share and per share data for all periods presented in the accompanying financial statements and the related disclosures have been adjusted retrospectively to reflect the Reverse Stock Split. The number of authorized shares of common stock and the par value per share remains unchanged.

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, revenue recognition, costs of product revenues, inventory reserves, the accounting for common stock warrants, stock-based compensation, and accounting for

research and development costs. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Risks and Uncertainties

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

It should be noted that current public health threats could adversely affect 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 most significant impacts to the Company's business were encountered by sales representatives promoting Twirla in the field, as some offices limited opportunities for face-to-face interactions with healthcare providers. In many cases COVID-19 restrictions have recently eased, but re-implementation of such restrictions, if necessary in the future may disrupt the Company's business and/or could adversely affect the Company's commercialization plans and results. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if the Company or any of the third parties with whom 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 the Company has been able to continue to execute its overall business plan, some of its business activities slowed and took longer to complete as the Company adjusted to the challenges of operating in a largely remote setting with its employees. While the Company has acclimated to a hybrid work model with its employees, another shut down necessitating work in a completely remote environment could result in delays to its business activities and commercialization plan. Overall, the Company recognizes the challenges of commercializing a new product in a pandemic, and it will continue to closely monitor events as they develop and plan for alternative and mitigating measures that 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 U.S. financial institutions. Cash and cash equivalents include money market funds that invest primarily in commercial paper and U.S. government and U.S. government agency obligations.

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

Trade Accounts Receivable and Allowances

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The trade accounts receivable are recorded at the invoice amount, less prompt pay and other discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses represents the Company's estimate of losses over the life of the receivables. The Company evaluates forward looking economic factors and uses professional judgment to determine the allowance for credit losses. The credit loss reserves are reviewed and adjusted periodically. Credit loss reserves were not material as of September 30, 2022 or December 31, 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 and cash equivalents are carried at fair value (see Note 3).

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

Inventory

Inventory is valued utilizing the weighted average costing method. The Company records an inventory reserve for losses associated with dated, expired, excess or obsolete items. This reserve is based on management's current knowledge with respect to inventory levels, planned production and sales volume assumptions.

Property and Equipment

Property and equipment, consisting of manufacturing equipment, office equipment and computer equipment, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are charged to earnings in the period in which costs are incurred.

In the third quarter, the Company transferred manufacturing equipment with a book value of $11.1 million to Corium in exchange for relief from minimum material purchase requirements. The Company recorded a loss of $11.1 million for both the three and nine months ended September 30, 2022 on this disposition.

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. At September 30, 2022, no indicators of impairment were present.

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 $0.9 million and $2.7 million for the three months ended September 30, 2022 and 2021, respectively, and totaled $6.1 million and $8.8 million for the nine months ending September 30, 2022 and 2021, respectively.

Deferred Financing Costs

Costs directly attributable to the Company's senior secured term loan (see Note 7) are deferred and reported as a reduction of the related term loan. These costs represent a 1% facility fee paid directly to the lender, legal fees and other costs related to the term loan and are being amortized over the term of the loan. Amortization of deferred financing costs charged to interest expense was $146,000 and $69,000 for the three months ended September 30, 2022 and 2021, respectively, and was $284,000 and $208,000 for the nine months ended September 30, 2022 and 2021, respectively.

Concentrations of Credit Risk

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

Major customers of the Company are defined as those constituting greater than 10% of its total revenue. In the three months ended September 30, 2022, the Company had sales to five customers that individually accounted for more than 10% of its total revenue. These customers had sales of $0.8 million, $0.7 million, $0.6 million, $0.5 million and $0.3 million, respectively, which represented 95% of total revenues in the quarter. In the nine months ended September 30, 2022, the Company had sales to three customers that individually accounted for more than 10% of its total revenue. These customers had sales of $2.0 million, $1.8 million and $1.6 million, respectively,which represented 79% of total revenues for the nine months ended September 30, 2022. Accounts receivable related to the five customers comprised 32%, 25%, 24%, 8%, and 10%, respectively, as of September 30, 2022.

Revenue Recognition

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

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

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

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

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

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

provisions are analyzed, and adjustments are made if necessary. Any adjustments made to these provisions would affect net product revenue and earnings in the current period.

In accordance with ASC 606, the Company must make significant judgments to determine the estimate for certain variable consideration. For example, the Company must estimate the percentage of end-users that will obtain the product through public insurance such as Medicaid or through private commercial insurance. To determine these estimates, the Company 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 September 30, 2022 was made based on industry-standard data and trend analysis. As time passes and historical data becomes available, the Company will use historical sales and return data to estimate future product returns.

Chargebacks – Certain government entities and indirect customers (for example group purchasing organizations and 340B covered entities) will be able to purchase the product at a price discounted below WAC. The difference between the price paid by the government or other indirect purchaser and the price paid by the wholesale distributor will be charged back to the Company. The Company estimates the amount in chargebacks based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the balance sheet.

Rebates – The Company will be subject to mandatory discount obligations under the Medicaid and Tricare programs. The 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 $3.2 million and $0.6 million for the three months ending September 30, 2022 and September 30, 2021, respectively, and $6.1 million and $0.9 million for the nine months ending September 30, 2022 and 2021, respectively. As of September 30, 2022, reserves on the balance sheet associated with variable consideration were $3.7 million.

Warrants

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

In connection with entering into a senior secured term loan facility in February 2020, the Company issued warrants to purchase 35,000 shares of its common stock. In connection with an amendment to that facility in February 2021, the Company issued a warrant to purchase 11,250 shares of the Company's common stock. These warrant instruments qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. These warrants are subject to repricing in the event of an offering of securities at a price lower than the existing strike price before December 31, 2022. See Note 7 for additional information.

In connection with an underwritten public offering completed in October 2021, the Company issued warrants to purchase 333,333 shares of its common stock. This offering also triggered an adjustment to the exercise price of the existing warrants mentioned above, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 7 and 8 for additional information.

In connection with a registered direct offering completed in March 2022, the Company issued warrants to purchase 1,242,813 shares of its common stock. This offering also triggered an adjustment to the exercise price of the existing warrants mentioned above, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 7 and 8 for additional information.

In connection with a letter agreement and waiver entered into with an investor on April 2022, the Company issued warrants to purchase 212,188 shares of common stock, subject to adjustment thereunder. See Note 8 for additional information.

In connection with a public offering completed in July 2022, the Company issued warrants to purchase 54,666,665 shares of its common stock. This offering also triggered an adjustment to the exercise price of the existing warrants in connection with the senior secured term loan facility mentioned above, which resulted in a reduction of the strike price for these warrants.

Income Taxes

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

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions which prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no uncertain tax positions as of September 30, 2022 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees

with an exercise price equal to no less than the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company elects to account for forfeitures when they occur. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

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

Net Loss Per Share

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

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share for both the three and nine months ended September 30, 2022 and 2021, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	September 30,	
	2022	2021
Common stock warrants	56,501,249	46,250
Unvested restricted stock units	7,125	6,342
Common stock options	278,854	258,808
Total	56,787,228	311,400

Recent Accounting Pronouncements

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

3. Fair Value Measurements

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

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

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

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

- Level 3 — Unobservable inputs that are supported by little or no market data and which require internal development of assumptions about how market participants price the fair value of the assets or liabilities. The Company has no Level 3 assets 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 September 30, 2022 and December 31, 2021 (in thousands):

	Level 1	Level 2	Level 3
September 30, 2022			
Assets:			
Cash and cash equivalents	$ 6,145	$ —	$ —
Total assets at fair value	$ 6,145	$ —	$ —

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

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

4. Prepaid Expenses and Other Current Assets

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

	September 30, 2022	December 31, 2021
Prepaid insurance	$ 1,033	$ 775
Other	2,801	1,508
Total prepaid expenses and other current assets	$ 3,834	$ 2,283

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued compensation	$ 1,955	$ 2,086
Accrued professional fees and other	3,197	1,477
Total accrued liabilities	$ 5,152	$ 3,563

6. Leases

The Company has no finance leases and one operating lease for its corporate headquarters in Princeton, NJ. The current lease commenced on December 1, 2021 and terminates on March 31, 2025. The lease provides the Company with an option to extend the lease for an additional five years. Under the terms of the lease, the Company pays base annual rent subject to a fixed dollar amount increase each year, a fixed monthly charge for electricity, and other normal operating expenses such as taxes, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. The lease does not require variable lease payments, residual value guarantees or restrictive covenants.

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

Operating lease expense was $90,000 and $38,000 for the three months ended September 30, 2022 and 2021, respectively. Operating lease expense was $271,000 and $113,000 for the nine months ended September 30, 2022 and 2021, respectively. Operating cash flows used for operating leases during the three months ended September 30, 2022 and 2021 were $42,000 and $35,000, respectively. Operating cash flows used for operating leases during the nine months ended September 30, 2022 and 2021 were $132,000 and $102,000 respectively. As of September 30, 2022, the weighted-average remaining lease term was 2.50 years and the weighted average discount rate was 11.8%.

