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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from to

Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

101 Poor Farm Road
Princeton, New Jersey 08540
(Address including zip code of principal executive offices)

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

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

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

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

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

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

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

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

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

There were 87,297,605 shares of the registrant's common stock, $0.0001 par value, outstanding as of August 7, 2020.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2020

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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 uptake of Twirla and the development of our 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 development and validation of manufacturing capabilities, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

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

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

- our ability to successfully launch and commercialize Twirla;
- our ability along with the ability of our third-party manufacturer, Corium International, Inc., or Corium, to complete successfully the scale up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility;
- the rate and degree of market acceptance of Twirla and any of our product candidates;
- the size and growth of the markets for Twirla and our product candidates and our ability to serve those markets;
- the effects of the COVID-19 pandemic on our 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;
- our available cash and our ability to obtain additional funding to fund our business plan without delay;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our inability to timely obtain from Corium sufficient quantities or quality of Twirla and our potential product candidates or other materials required for a clinical trial or other tests or 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 its 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 conduct a small post-marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla;

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

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

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

- our plans to develop our other potential product candidates;

- the successful development of our sales and marketing capabilities, including our ability to recruit, train, and retain an effective sales force or failure to build out and implement an effective health care compliance program;

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

- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q. You should also read carefully the factors described in the “Risk Factors” included in Part II, Item 1A of this Quarterly Report and Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed with the Securities and Exchange Commission on February 20, 2020 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 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 ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Agile Therapeutics, Inc.
Part I — Financial Information

ITEM 1. Financial Statements

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 39,446	$ 34,479
Marketable securities	47,789	—
Prepaid expenses	1,527	840
Total current assets	88,762	35,319
Property and equipment, net	14,208	14,044
Right of use and other assets	94	177
Total assets	$ 103,064	$ 49,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,121	$ 1,819
Accrued expenses	1,290	1,804
Lease liability, current portion	82	172
Total current liabilities	6,493	3,795
Long-term debt	15,775	—
Total liabilities	22,268	3,795
Commitments and contingencies (Note 13)		
Stockholders' equity		
Common stock, $.0001 par value, 150,000,000 shares authorized, 87,297,605 and 69,810,305 issued and outstanding at June 30, 2020 and December 31, 2019, respectively	9	7
Additional paid-in capital	359,856	306,108
Accumulated other comprehensive income	10	—
Accumulated deficit	(279,079)	(260,370)
Total stockholders' equity	80,796	45,745
Total liabilities and stockholders' equity	$ 103,064	$ 49,540

See accompanying notes to unaudited financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 3,661	$ 1,779	$ 6,825	$ 4,660
General and administrative	6,378	1,768	10,831	3,594
Total operating expenses	10,039	3,547	17,656	8,254
Loss from operations	(10,039)	(3,547)	(17,656)	(8,254)
Other income (expense)				
Interest income	115	63	247	101
Interest expense	(902)	—	(1,300)	—
Total other income (expense), net	(787)	63	(1,053)	101
Loss before benefit from income taxes	(10,826)	(3,484)	(18,709)	(8,153)
Benefit from income taxes	—	—	—	—
Net loss	$ (10,826)	$ (3,484)	$ (18,709)	$ (8,153)
Net loss per share (basic and diluted)	$ (0.12)	$ (0.08)	$ (0.23)	$ (0.20)
Weighted-average common shares (basic and diluted)	87,221,441	43,776,549	81,936,815	40,560,259
Comprehensive loss:				
Net loss	$ (10,826)	$ (3,484)	$ (18,709)	$ (8,153)
Other comprehensive income:				
Unrealized gain on marketable securities	10	—	10	—
Comprehensive loss	$ (10,816)	$ (3,484)	$ (18,699)	$ (8,153)