Future minimum lease payments under non-cancellable leases as of September 30, 2022 were as follows (in thousands):

2022	$	66
2023		390
2024		398
2025		100
Total	$	954
Less: Interest		(127)
Present value of lease liability	$	827

7. Credit Agreement and Guaranty

On February 10, 2020 (the "Closing Date"), the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party ("Perceptive"), for a senior secured term loan credit facility of up to $35.0 million, (the "Perceptive Credit Agreement"). A first tranche of $5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15.0 million was funded as a result of the approval of Twirla by the FDA. On February 26, 2021 the Perceptive Credit Agreement was amended (the "Amended Perceptive Credit Agreement") by creating a fourth tranche of $10.0 million that was to be available to the Company based on the achievement of a revenue milestone. The other tranches of debt under the Amended Perceptive Credit Agreement are no longer available to the Company. On January 7, 2022, the Company prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 8, 2022, the Company prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 25, 2022, the Company entered into a fifth amendment to the Amended Perceptive Credit Agreement, as amended (the "Fifth Amendment"). Pursuant to the Fifth Amendment, Perceptive agreed to release its security interest in certain assets being transferred from the Company to Corium in connection with an amendment to the Company's Manufacturing and Commercialization Agreement with Corium and waive the Company's obligations to comply with certain financial covenants through the end of 2022. In exchange, the Company agreed to prepay $7 million of outstanding principal under the Amended Perceptive Credit Agreement using the proceeds of recent sales under the Company's ATM program with H.C. Wainwright & Co., LLC. Such payment was made on July 25, 2022.

The facility will mature on February 10, 2024 (the "Maturity Date"). Pursuant to the Fifth Amendment, beginning August 31, 2022, the Company began making monthly principal payments in an amount equal to $75,000, continuing until February 10, 2024, at which time all remaining principal amount outstanding is due.

Borrowings under the Fifth Amendment will accrue interest at an annual rate equal to the London Interbank Offered Rate for one-month deposits ("LIBOR") plus 10.25%, provided that LIBOR shall not be less than 1.5%. The rate of interest in effect as of the Closing Date and at September 30, 2022 was 11.75%. Upon the occurrence and during the continuance of any event of default under the Fifth Amendment, the interest rate automatically increases by 3.0% per annum.

The Company may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment premium of 4.0% if such prepayment occurs after February 10, 2022 and on or prior to February 10, 2023; and 2.0% if such prepayment occurs after February 10, 2023 and prior to the Maturity Date.

All of the Company's obligations under the Amended Perceptive 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 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 December 31, 2022, report revenues for the trailing 12-month period that exceed the amounts set forth in the Amended Perceptive Credit Agreement, which range from $53.0 million for the fiscal quarter ending December 31, 2022 to $87.1 million for the fiscal quarter ending December 31, 2023. In the event the Company does not pay off the remainder of the outstanding principal under the facility, the Company will need to negotiate for a waiver of its obligations to comply with the covenants relating to revenues for Twirla in the first quarter of 2023.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 35,000 shares of the Company's common stock (together, the "2020 Perceptive Warrants"). The first warrant is exercisable for 17,500 shares of common stock at an exercise price of $149.60 per share. The second warrant is exercisable for 17,500 shares of common stock at an exercise price of $186.80 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Amended Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 11,250 shares of the Company's common stock (the "2021 Perceptive Warrant" and, together with the 2020 Perceptive Warrants, the "Perceptive Warrants") at an exercise price of $114.80 per share. The 2021 Perceptive Warrant expires on February 26, 2028. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections and are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of the Company's common stock as a result of the exercise.

As a result of the public offering of the Company's common stock completed in October 2021 (see Note 8), the anti-dilution provision of the Perceptive Warrants was triggered, resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an exercise price of $186.80 per share were reduced to $141.60 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of $149.60 per share were reduced to $115.20 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of $114.80 per share were reduced to $90.80 per share.

As a result of the registered direct offering completed in March 2022 (see Note 8), the anti-dilution provision of the Perceptive Warrants was again triggered resulting in a further reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of $141.60 per share were reduced to $105.52 per share, warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of $115.20 per share were reduced to $86.61 per share, and warrants to purchase 11,250 shares of common stock that had an adjusted exercise price of $90.80 per share were reduced to $69.13 per share.

As a result of the public offering of the Company's common stock completed in July 2022 (see Note 8), the anti-dilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an exercise price of $105.52 per share were reduced to $14.90 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of $86.61 per share were reduced to $12.37 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of $69.13 per share were reduced to $10.03 per share.

The Company allocated the proceeds of $20.0 million in accordance with ASC 470 based on the relative fair values of the debt and the Perceptive Warrants. The relative fair value of the Perceptive Warrants of approximately $3.6 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in

preparing the option pricing model for valuing the Perceptive Warrants issued include (i) volatility (70.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 7-year life), (iii) strike prices of $149.60 and $186.80 for the common stock warrants, (iv) fair value of common stock ($160.40) and (v) expected life (7 years). The fair value of the 2021 Perceptive Warrants of approximately $1.1 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in preparing the option pricing model for valuing the 2021 Perceptive Warrants issued include (i) volatility (103.5%), (ii) risk free interest rate of 1.15% (estimated using treasury bonds with a 7-year life), (iii) strike price of $114.80 for the common stock warrant, (iv) fair value of common stock ($114.80) and (v) expected life (7 years). The fair value of the warrants as well as the debt issue costs incurred in connection with the entry into the Perceptive Credit Agreement, including a facility fee of 1% of the total amount of loans available under the facility, are presented as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet as detailed below (in thousands).

	September 30, 2022	December 31, 2021
Notes payable	$ 2,850	$ 20,000
Debt issuance costs	(266)	(550)
Warrant discount	(1,266)	(2,617)
Total debt	$ 1,318	$ 16,833
Less, current portion	1,318	16,833
Long-term debt, less current portion	$ —	$ —

The fair value of the warrants and the debt issue costs are being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of $838,000 and $399,000 for the three months ended September 30, 2022 and 2021, respectively. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of $1,635,000 and $1,132,000 for the nine months ended September 30, 2022 and 2021, respectively.

8. Stockholders' Equity

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

On April 26, 2022, the Company filed with the Secretary of State of the State of Delaware a certificate of amendment, or the Certificate of Amendment, to the Company's Amended and Restated Certificate of Incorporation, which became effective on April 26, 2022. The Certificate of Amendment implemented the Reverse Stock Split. On the effective date of April 26, 2022, the number of the Company's issued and outstanding shares of common stock was decreased from 146,741,862 to 3,668,546 and the par value remained unchanged. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The Reverse Stock Split affected all shares of the Company's common stock outstanding immediately prior to the effective date of the Reverse Stock Split, as well as the number of shares of common stock available for issuance under the Company's equity incentive plans. In addition, the Reverse Stock Split effected a reduction in the number of shares of common stock issuable upon the exercise of stock options, restricted stock units, or warrants outstanding.

Shelf Registration Statement

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

Public Offerings

In October 2021, the Company completed a public offering of 666,666 shares of its common stock and warrants to purchase 333,333 shares of its common stock at a combined price of $34.00 per share of common stock and one-half of a warrant to purchase one share of common stock. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $21.1 million.

In July 2022, the Company completed a public offering of (1) 19,148,332 shares of its common stock and warrants to purchase 38,296,664 shares of its common stock at a combined price of $0.90 per share of common stock and warrants and (2) 7,518,334 pre-funded warrants to purchase 7,518,334 shares of its common stock and warrants to purchase 15,036,668 shares of its common stock at a combined price of $0.8999 per share of common stock and pre-funded warrant. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $22.0 million.

ATM Sales Agreement

In March 2021, the Company entered into a common stock sales agreement (the "2021 ATM 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 2021 ATM Agreement. During the year ended December 31, 2021, the Company issued and sold 172,879 shares of common stock under the 2021 ATM Agreement resulting in net proceeds to the Company of approximately $9.3 million.

On January 10, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering an at-the-market offering program (the "January 2022 ATM") the Company entered into for the sale of up to $50.0 million of shares of its common stock. The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the January 2022 ATM. During the nine months ended September 30, 2022, the Company issued and sold 25,623 shares of common stock under the January 2022 ATM resulting in net proceeds to the Company of approximately $0.3 million. On April 26, 2022, the Company terminated the January 2022 ATM.

On April 27, 2022, the Company entered into a new at-the-market offering program ("April 2022 ATM") with H.C. Wainwright LLC and Co. (the "Sales Agent"), under which the Company may, from time to time in its sole discretion, issue and sell through or to the Sales Agent, acting as the Company's agent, up to $12,841,000 of shares of the Company's common stock (the "Placement Shares"). The Company agreed to pay the Sales Agent a commission of up to 3.0% of the gross sales proceeds of any Placement Shares sold under the April 2022 ATM. Through September 30, 2022, the Company issued and sold a total of 8,687,502 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately $12.2 million. On August 22, 2022, the Company increased the April 2022 ATM ("August 2022 ATM"). As increased, the Company may now offer and sell, from time to time through the Sales Agent, shares of the Company's common stock having an aggregate offering price of up to$75.0 million.

Registered Direct Offering

On March 14, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering a direct offering (the "2022 Preferred Stock Offering") of 2,425 shares of Series A convertible preferred stock (the "Series A Preferred Stock") and 2,425 shares of Series B convertible preferred stock (the "Series B Preferred Stock") and Series A warrants (the "Series A Warrants") to purchase up to an aggregate of 606,250 shares of the common stock of the Company and Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 606,250 shares of common Stock. Each share of Series A Preferred Stock and Series B Preferred Stock has a stated value of $1,000 per share and a conversion price of $8.00 per share. The shares of preferred stock issued in the 2022 Preferred Stock Offering are convertible into an aggregate of 606,250 shares of common stock. The Series A Warrants have an exercise price of $10.40 per share, will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The Series B Warrants have an exercise price of $10.40 per share, will become exercisable six months following the date of issuance, and will expire one and one-half years following the initial exercise date. Proceeds from the 2022 Preferred Stock Offering, net of the placement

agent's fees and offering expenses were approximately $4.1 million. A portion of the placement agent's fees included warrants to purchase 30,313 shares of the common stock of the Company at a strike price of $10.00 per share. The warrants become exercisable six months following the date of issuance and will expire 5 years following the commencement of sales in the 2022 Preferred Stock Offering.

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

On March 15, 2022, 2,425 shares of the Series A Preferred Stock were converted into 303,125 shares of the Company's common stock. On April 4, 2022, 2,425 shares of the Series B Preferred Stock were converted into 303,125 shares of the Company's common stock.

On April 25, 2022, the Company entered into a letter agreement and waiver (the "Letter Agreement") with Armistice Capital Master Fund Ltd. ("Armistice"), pursuant to which Armistice consented to the Company entering into and effecting an at-the-market ("ATM") offering facility. On March 14, 2022, the Company entered into the 2022 Preferred Stock Offering with Armistice, under which agreement, the Company was restricted from entering into and effecting an ATM offering facility until the 180-day anniversary of the Closing Date. Pursuant to the Letter Agreement, the Company issued to Armisitice a new common stock purchase warrant ("New Warrant"), on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 212,188 warrant shares, subject to adjustment thereunder. The Series A Warrants have an exercise price of $10.40 per share, and will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The New Warrant is exercisable 6 months after the date of the Letter Agreement.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of goods sold	$ 29	$ 84	$ 104	$ 219
Research and development	90	134	284	362
Selling and marketing	40	31	120	109
General and administrative	377	638	1,461	1,782
Total	$ 536	$ 887	$ 1,969	$ 2,472

9. Income Taxes

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

10. Commitments and Contingencies

The Company has several firm purchase commitments, primarily related to the manufacture and supply of Twirla and the supply of a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services. Future firm purchase commitments under these agreements, the last of which ends in 2033 total $239.1 million. This amount does not represent all of the Company's anticipated purchases in the future, but instead represents only purchases that are the subject of contractually obligated minimum purchases. The minimum commitments disclosed are determined based on non-cancelable minimum spend in 2021 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

In April 2020, the Company entered into a manufacturing and commercialization agreement with Corium, Inc., (the "Corium Agreement"). Under the Corium Agreement, the Company has a requirement to order quarterly minimum volumes of approximately $5.6 million of product. In the event that the Company does not order the minimum volume, the Company is required to pay an additional fee equal to twenty-five percent (25%) per unit of the transfer price for all units ordered in that quarter. The Company did not meet the minimum volume order in the first or second quarter of 2022, and has, therefore, paid the additional 25% per unit fee as a penalty for all units ordered during the period. Based on current demand expectations for Twirla, the Company did not expect to meet the minimum volume order for the balance of 2022 and would be subject to the additional fee on future purchases. On July 25, 2022 the Company and Corium entered into Amendment No. 1 to the Corium Agreement (the "Amendment") that is designed to restructure the contract minimums applicable to the purchase of manufactured Twirla and other services provided by Corium, transfer equipment ownership to Corium to support the manufacture of Twirla and extend the term of the Corium Agreement. Pursuant to the Amendment, the parties agreed to adjust the process for the Company providing Corium certain binding and non-binding forecasts required under the Corium Agreement. Additionally, Corium will not enforce the original quantity minimums in the Corium Agreement, which are waived and replaced by new minimums that are based on Corium's revenue for product purchased by the Company, expiring raw materials, and other services billed by Corium to support batch production and release. The guaranteed minimum revenue requirement for 2022 is $5.3 million, for 2023 is $7.0 million, and is $22.5 million for 2024 and each year thereafter. In the event that the Company does not meet the guaranteed minimum revenue requirements in any given year, the Company will be required to make additional payments to Corium for the shortfall. The Company agreed to make certain monthly supplemental payments to Corium through December 2023, which payments are eligible to be retroactively reduced based upon product orders placed by the Company during 2022 and 2023 meeting certain designated thresholds. In connection with the supplemental payments, Corium will retain the proceeds for the sale of certain raw materials to which the Company would otherwise have economic right to offset such supplemental payments. Further, the Company agreed to reimburse Corium for any unused raw materials in the event the Company's actual product requirements are lower than initially forecasted. Pursuant to the Amendment, the term of the Corium Agreement was extended to December 31, 2033. Pursuant to the Amendment, the parties agreed to transfer ownership of certain manufacturing equipment used in the manufacture of Twirla from the Company to Corium under a Bill of Sale dated July 25, 2022.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company's operations or its financial position. As of September 30, 2022, 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 30, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Dollars in the text and in tabular format are presented in thousands, except per share data, or as otherwise indicated.

Overview

We are a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. We are committed to innovating in women's healthcare where there continues to be unmet needs – not only in contraception – but also in other meaningful women's health therapeutic areas.

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

With the approval of Twirla we are now focused on our advancement as a commercial company. During 2022, we plan to continue implementing our commercialization plan for Twirla, with the goal of becoming a contraceptive market leader, and ultimately, pursuing opportunities to broaden our portfolio to address areas of unmet medical need in women's health.

Our Strategy

Our near-term goal is to establish an initial franchise in the multi-billion dollar U.S. hormonal contraceptive market built on approval of Twirla in the U.S. Our resources are currently focused on the commercialization of Twirla. We also expect to explore possible expansion through business development activities, such as acquiring access to new products through in-licensing, co-promotion or other collaborative arrangements.

Our current priorities are as follows:

- Continue to implement our commercialization plans for Twirla to increase uptake of Twirla in the United States, through targeted digital direct to consumer advertising, including Connected TV ("CTV") advertising in key markets, growing our telemedicine presence, and driving growth in the non-retail channel;
- Continue to expand access to Twirla through multiple business channels including third-party payor contracts, retail and specialty pharmacies, telemedicine and government contracting, and non-retail channels, including public health centers;
- Reduce our operating loss and continue to progress towards generating positive cash flows;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- Maintain and manage the supply chain for Twirla to support increased commercialization of Twirla across the United States and working through existing and future inventory prior to product becoming short-dated;
- Continue to manage our available cash and obtain financing to fund our business plan without delay;
- Evaluate the advancement of our existing pipeline and its possible expansion through business development activities; and
- Continue to implement our obligations related to our post-marketing commitment and the post-marketing requirement studies of Twirla.

It should be noted that current public health threats could adversely affect our ongoing or planned business operations. In particular, the ongoing COVID-19 pandemic has resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public

gatherings, and stay at home orders. The most significant impacts to our business were encountered by sales representatives promoting Twirla in the field, as some offices limited opportunities for face-to-face interactions with healthcare providers. In many cases COVID-19 restrictions have recently eased, but re-implementation of such restrictions if necessary in the future may disrupt our business and/or could adversely affect our commercialization plans and results. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including personnel at third-party manufacturing facilities and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted. It is unknown how long these conditions will last and what the complete effect will be on us. While to date we have been able to continue to execute our overall business plan, some of our business activities slowed and took longer to complete as we adjusted to the challenges of operating in a largely remote setting with our employees. While we have acclimated to a hybrid work model with our employees, another shut down necessitating work in a completely remote environment could result in delays to our business activities and commercialization plan. Overall, we recognize the challenges of commercializing a new product in a pandemic, will continue to closely monitor events as they develop, and plan for alternative and mitigating measures that we can implement if needed.

Financial Overview

Since our inception in 1997, we have devoted substantial resources to developing and seeking regulatory approval for Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. While we anticipate that a portion of our operating expenses will continue to be related to research and development as we pursue our post-marketing studies for Twirla, including planning our long-term, prospective observational safety study, which is a post marketing requirement from the FDA, and evaluate the development of our pipeline, our operating expenses have substantially shifted towards commercialization activities for Twirla. As of September 30, 2022, we have significantly reduced our operating expenses through a number of measures, including optimizing our sales force, reducing reliance on third-party service providers, targeting our advertising spend, and reorganizing our executive leadership team and general personnel. We are committed to continue to look for ways to reduce expenses and focus efforts and resources on commercialization and uptake of Twirla.

We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of September 30, 2022, and December 31, 2021, we had $6.1 million and $19.1 million in cash and cash equivalents, respectively.

On February 10, 2020, we entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party (“Perceptive”), for a senior secured term loan credit facility of up to $35.0 million (the “Perceptive Credit Agreement”). A first tranche of $5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15.0 million was funded as a result of the approval of Twirla by the FDA. On February 26, 2021 the Perceptive Credit Agreement was amended (the “Amended Perceptive Credit Agreement”) by creating a fourth tranche of $10.0 million that was to be available based on the achievement of a revenue milestone. The other tranches of debt under the Amended Perceptive Credit Facility are no longer available to us. In connection with the Amended Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 11,250 shares of the Company’s common stock with an exercise price of $10.03 per share.

On January 7, 2022, we prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 8, 2022, we prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 25, 2022, we entered into a fifth amendment to the Amended Perceptive Credit Agreement, as amended (the “Fifth Amendment”). Pursuant to the Fifth Amendment, Perceptive agreed to release its security interest in certain assets being transferred from the Company to Corium in connection with an amendment to the Company’s Manufacturing and Commercialization Agreement with Corium and waive our obligations to comply with certain financial covenants through the end of 2022. In exchange, we agreed to prepay $7 million of outstanding principal under the Amended Perceptive Credit Agreement using the proceeds of recent sales under our ATM program with H.C. Wainwright & Co., LLC. Such payment was made on July 25, 2022, and Perceptive waived the prepayment premium. Pursuant to the Fifth Amendment, beginning August 31, 2022, we began making monthly principal payments in an amount equal to $75,000 continuing until February 10, 2024, at which time all remaining principal amount outstanding is due.