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

See accompanying notes to unaudited financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount			
Balance December 31, 2018	34,377,329	$ 3	$ 261,722	$ (241,551)	$ 20,174
Adjustment to derivative liabilities upon adoption of ASU 2017-11	—	—	213	(213)	—
Share-based compensation - stock options and RSUs	—	—	490	—	490
Issuance of common stock in private placement, net of expenses	8,426,750	1	7,809	—	7,810
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	665,974	—	860	—	860
Vesting of RSUs	145,204	—	—	—	—
Net loss	—	—	—	(4,669)	(4,669)
Balance March 31, 2019	43,615,257	$ 4	$ 271,094	$ (246,433)	$ 24,665
Share-based compensation - stock options	—	—	479	—	479
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	992,072	—	1,389	—	1,389
Issuance of common stock upon exercise of stock options	25,000		15		15
Net loss	—	—	—	(3,484)	(3,484)
Balance June 30, 2019	44,632,329	$ 4	$ 272,977	$ (249,917)	$ 23,064

See accompanying notes to unaudited financial statements.

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

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (18,709)	$ (8,153)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	8	10
Amortization	82	71
Noncash stock-based compensation	1,460	969
Noncash interest	447	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(686)	429
Accounts payable and accrued expenses	2,839	(590)
Lease liability	(90)	(75)
Net cash used in operating activities	(14,649)	(7,339)
Cash flows from investing activities:		
Purchases of marketable securities	(47,822)	—
Acquisition of property and equipment	(222)	—
Net cash used in investing activities	(48,044)	—
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offering, net of offering costs	48,434	—
Proceeds from issuance of long-term debt	20,000	—
Debt financing costs paid	(1,059)	—
Proceeds from issuance of common stock in private placement, net of offering costs	—	7,810
Proceeds from At-the-Market sales of common stock, net of offering costs	—	2,249
Proceeds from exercise of stock options	285	15
Net cash provided by financing activities	67,660	10,074
Net increase in cash and cash equivalents	4,967	2,735
Cash and cash equivalents, beginning of period	34,479	7,851
Cash and cash equivalents, end of period	$ 39,446	$ 10,586
Supplemental disclosure of noncash financing activities		
Warrants issued in connection with long-term debt	$ 3,570	—
Supplemental cash flow information		
Interest paid	$ 896	$ —
Cash paid for income taxes	$ —	$ —

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 and performing research and development, including development of the Company's lead product candidate. The Company is headquartered in Princeton, New Jersey.

The Company's sole approved product, Twirla®, also known as AG200 15, is a once weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA in February 2020. Substantially all of the Company's resources are currently dedicated to commercializing Twirla in the United States. The Company has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the potential need to obtain additional capital necessary to fund the development of its products, competition from larger companies and compliance with the FDA and other government regulations. If the Company does not successfully commercialize any product candidates, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of June 30, 2020, the Company had an accumulated deficit of approximately $279 million.

The Company expects to continue to incur significant expenses and increased operating losses for the foreseeable future and that its operating expenses will increase substantially in connection with its ongoing activities, as the Company:

- establishes a sales and marketing infrastructure to commercialize Twirla in the United States;
- continues the validation process related to Corium's manufacturing facility in preparation for commercial operations;
- continues to evaluate additional line extensions for Twirla and initiates development of potential product candidates in addition to Twirla;
- maintains, leverages and expands the Company's intellectual property portfolio; and
- adds operational, financial and management information systems and personnel, including personnel to support the Company's product development and future commercialization efforts.

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 9), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

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, 2019 as filed with the SEC on February 20, 2020.

In the opinion of management, the unaudited interim financial statements reflect all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods presented. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the operating results for the full fiscal year or any future period.

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. Based on the Company's current business plan and ability to launch Twirla, the Company believes that its cash, cash equivalents and marketable securities as of June 30, 2020 will be sufficient to meet its projected operating requirements through the end of 2021. If the COVID-19 pandemic or other factors impact the Company's current business plan or its ability to generate revenue from the launch of Twirla, the Company believes it has the ability to revise its commercial plans, including curtailing sales and marketing spending, to allow it to continue to fund its operations.

2. Summary of Significant Accounting Policies

The Company's complete listing of significant accounting policies is described in Note 2 to the Company's audited financial statements as of December 31, 2019 included in its Annual Report on Form 10-K filed with the SEC.