In March 2021, we entered into a common stock sales agreement (the “2021 ATM Agreement”) under which we are authorized to sell up to an aggregate of $50.0 million in gross proceeds through the sale of shares of common stock from time to time in “at-the-market” equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. During the year ended December 31, 2021, we issued and sold a total of 172,879 shares of common stock under the 2021 ATM Agreement resulting in net proceeds of approximately $9.3 million.

In October 2021, we completed a public offering of 666,666 shares of our common stock and warrants to purchase 333,333 shares of our common stock at a combined price of $34.00 per share of common stock and one-half of a warrant to purchase one share of common stock. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $21.1 million.

In January 2022, we entered into a common stock sales agreement (the “January 2022 ATM”) under which we are authorized to sell up to an aggregate of $50.0 million in gross proceeds through the sale of shares of common stock from time to time in “at-the-market” equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. During the nine months ended September 30, 2022 we issued and sold a total of 25,623 shares of common stock under the January 2022 ATM resulting in net proceeds of approximately $0.3 million. On April 26, 2022, we terminated the January 2022 ATM.

On March 13, 2022, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with a single healthcare-focused institutional investor (the “Purchaser”), pursuant to which the Company issued, in a registered direct offering (the “2022 Preferred Stock Offering”), 2,425 shares of Series A convertible preferred stock (the “Series A Preferred Stock”) and 2,425 shares of Series B convertible preferred stock (the “Series B Preferred Stock”) and Series A warrants (the “Series A Warrants”) to purchase up to an aggregate of 606,250 shares of the common stock of the Company and Series B warrants (the “Series B Warrants”) to purchase up to an aggregate of 606,250 shares of common stock. Each share of Series A Preferred Stock and Series B Preferred Stock has a stated value of $1,000 per share and a conversion price of $8.00 per share. The shares of preferred stock issued in the offering are convertible into an aggregate of 606,250 shares of common stock. The Series A Warrants have an exercise price of $10.40 per share, will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The Series B Warrants have an exercise price of $10.40 per share, will become exercisable six months following the date of issuance, and will expire one and one-half years following the initial exercise date. The Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties. Total gross proceeds from the 2022 Preferred Stock Offering, before deducting the placement agent's fees and other estimated offering expenses, are $4.9 million. The 2022 Preferred Stock Offering closed on March 14, 2022.

On April 25, 2022, we entered into a letter agreement and waiver (the “Letter Agreement”) with Armistice Capital Master Fund Ltd. (“Armistice”), pursuant to which Armistice consented to us entering into and effecting an at-the-market (“ATM”) offering facility. Pursuant to the Letter Agreement, we issued to Armisitice a new common stock purchase warrant (“New Warrant”), on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 212,188 warrant shares, subject to adjustment thereunder. The Series A Warrants have an exercise price of $10.40 per share, and will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date.

On April 27, 2022, we entered into a new at-the-market offering program (the “April 2022 ATM”) with H.C. Wainwright LLC, and Co. (the “Sales Agent”) under which we were authorized to sell up to an aggregate of $12,841,000 in gross proceeds through the sale of shares of common stock from time to time in “at the market” equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. Through September 30, 2022, we issued and sold a total of 8,687,502 shares of common stock under the April 2022 ATM, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately $12.2 million. On August 22, 2022, the we increased the April 2022 ATM (“August 2022 ATM”). As increased, we may now offer and sell shares of the Company’s common stock having an aggregate offering price of up to$75.0 million.

On July 6, 2022, we completed a best efforts public offering (the “Offering”) in which we raised net proceeds of $22.0 million through the sale of 19,148,332 shares of common stock and 7,518,334 pre-funded warrants (“Series B pre-funded warrants”) to purchase 7,518,334 shares of common stock. Both the sales of shares of common stock and

pre-funded warrants were accompanied by Series A-1 and Series A-2 warrants (together the "Series A warrants") to purchase shares of common stock. The Series A-1 warrants are exercisable immediately and will expire five years from the date of issuance, and the Series A-2 warrants are exercisable immediately and will expire thirteen months from the date of issuance. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. We also issued to certain designees of H.C. Wainwright warrants to purchase up to 1,333,333 shares of commons stock with an exercise price of $1.125 per share.

Moving forward, we plan to monitor our cash and cash equivalents balances, in an effort to ensure we have adequate liquidity to fund our operations. If the COVID-19 pandemic or other factors impact our current business plan or our ability to generate revenue from the launch of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations.

We have generated minimal revenue and have never been profitable for any year. Our net loss was $74.9 million, $51.9 million and $18.6 million for the years ended December 31, 2021, 2020 and 2019, respectively. Our net loss was $20.0 million and $16.8 million for the three months ended September 30, 2022 and 2021, respectively. Our net loss was $43.6 million and $51.5 million for the nine months ended September 30, 2022 and 2021, respectively. We expect to continue to incur significant operating losses for the foreseeable future as we commercialize Twirla. This includes commercially launching Twirla, advancing our other potential product candidates and expanding our research and development programs.

Going Concern

As of September 30, 2022, we had cash and cash equivalents of $6.1 million. We believe our current cash will support operations through December 31, 2022.

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

The unaudited financial statements as of September 30, 2022 have been prepared under the assumption that we will continue as a going concern for the next 12 months.

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

Financial Operations Overview

Revenue

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

For the three months ended September 30, 2022 and 2021, net sales totaled $3.1 million and $1.3 million, respectively, representing the sale of 33,282 units and 10,650 units, respectively. For the nine months ended September 30, 2022 and 2021, net sales totaled $7.0 million and $2.6 million, respectively, representing the sale of 71,652 units and 20,976 units, respectively. The increase in net sales was driven by increased sales in both the retail and non-retail channel through our collaboration with Afaxys.

Cost of Product Revenues

Cost of product revenues include direct and indirect costs related to the manufacturing of Twirla sold, including packaging services, freight, obsolescence, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. We expect these relatively fixed costs to become less significant as a percentage of sales with anticipated volume increases. There was no direct cost of product revenue on approximately 3,000 units sold in the nine months ended September 30, 2021, as those units were validation inventory which was previously expensed as research and development expense in the fourth quarter of 2020.

For the three months ended September 30, 2022 and 2021, cost of product revenues totaled $1.4 million and $2.7 million, respectively. For the nine months ended September 30, 2022 and 2021, cost of product revenues totaled $5.2 million and $5.0 million, respectively.

Research and Development Expenses

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

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

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

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 September 30, 2022 and 2021, our research and development expenses were approximately $0.8 million and $1.6 million, respectively. For the nine months ended September 30, 2022 and 2021, our research and development expenses were approximately $2.9 million and $4.6 million, respectively The following table summarizes our research and development expenses by functional area.

	Three Months Ended September 30, (In thousands)		Nine Months Ended September 30, (In thousands)	
	2022	2021	2022	2021
Clinical development	$ 115	$ 1,011	$ 917	$ 2,496
Regulatory	107	36	366	174
Personnel related	476	397	1,334	1,592

Manufacturing—commercialization	—	15	—	(56)
Stock-based compensation	90	134	284	362
Total research and development expenses	$ 788	$ 1,593	$ 2,901	$ 4,568

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

Future research and development costs incurred for our potential product candidates and required post-marketing studies will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, access to additional capital, and significant and changing government regulation. For the foreseeable future, we expect the current public health crisis to have a negative effect on the conduct of clinical trials. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, coupled with an assessment of each product candidate's commercial potential. Substantially all of our resources are currently dedicated to commercializing Twirla.

Selling and Marketing Expenses

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

For the three months ended September 30, 2022 and 2021, our selling and marketing expenses totaled approximately $5.6 million and $9.4 million, respectively. For the nine months ended September 30, 2022 and 2021, our selling and marketing expenses totaled approximately $23.5 million and $30.3 million, respectively. Our commercial launch of Twirla in the United States utilized a contract sales force. We anticipate that our selling and marketing expenses will continue to be significant as our commercialization efforts continue.

General and Administrative Expenses

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

For the three months ended September 30, 2022 and 2021, our general and administrative expenses totaled approximately $2.8 million and $3.4 million, respectively. For the nine months ended September 30, 2022 and 2021, our general and administrative expenses totaled approximately $9.8 million and $11.4 million, respectively. We anticipate that our general and administrative expenses will stabilize in the future.

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to our critical accounting policies and estimates from the information discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K, as filed with the SEC on March 30, 2022.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

	Three Months Ended September 30, (In thousands)		
	2022	2021	Change
Revenues, net	$ 3,002	$ 1,287	$ 1,715
Cost of product revenues	1,425	2,711	(1,286)
Gross profit	1,577	(1,424)	3,001
Operating expenses:			
Research and development	$ 788	$ 1,593	$ (805)
Selling and marketing	5,560	9,386	(3,826)
General and administrative	2,815	3,371	(556)
Loss on disposition of assets	11,122	—	11,122
Total operating expenses	20,285	14,350	5,935
Loss from operations	$ (18,708)	$ (15,774)	(2,934)
Other income (expense)			
Interest income	46	1	45
Interest expense	(1,004)	(999)	(5)
Total other income (expense), net	(958)	(998)	40
Loss before benefit from income taxes	(19,666)	(16,772)	(2,894)
Benefit from income taxes	—	—	—
Net loss	$ (19,666)	$ (16,772)	$ (2,894)

Revenues. Revenues, net increased by $1.7 million or 133% from $1.3 million for the three months ended September 30, 2021 to $3.0 million for the three months ended September 30, 2022. Revenue, net consists of sales of Twirla, which was approved by the FDA in February 2020 and launched in the US in December 2020, and reflects the shipment of Twirla to specialty distributors, net of estimates for applicable variable consideration, which consist primarily of wholesale distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns and co-pay assistance programs.

Cost of product revenues. Cost of product revenues totaled $1.4 million and consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. Cost of product revenues in the prior period included $1.4 million of obsolescence reserves for inventory not expected to be sold prior to its shelf life date.

Research and development expenses. Research and development expenses decreased by $0.8 million, or 51%, from $1.6 million for the three months ended September 30, 2021 to $0.8 million for the three months ended September 30, 2022. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses of $0.9 million for the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. This decrease reflects a reduction in spending related to our pipeline evaluation and development.

Selling and marketing expenses. Selling and marketing expenses decreased by $3.8 million, or 41%, from $9.4 million for the three months ended September 30, 2021 to $5.6 million for the three months ended September 30, 2022. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the optimization of our contract sales force.

General and administrative expenses. General and administrative expenses decreased by $0.6 million, or 16%, from $3.4 million for the three months ended September 30, 2021 to $2.8 million for the three months ended September 30, 2022. This decrease in general and administrative expense was primarily due to reduced headcount.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an $11.1 million one-time, non-cash charge, which represents the loss on the transfer of fixed assets to Corium in connection with the amended Corium agreement (see Note 10 to the financial statements).

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

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense was flat at $1.0 million for both the three months ended September 30, 2022 and September 30, 2021 as higher non-cash interest amortization of the fair value of the warrants and debt issue costs offset lower cash interest due to principal payments made on the term loan.

Comparison of the Nine Months Ended September 30, 2022 and 2021

	Nine Months Ended September 30, (In thousands)		
	2022	2021	Change
Revenues, net	$ 6,888	$ 2,587	$ 4,301
Cost of product revenues	5,183	5,017	166
Gross profit	1,705	(2,430)	4,135
Operating expenses:			
Research and development	$ 2,901	$ 4,568	$ (1,667)
Selling and marketing	23,523	30,263	(6,740)
General and administrative	9,837	11,386	(1,549)
Loss on disposition of assets	11,122	—	11,122
Total operating expenses	47,383	46,217	1,166
Loss from operations	$ (45,678)	$ (48,647)	2,969
Other income (expense)			
Interest income	50	24	26
Interest expense	(2,699)	(2,914)	215
Total other income (expense), net	(2,649)	(2,890)	241
Loss before benefit from income taxes	(48,327)	(51,537)	3,210
Benefit from income taxes	4,675	—	4,675
Net loss	$ (43,652)	$ (51,537)	$ 7,885

Revenues. Revenues, net increased by $4.3 million or 166% from $2.6 million for the nine months ended September 30, 2021 to $6.9 million for the nine months ended September 30, 2022. Revenue, net consists of sales of Twirla, which was approved by the FDA in February 2020 and launched in the US in December 2020, and reflects the shipment of Twirla to specialty distributors, net of estimates for applicable variable consideration, which consist primarily of wholesale distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns and co-pay assistance programs.

Cost of product revenues. Cost of product revenues totaled $5.2 million and consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. Additional costs incurred in the nine months ending September 30, 2022 include $0.7 million of supplemental payments and expired raw materials payments to Corium as agreed to under the amended Corium agreement. Additional costs incurred in the nine months ending September 30, 2021 include $1.4 million obsolescence reserves for inventory not expected to be sold prior to its shelf life date.

Research and development expenses. Research and development expenses decreased by $1.7 million, or 36%, from $4.6 million for the nine months ended September 30, 2021 to $2.9 million for the nine months ended September 30, 2022. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses of $1.6 million for the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. This decrease reflects a reduction in spending related to our pipeline evaluation and development.

Selling and marketing expenses. Selling and marketing expenses decreased by $6.7 million, or 22%, from $30.3 million for the nine months ended September 30, 2021 to $23.5 million for the nine months ended September 30, 2022. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the optimization of our contract sales force.

General and administrative expenses. General and administrative expenses decreased by $1.5 million, or 14%, from $11.4 million for the nine months ended September 30, 2021 to $9.8 million for the nine months ended September 30, 2022. This decrease in general and administrative expense was primarily due to the previously announced forfeiture of senior management bonuses for 2021and reduced headcount, partially offset by higher professional fees.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an $11.1 million one-time, non-cash charge, which represents the loss on the transfer of fixed assets to Corium in connection with the amended Corium agreement (see Note 10 to the financial statements).

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

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense decreased by $215,000 for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 as higher non-cash interest amortization of the fair value of the warrants and debt issue costs offset lower cash interest due to principal payments made on the term loan.

Benefit from income taxes. Benefit from income taxes reflects $4.7 million received under the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program") sponsored by The New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused NOLs and unused research and development credits to sell these tax benefits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The Program is administered by The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation. We have reached the maximum lifetime benefit $20.0 million.

Liquidity and Capital Resources

At September 30, 2022, we had cash and cash equivalents totaling $6.1 million. We invest our cash equivalents in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

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

	Nine Months Ended September 30, (In thousands)	
	2022	2021
Net cash used in operating activities	$ (34,388)	$ (48,584)
Net cash (used in) provided by investing activities	(133)	39,515
Net cash provided by financing activities	21,523	9,341
Net (decrease) increase in cash and cash equivalents	$ (12,998)	$ 272

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 $34.4 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of $43.6 million and negative working capital changes of $7.0 million, offset by non-cash stock-based compensation expense of $2.0 million, depreciation expense of $1.3 million, a $11.1 million non-cash loss on the disposition of fixed assets, and $1.8 million of other non-cash charges, primarily interest expense. Net cash used in operating activities was $48.6 million for the nine months ended September 30, 2021 and consisted primarily of a net loss of $51.5 million and $3.8 million in negative working capital changes, offset by a non-cash inventory reserve of $1.4 million, non-cash stock-based compensation expense of $2.5 million, depreciation expense of $1.5 million, and $1.4 million of other non-cash charges, primarily interest expense.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 was $0.1 million and consisted of acquisitions of equipment. Net cash provided by investing activities for the nine months ended September 30, 2021 was $39.5 million and primarily represents net sales and maturities of marketable securities.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was $21.5 million, which consists of net proceeds of $4.1 million from the sale of preferred stock in a registered direct offering, net proceeds of $22.0 million from the sale 26,666,666 shares of our common stock in a public offering, and proceeds of $12.6 million from the sale of 8,713,125 shares of our common stock through an at-the-market, or ATM sales program, partially offset by a principal payment of short-term debt of $17.0 million. Net cash provided by financing activities for the nine months ended September 30, 2021 was $9.3 million, which consists of net proceeds of $9.3 million from the sale of 6,915,151 shares of our common stock under the 2021 ATM Agreement, and stock option proceeds of $0.1 million.

Funding Requirements and Other Liquidity Matters

We closely monitor our cash and cash equivalents balances, in an effort to ensure we have adequate liquidity to fund the operations of the Company. If the COVID-19 pandemic or other factors impact our current business plan or our ability to generate revenue from the launch of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations. In addition, on October 2, 2020 we filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of $200.0 million (the “2020 Shelf Registration Statement”). On October 14, 2020, the 2020 Shelf Registration Statement was declared effective by the SEC. In the future, we may periodically offer one or more of these securities in amounts, at prices, and on terms to be announced when and if the securities are offered. At any 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.

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

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

On January 10, 2022, we filed a prospectus supplement to our 2020 Shelf Registration Statement registering the January 2022 ATM. During the nine months ending September 30, 2022, we sold and issued 25,623 shares of common stock resulting in net proceeds of $0.3 million under the January 2022 ATM. On April, 26, 2022, we terminated the January 2022 ATM.

On March 13, 2022, we entered into the 2022 Preferred Stock Offering. The 2022 Preferred Stock Offering closed on March 14, 2022 and total net proceeds were approximately $4.1 million.

On April 27, 2022, we entered into the April 2022 ATM. Through September 30, 2022, we issued and sold a total of 8,687,502 shares of common stock under the April 2022 ATM, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately $12.2 million. On August 22, 2022, we increased the April 2022 ATM ("August 2022 ATM"). As increased, we may now offer and sell shares of the Company's common stock having an aggregate offering price of up to$75.0 million.

On July 6, 2022, we completed the Offering. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate procees raised in the Offering. We also issued to certain designees of H.C. Wainwright warrants to purchase up to 1,333,333 shares of common stock with an exercise price of $1.125 per share. Proceeds from the Offering, net of placement agent fees and offering expenses were approximately $22.0 million.

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 commercialize Twirla and seek increased uptake of Twirla in the United States;
- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- maintain operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Contractual Obligations and Commitments

In April 2020, we entered into a Manufacturing and Commercialization agreement with Corium, Inc., which we refer to as the Corium Agreement, and which replaced our previous development agreement. Pursuant to the Corium Agreement, Corium will manufacture and supply all of our product requirements for Twirla at certain specified rates. Under the terms of the Corium Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement included a quarterly minimum purchase commitment and a fixed price per unit for two years from December 2020, the date of the first commercial batch purchase order invoice, depending on annual purchase volume. During 2021, we did not meet all of our minimum quantity purchases from Corium, and as a result, paid penalties as required by our agreement with Corium. On July 25, we, along with Corium, amended the Corium Agreement to restructure the minimums applicable to the purchase of manufactured Twirla and to extend the term of the Corium Agreement until December 31, 2033. The Corium Agreement terminates automatically on December 31, 2033, but may be terminated for any reason upon the written mutual agreement of both parties; provided, however, that the parties must confer in good faith regarding possible mutual termination. In the event of such termination, we may still effect purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of September 30, 2022, the minimum amount committed totals $234.7 million.

In April 2020, we entered into a project agreement with inVentiv Commercial Services, LLC, or inVentiv, a Syneos Health Group Company, which we refer to as the Syneos Agreement, under our Master Services Agreement with inVentiv. Pursuant to the Syneos Agreement, inVentiv, through its affiliate Syneos Selling Solutions, will provide a field force of sales representatives to provide certain detailing services, sales operation services,

compliance services and training services with respect to Twirla to us in exchange for an up-front implementation fee and a fixed monthly fee. Effective February 1, 2022, we entered into an amendment to the Syneos Agreement that extended the term until August 23, 2024. At that time, the Syneos Agreement will terminate automatically unless extended upon the mutual written agreement of the Parties. We may terminate the Syneos Agreement for any reason upon timely written notice without incurring a termination fee. As of September 30, 2022, the minimum amount committed totals $3.4 million.

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. The lease for this space commenced in December 2021, and the minimum payments over the remaining 33 month term totals $1.0 million as of September 30, 2022.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

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

We had cash and cash equivalents of $6.1 million and $19.1 million at September 30, 2022 and December 31, 2021, respectively, consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows are subject to fluctuations due to changes in interest rates. We do not believe that we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a 1% unfavorable change in interest rates would not have a material effect on interest expense for the nine months ended September 30, 2022.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the three months ended September 30, 2022.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including

our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes to Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II: Other Information

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

The following updated risk factor should be considered in addition to our risk factors previously reported in our Annual Report on Form 10-K for the year ended December 31, 2021.

Risks Related to Ownership of Our Common Stock

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

On August 15, 2022, we received a deficiency letter from the Nasdaq Stock Market, or Nasdaq, indicating that we have failed to comply with the minimum bid price requirement, which requires that companies listed on the Nasdaq Capital Market maintain a minimum bid price of at least $1.00 per share (the "Bid Price Requirement"). The notification of noncompliance had no immediate effect on the listing of our common stock.

In accordance with Nasdaq rules, we have a 180-calendar day grace period, or until February 13, 2023 (the "Compliance Date"), to regain compliance with the Bid Price Requirement. The continued listing standard would have been met if our common stock had a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day grace period. If we do not regain compliance with the Bid Price Requirement by the Compliance Date, Nasdaq may grant an additional 180 calendar day compliance period, if we meet the continued listing requirement for value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market and provide written notice of our intention to cure the deficiency during the second 180 calendar day compliance period by effecting a reverse stock split, if necessary.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. At that time, we may appeal the Nasdaq staff's determination to a Hearings Panel.

We intend to monitor the closing bid price of our common stock and consider our available options to resolve the noncompliance with the Bid Price Requirement. There can be no assurance that we will be able to regain compliance with the Bid Price Requirement or will otherwise be in compliance with other Nasdaq listing criteria. If our securities are delisted, it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair the liquidity of our common stock and could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

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Item 6. Exhibits.

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

Exhibit Index

Exhibit Number	Description of Document
4.1	Form of Series A-1 Warrant (incorporated by reference, Exhibit 4.1 to the Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
4.2	Form of Series A-2 Warrant (incorporated by reference, Exhibit 4.2 to the Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
4.3	Form of Series B Pre-Funded Warrant (incorporated by reference, Exhibit 4.3 to the Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
4.4	Form of Placement Agent Warrant (incorporated by reference, Exhibit 4.4 to the Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
10.1	Fifth Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of July 25, 2022.
10.2	Amendment No. 1 to Manufacturing and Commercialization Agreement, by and between Corium, Inc. and Agile Therapeutics, Inc., dated as of July 25, 2022, and Bill of Sale by Agile Therapeutics, Inc. to Corium, Inc., dated as of July 25, 2022.
10.3	Form of Securities Purchase Agreement, by and between Agile Therapeutics, Inc. and certain purchasers (incorporated by reference, Exhibit 10.1 to the Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
31.1	Certification of the Registrant's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Registrant's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Registrant's Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Registrant's Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 formatted in Inline Extensible Business Reporting Language (XBRL): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders' Equity, (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

** 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.

Agile Therapeutics, Inc.

Date: November 7, 2022

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

Date: November 7, 2022

By: /s/ Jason Butch
Jason Butch
Vice President and Chief Accounting Officer
(Principal Financial Officer)

FIFTH AMENDMENT TO CREDIT AGREEMENT AND GUARANTY

This Fifth Amendment to Credit Agreement and Guaranty (herein, this "*Agreement*") is entered into as of July 25, 2022 (the "*Fifth Amendment Effective Date*"), by and among Agile Therapeutics, Inc., a Delaware corporation (the "*Borrower*"), the Lenders party hereto (each a "*Lender*" and collectively, the "*Lenders*") and Perceptive Credit Holdings III, LP, a Delaware limited partnership, as a lender and as administrative agent for the Lenders (in such capacity, together with its successors and assigns, the "*Administrative Agent*").

RECITALS:

A. The Lenders have extended credit to the Borrower on the terms and conditions set forth in that certain Credit Agreement and Guaranty, dated as of February 10, 2020 (as amended by that certain Waiver and First Amendment to Credit Agreement and Guaranty dated as of February 26, 2021, that certain Waiver and Second Amendment to Credit Agreement and Guaranty dated as of January 7, 2022, that certain Waiver and Third Amendment to Credit Agreement and Guaranty dated as of March 10, 2022 and that certain Fourth Amendment to Credit Agreement and Guaranty dated as of May 11, 2022, the "*Existing Credit Agreement*"; the Existing Credit Agreement as amended by this Agreement, the "*Credit Agreement*").

B. In connection with the Credit Agreement, the Borrower issued the Warrants.

C. The Borrower desires to sell the equipment (the "*Transferred Assets*") explicitly listed on the bill of sale, a form of which is attached as Schedule 1 hereto, between the Borrower and Corium, Inc. (the "*Bill of Sale*").

D. The Borrower has requested that the Administrative Agent and the Lenders agree to amend certain provisions of the Existing Credit Agreement to permit the sale of the Transferred Assets pursuant to the Bill of Sale.

E. The parties hereto agree to amend the Existing Credit Agreement pursuant to the terms of this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. *Incorporation of Recitals; Defined Terms.* The parties hereto acknowledge that the Recitals set forth above are true and correct in all material respects. The defined terms in the Recitals set forth above are hereby incorporated into this Agreement by reference. All other capitalized terms used herein without definition shall have the same meanings herein as such terms have in the Credit Agreement.

2. *Fifth Amendment to Existing Credit Agreement*. Upon satisfaction of the conditions set forth in Section 5 hereof, the Borrower, the Lenders and the Administrative Agent hereby agree that the Existing Credit Agreement is hereby amended by incorporating the changes shown on the

marked copy of the Existing Credit Agreement attached hereto as Annex A. Deletions of text in the Existing Credit Agreement as amended hereby are indicated by struck-through red text, and insertions of text as amended hereby are indicated by underlined blue text. Attached hereto as Annex B is a clean copy of the Credit Agreement conformed through the Fifth Amendment.

3. *Partial Release and Acknowledgement of Liens*.

(A) Upon satisfaction of the conditions set forth in Section 5 hereof and consummation of the purchase and sale transaction contemplated by the Bill of Sale, all Liens on the Transferred Assets granted to or created in favor of the Administrative Agent as security for the Obligations, including without limitation all Liens on and any other security interest in the Transferred Assets created by or granted or arising under each of the Security Documents, shall automatically terminate and be released and discharged, without any further action by the Borrower, the Administrative Agent or any other Person.

(B) The Borrower hereby acknowledges and agrees that, except as specified in Section 3(a) hereof, the Obligations owing to the Administrative Agent and the Lenders arising out of or in any manner relating to the Loan Documents shall continue to be secured by the Liens granted as security therefor in the Loan Documents, to the extent provided for in the Loan Documents heretofore executed and delivered by the Borrower; and, except as specified in Section 3(a) hereof, nothing herein contained shall in any manner affect or impair the priority of the Liens created and provided for thereby as to the indebtedness, obligations, and liabilities which would be secured thereby prior to giving effect to this Agreement.

4. *Representations And Warranties.* In order to induce the Administrative Agent and the Lenders to enter into this Agreement, the Borrower hereby represents and warrants to the Administrative Agent and the Lenders as follows:

(A) After giving effect to this Agreement, the representations and warranties of the Borrower contained in Article 7 of the Credit Agreement and in each other Loan Document shall be true and correct in all material respects on and as of the date hereof; provided that to the extent that such representations and warranties specifically refer to an earlier date, they shall be true and correct in all material respects as of such earlier date; provided further that any representation and warranty that is qualified as to "materiality", "Material Adverse Effect" or similar language shall be true and correct (after giving effect to any qualification therein) in all respects on such respective dates.

(B) The execution, delivery and performance of this Agreement has been duly authorized by all necessary corporate action on the part of, and duly executed and delivered by, the Borrower.

(C) No Default or Event of Default has occurred and is continuing or shall occur and be continuing immediately after giving effect to this Agreement.

5. *Conditions Precedent.* The effectiveness of this Agreement is subject to the satisfaction of the following conditions precedent:

(A) The Administrative Agent and the Lenders shall have received executed counterparts of this Agreement duly executed and delivered by the Borrower

(B) The Borrower shall have repaid $7,000,000 of the outstanding principal amount of the Term Loans on or immediately prior to the Fifth Amendment Effective Date (the "*Fifth Amendment Prepayment*"), such that the outstanding principal amount of the Terms Loans, as of the Fifth Amendment Effective Date, shall be $3,000,000. Notwithstanding the terms of the Credit Agreement, no Prepayment Premium shall be due and payable with respect to the Fifth Amendment Prepayment.

(C) The Administrative Agent shall have received reasonably satisfactory certificates as to adjustments pursuant to Section 3.1(h) of the Warrants.

6. *Reference to and Effect on the Loan Documents; No Novation.*

(A) This Agreement constitutes a Loan Document. On and after the date hereof, words of like import referring to the Credit Agreement, and each reference in the other Loan Documents to the "Credit Agreement", "thereunder", "thereof" or words of like import referring to the Credit Agreement shall mean and be a reference to the Credit Agreement after giving effect to this Agreement.

(B) Except as specifically set forth in this Agreement, the Credit Agreement and the other Loan Documents shall remain in full force and effect and are hereby ratified and confirmed.

(C) Except as expressly set forth in this Agreement, the Loan Documents and all of the obligations of the Loan Parties thereunder and the rights and benefits of the Administrative Agent and the Lenders thereunder remain in full force and effect. This Agreement is not a novation nor is it to be construed as a release, waiver or modification of any of the terms, conditions, representations, warranties, covenants, rights or remedies set forth in the Loan Documents, except as specifically set forth herein. Without limiting the foregoing, the Loan Parties agree to comply with all of the terms, conditions, and provisions of the Loan Documents except to the extent such compliance is irreconcilably inconsistent with the express provisions of this Agreement. This Agreement may not be amended, supplemented, or otherwise modified except by a written agreement entered into in accordance with Section 13.04 of the Credit Agreement. THIS AGREEMENT REPRESENTS THE FINAL AGREEMENT BETWEEN THE PARTIES AND MAY NOT BE CONTRADICTED BY EVIDENCE OF PRIOR, CONTEMPORANEOUS OR SUBSEQUENT ORAL AGREEMENTS OF THE PARTIES. THERE ARE NO UNWRITTEN ORAL AGREEMENTS BETWEEN THE PARTIES.

7. *Headings.* The headings in this Agreement are included for convenience of reference only and will not affect in any way the meaning or interpretation of this Agreement.

8. *Governing Law*. This Agreement, and all questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York.

9. *Incorporation of Sections 13.10 and 13.11 of the Credit Agreement*. The provisions set forth in Sections 13.10 (Jurisdiction, Service of Process and Venue) and 13.11 (Waiver of Jury Trial) of the Credit Agreement shall apply to this Agreement in all respects.

10. *Counterparts*. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement. Delivery of an executed counterpart of this Agreement by facsimile, DocuSign or a scanned copy by electronic mail shall be equally as effective as delivery of an original executed counterpart of this Agreement.

11. *Severability*. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law, or public policy, all other conditions and provisions of this Agreement will nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto will negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner to the end that the transactions contemplated hereby are fulfilled to the extent possible.

12. *Binding Effect*. This Agreement will be binding upon and inure to the benefit of and is enforceable by the respective successors and permitted assigns of the parties hereto.

[SIGNATURE PAGES TO FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered by their respective officers thereunto duly authorized as of the date first written above.

AGILE THERAPEUTICS, INC., as Borrower

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

PERCEPTIVE CREDIT HOLDINGS III, LP,
as Agent and Lender

By: Perceptive Credit Opportunities GP, LLC, its general partner

By: /s/ Sandeep Dixit
Name: Sandeep Dixit
Title: Chief Credit Officer

By: /s/ Sam Chawla
Name: Sam Chawla
Title: Portfolio Manager

SCHEDULE 1

Bill of Sale

ANNEX A

Marked Credit Agreement

ANNEX B

Conformed Credit Agreement

(Fifth Amendment)

Exhibit 10.2

AMENDMENT NO. 1 TO MANUFACTURING AND COMMERCIALIZATION AGREEMENT

This Amendment No. 1 to Manufacturing and Commercialization Agreement ("Amendment") is made and entered into as of July 25, 2022 ("Amendment Effective Date"), by and between Corium, Inc., a Delaware corporation having its principal place of business at 4558 50th Street, S.E., Grand Rapids, MI 49512, including its Affiliates ("Corium"), and Agile Therapeutics, Inc., a Delaware corporation, having its principal place of business at 500 College Rd. East Suite 310 Princeton, NJ 08540, including its Affiliates ("Agile"), and amends that certain Manufacturing and Commercialization Agreement (the "Agreement"), entered into as of April 30, 2020, by and between Corium and Agile. All capitalized terms used herein and not otherwise defined herein shall have the meanings assigned to them in the Agreement.

WHEREAS, Agile engaged Corium to Manufacture and supply Product to Agile in accordance with the Agreement;

WHEREAS, Agile's demand for Product has decreased;

WHEREAS, Corium and Agile desire to amend the Agreement, in accordance with Section 12.1 of the Agreement, to account for such decrease;

NOW, **THEREFORE**, **THE PARTIES HERETO AGREE AS FOLLOWS**:

1. Section 2.12(e) of the Agreement is hereby deleted and replaced in its entirety with the following:

"All equipment used in the Manufacture of the Product as set forth on Exhibit C ("Equipment") hereto shall be solely owned by Corium, and concurrently with the execution of this Amendment, Agile will execute the Bill of Sale attached hereto as Attachment 1. Corium shall, at its cost and expense, perform all required upkeep and maintenance on Equipment. Significant modifications to Equipment considered by Corium will be reviewed with Agile to mutually assess the technical and regulatory impacts of the proposed modifications on the Manufacture and supply of Product. Equipment changes that incur costs that will be shared between the Parties for development activities and/or regulatory preparations shall be mutually agreed upon by the Parties in writing."

2. The last sentence of Section 3.3 of the Agreement is hereby deleted and replaced in entirety with the following:

"Where permitted by law and regulation, Corium shall use commercially reasonable efforts to maintain on hand a sufficient quantity of all raw materials and packaging components sourced from outside the United States [***] necessary for the Manufacture of Products required for the [***] according to Agile's Purchase Order and Firm Forecast."

3. Section 3.4(b) of the Agreement is hereby deleted and replaced in entirety with the following

"Beginning on [***] prior to the beginning of each [***], Agile shall provide to Corium [***] worth of forecasts for the Product as follows: (1) a binding purchase order for Product for the upcoming [***] (the "Purchase Order"), (2) a firm forecast for the [***] (the "Firm Forecast"), and (3) a non-binding forecast of its estimated requirements for Product in the [***] thereafter, along with requested shipment dates for Product. Agile's Purchase Order shall be binding upon Agile and shall be accepted by Corium provided that the quantities ordered are within [***] of the amounts forecast by Agile in the Firm Forecast for such [***]. By way of example, [***]."

4. Section 3.4(c) is hereby deleted in its entirety.

5. The following language is hereby inserted at the end of Section 3.4:

"Corium will continue to purchase raw materials to support forecast volume as provided in Section 3.3. In the event actual volume is less than forecast, and this deficiency causes scrap or expiry of raw materials, Agile will reimburse Corium for the unusable raw materials at cost plus disposal fees. Corium will continue to provide Agile an accounting of inventory, expected expiring materials and value, no more than [***]. Corium may invoice Agile for the scrap or expired raw materials plus disposal fees following such accounting, and Agile shall pay such invoices within [***] after the date of the invoice. Agile reserves the right to audit this data as provided in Section 4.3."

6. The following language is hereby inserted at the end of Section 4:

"Agile will pay Corium [***] per month from April 2022 through December 2023 (each monthly payment, a "Supplemental Fee"). In the event Agile orders at least [***] of Product in calendar year 2022 [***], the Supplemental Fee will be retroactively reduced to [***] per month for April 2022 through December 2022. In the event Agile orders at least [***] of Product in calendar year 2023, the Supplemental Fee will be retroactively reduced to [***] per month for January 2023 through December 2023. Any retroactive reduction in Supplemental Fees already paid shall be offset against future amounts owed by Agile to Corium. Notwithstanding anything to the contrary in this Agreement, each Supplemental Fee is due within [***] after the start of the applicable month. Agile will pay Corium the total applicable Supplemental Fees, in the amount of [***] per month, for the months of April 2022, May 2022, June 2022, and July 2022, within [***] after the Amendment Effective Date (notwithstanding anything to the contrary in this Agreement), subject to any applicable credits. All such amounts paid pursuant to this Section are non-refundable."

7. Section 11.1 of the Agreement is hereby deleted and replaced in entirety with the following:

"The term of this Agreement (the "Term") shall commence on the Effective Date, and shall continue until December 31, 2033, unless terminated earlier pursuant to Section 11.2."

8. Section 11.3(d) is hereby deleted in its entirety.

9. Exhibit A of the Agreement is hereby deleted and replaced in entirety with the version of Exhibit A in Attachment 2 hereto.

10. Exhibit B of the Agreement is hereby deleted and replaced in entirety with the version of Exhibit B in Attachment 3 hereto.

11. In addition, Agile hereby agrees that Corium may retain the approximately [***] payment to be made to Corium [***] for the sale [***] of a certain amount of [***], and Agile shall have no rights to any part of such [***], even if Agile reimbursed Corium previously for such [***] to be sold to [***]; provided, however, that the actual amount of cash Corium receives from [***] for the [***] shall be credited dollar for dollar against the amount of Supplemental Fees that Agile owes to Corium.

12. This Amendment supersedes all proposals, oral or written, all negotiations, conversations, and discussions between the parties relating to the subject matter of this Amendment and all past dealing and industry custom. This Amendment shall be integrated in and form part of the Agreement upon execution, which Agreement the parties acknowledge and agree remains in full force and effect as of the Amendment Effective Date. All terms and conditions of the Agreement shall remain unchanged except as modified in this Amendment; and the terms of the Agreement, as modified by this Amendment, are hereby ratified and confirmed. Except as set forth in Sections 1 through 11 (inclusive) above, no other term of the Agreement is amended or modified in any manner. Where the terms of the Agreement conflict with those of this Amendment, however, the terms of this Amendment shall control only with respect to the conflict. This Amendment shall be governed by and construed in accordance with the laws of the State of New York.

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have caused this Amendment to be duly executed.

Corium, Inc.	**Agile Therapeutics, Inc.**
By: /s/ Perry Sternberg	By: /s/ Al Altomari
Name: Perry Sternberg	Name: Al Altomari
Title: President and CEO	Title: CEO
Date: 7/25/2022	Date: 7/25/2022

ATTACHMENT 1

Bill of Sale

See attached.

ATTACHMENT 2

Exhibit A
Guaranteed Minimum Billed Revenue

In the event the billed revenue (as defined below) during any calendar year starting in calendar year 2022 is less than the applicable Guaranteed Minimum Billed Revenue (as defined below), Agile agrees to make an additional true-up payment to Corium to ensure that Corium receives total revenue for such calendar year equal to the Guaranteed Minimum Billed Revenue. The Guaranteed Minimum Billed Revenue for calendar year 2022 is $5,278,125; the Guaranteed Minimum Billed Revenue for calendar year 2023 is $7,037,500, and the Guaranteed Minimum Billed Revenue for each calendar year 2024 and beyond is $22,500,000 (as applicable to each calendar year, the "Guaranteed Minimum Billed Revenue").

In the event that Corium does not receive at least the applicable Guaranteed Minimum Billed Revenue in any calendar year, Agile agrees to make an additional true-up payment (each such payment, a "True-Up Payment") to Corium to ensure that Corium receives at least the applicable Guaranteed Minimum Billed Revenue. Any True-Up Payments will be calculated and paid in [***]: Within [***] the preceding [***] of billed revenue will be compared to the corresponding [***] portion of the applicable Guaranteed Minimum Billed Revenue. In the event the billed revenue in this [***] period is less than the applicable [***] portion of the Guaranteed Minimum Billed Revenue, Corium will invoice Agile in the amount of the difference and payment shall be due within [***] of the date of such invoice.

As used herein, "billed revenue" is limited to the revenue for the following items: [***]. For clarity, research and development activities will not count toward billed revenue minimums.

Corium will not enforce the original guaranteed quantity minimums in the Supply Agreement which are waived and replaced by the Guaranteed Minimum Billed Revenue pursuant to this Amendment.

ATTACHMENT 3

Exhibit B
Commercial Terms

Transfer Pricing

Agile shall pay Corium a transfer price for all commercially saleable product it purchases pursuant to Section 3. Through [***], the transfer price will be the Base Price (listed below). Thereafter, the transfer price will be the Adjusted Base Price, which will be recalculated [***] as set forth below.

The Base Price for standard Product (containing 3 Units) is the following:

Annual Volume (millions)	**Per Unit**	**Per Cycle**
[***]	$[***]	$[***]
[***]	$[***]	$[***]
[***]	$[***]	$[***]
[***]	$[***]	$[***]
[***]	$[***]	$[***]

For each year beginning [***] after the first commercial batch Purchase Order invoice date the Adjusted Base Price will be calculated as follows: The previous year's transfer price will be [***]

In the event that the total cost of raw materials used in the Manufacture of the Product on a per Unit basis [***], the Parties will meet to renegotiate the transfer price in good faith for the purpose of sharing the [***] fairly between the Parties.

BILL OF SALE

For the consideration set forth in Section 4 below, the receipt of which is hereby acknowledged, Agile Therapeutics, Inc., a Delaware corporation ("Seller"), hereby GRANTS, BARGAINS, SELLS, TRANSFERS, ASSIGNS, CONVEYS AND DELIVERS to Corium, Inc. a Delaware corporation, its successors and assigns ("Buyer") (together with the Seller, the "Parties"), effective as of July 25, 2022 (the "Effective Date"), all of Seller's right, title, and interest in and to the Assets (as defined in Section 1 below). Reference is made herein to that certain Manufacturing and Commercialization Agreement (the "MCA") entered into as of April 30, 2020, by and between the Parties.

THE ASSETS TRANSFERRED BY SELLER TO BUYER

Seller hereby transfers to Buyer that certain equipment specified in Exhibit A attached hereto, including rights to the warranties received from the manufacturer of such items and to any related claims, credits, and rights of recovery with respect to such items (collectively, "the Assets"); TO HAVE AND TO HOLD by Buyer, its successors and assigns, to and for its or their use forever.

REPRESENTATIONS OF SELLER

Seller has good and marketable title to the Assets hereby granted, bargained, sold, transferred, assigned, conveyed, and delivered, and owns such Assets free and clear of any and all liens, mortgages, licenses, leases, encumbrances, claims, charges, security interests, pledges, covenants, debts, liabilities, or other restrictions of any kind whatsoever.

The execution, delivery, and performance of this Bill of Sale (the "Bill of Sale") by Seller will not (i) violate any order, judgment, decree, rule or regulation applicable to Seller or the Assets or (ii) require of Seller any consent, approval order or authorization of, or notice to, any person or entity.

Except as otherwise provided in this Bill of Sale, each material, tangible Asset is being transferred on a "where is" and, as to condition, "as is" basis.

COVENANTS OF SELLER

Seller, for itself, its successors and assigns, hereby covenants and agrees that, at any time and from time to time forthwith upon the written request of Buyer, Seller will do, execute, acknowledge and deliver or cause to be done, executed, acknowledged and delivered, each and all of such further acts, deeds, assignments, transfers, conveyances, powers of attorney and assurances as may reasonably be required by Buyer in order to assign, transfer, set over, convey, assure and confirm unto and vest in Buyer, its successors and assigns, title to the Assets granted, bargained, sold, transferred assigned, conveyed and delivered pursuant to this Bill of Sale.

CONSIDERATION

As full and complete consideration and payment for the transfer of the Assets as described in this Bill of Sale, Buyer agrees to enter into an Amendment to the MCA, on terms mutually acceptable to the Parties (the "Consideration"), and that it will not enforce the original guaranteed quantity purchase minimums in the Supply Agreement which are waived and replaced by the Guaranteed Minimum Billed Revenue pursuant to the Amendment to the MCA.

TAXES

Each party will bear their own taxes, duties, levies, and similar charges (and any related interest and penalties), however designated, imposed as a result of the existence or operation of this Bill of Sale. Seller and Buyer agree to cooperate to minimize any sales, use and other transfer taxes and fees incurred in connection with the assignment, conveyance, transfer and/or delivery of the Assets hereunder.

FURTHER ASSURANCES, NATURE OF SALE AND BINDING EFFECT

Each of Seller and Buyer (the "first party") hereby represents and warrants to the other that (i) the execution and delivery of this Bill of Sale and the consummation of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action required on the part of the first party and no other proceedings on the part of the first party are necessary to authorize this Bill of Sale to which it is a party or to consummate the transactions contemplated hereby, and (ii) this Bill of Sale has been duly and validly executed and delivered by the first party and constitutes the legal, valid and binding agreement of the first party, enforceable against the first party in accordance with its terms.

Any individual, partnership, corporation, or other entity may rely without further inquiry upon the powers and rights herein granted to either party hereunder and upon any notarization, certification, verification, affidavit, or attestation by any notary public of any state relating to the authorization, execution, and delivery of this Bill of Sale or to the authenticity of any copy, conformed or otherwise, hereof.

This Bill of Sale shall be binding upon Seller and Buyer and their respective successors and assigns.

SEVERABILITY OF TERMS

The provisions of this Bill of Sale are severable, and, in the event that any one or more provisions are deemed illegal or unenforceable, the remaining provisions shall remain in full force and effect unless the deletion of such provision shall cause this Bill of Sale to become materially adverse to either party, in which event the parties shall use reasonable best efforts to arrive at an accommodation that best preserves for the parties the benefits and obligations of the offending provision.

GOVERNING LAW

This Bill of Sale shall be governed by and construed and enforced in accordance with the laws of the State of Delaware without regard to its principles of conflicts of law.

COUNTERPARTS

This Bill of Sale may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures provided by portable document format (pdf) transmission or other electronic means will be deemed to have the same force and effect as original signatures.

ENTIRE AGREEMENT

The terms and conditions of this Bill of Sale constitute the entire agreement as between Seller and Buyer with respect to the subject matter hereof.

Signature Page Follows

IN WITNESS WHEREOF, Seller and Buyer have caused this Bill of Sale to be signed by their respective duly authorized officers, and are so bound by such execution.

Seller:

Agile Therapeutics, Inc.

By: /s/ Al Altomari

Name: Al Altomari

Title: CEO

Date: 7/25/2022

Buyer:

Corium, Inc.

By: /s/ Perry Sternberg

Name: Perry Sternberg

Title: President and CEO

Date: 7/25/2022

Exhibit A

Equipment

[***]

Exhibit 31.1

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

I, Alfred Altomari, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2022

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

Exhibit 31.2

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

I, Jason Butch, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2022

/s/ Jason Butch
Jason Butch
Chief Accounting Officer
Principal Financial Officer

Exhibit 32.1

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

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Alfred Altomari, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: November 7, 2022

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

Exhibit 32.2

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

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Jason Butch, 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: November 7, 2022

/s/ Jason Butch
Jason Butch
Chief Accounting Officer
Principal Financial Officer