Use of Estimates

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

Risks and Uncertainties

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

It should be noted that current public health threats could adversely affect the Company's ongoing or planned business operations. In particular, the World Health Organization has declared the outbreak of a novel strain of coronavirus, now referred to as COVID-19, a pandemic resulting in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures the Company has taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt the Company's business and could delay the Company's commercialization timeline. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if the Company or any of the third parties with whom it engages, including personnel at third-party manufacturing facilities and other third parties with whom the Company conducts business, were to experience shutdowns or other business disruptions, the Company's ability to conduct its business in the manner and on the timeline presently planned could be materially and adversely impacted. While it is unknown how long these conditions will last and what the complete effect will be on the Company, to date, the Company has been able to continue to execute on its plans according to the related timelines. The Company will continue to closely monitor events as they develop and evaluate alternative, mitigating measures it can implement if needed.

Cash and Cash Equivalents

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

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

Marketable Securities

The Company invests a portion of its excess cash balances in marketable securities, including U.S. government agency securities, and highly rated corporate bonds. The Company classifies all of its marketable securities as current assets on the balance sheet because they are available-for-sale and available to fund current operations. Marketable securities are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity, until such gains and losses are realized. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is reclassified from accumulated other comprehensive income (loss) to the statements of operations. Realized gains and losses are determined on the specific identification method and are included in other income.

Fair Value of Financial Instruments

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

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

Pre-Launch Validation Product

The Company's third-party manufacturer, Corium, is currently manufacturing three validation batches of Twirla. The costs associated with validation are being expensed as research and development expenses during the period the costs are incurred. If validation is successful, the Company plans to utilize this validation product for commercial supplies and samples of Twirla. The Company does not plan to capitalize any validation product. After validation is complete, the Company will capitalize commercial supplies as inventory on subsequent production.

Property and Equipment

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

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

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe that there has been any impairment of the carrying value of any long-lived assets as of June 30, 2020.

Research and Development Expenses

Research and development costs are expensed as incurred. 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 drug development. All research and development costs are charged to operations as incurred in accordance with ASC 730, *Research and Development*.

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

Deferred Financing Costs

Costs directly attributable to the Company's senior secured term loan (see Note 8) are deferred and reported as a reduction of the related term loan. These costs represent a 1% facility fee paid directly to the lender, legal fees and other costs related to the term loan and are being amortized over the term of the loan. Amortization of deferred financing costs charged to interest expense was approximately $69 and $92 for the three and six months ended June 30, 2020.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash, cash equivalents and marketable securities. 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.

Warrants

The Company accounts for its warrants to purchase common stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*. On January 1, 2019, the Company adopted the provisions of Accounting Standards Update ("ASU") 2017-11 *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception*, which indicate that a down round feature no longer precludes equity classification when assessing whether an investment is indexed to an entity's own stock. The Company used a modified retrospective approach to adoption, which does not restate its financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $213 with a corresponding adjustment to additional paid-in capital.

The warrants issued in connection with the Company's debt financing completed in February 2015 are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model. These warrants expired without being exercised on February 24, 2020.

In connection with entering into a senior secured term loan facility in February 2020, the Company issued warrants to purchase 1,400,000 shares of its common stock. These warrant instruments qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. See Note 8 for additional information.

Income Taxes

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

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions which prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The

Company has no uncertain tax positions as of June 30, 2020 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to no less than the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company elects to account for forfeitures when they occur. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

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

Net Loss Per Share

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

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share for the three and six months ended June 30, 2020 and 2019, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	June 30,	
	2020	2019
Common stock warrants	1,400,000	242,779
Unvested restricted stock units	159,795	—
Common stock options	8,503,254	7,526,820
Total	10,063,049	7,769,599

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. ASU 2016-13 was adopted by the Company on January 1, 2020 and has no current impact on the Company as we do not have any financial instruments covered by the topic.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying financial statements.

3. Fair Value Measurements

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

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

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

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

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

The following table sets forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of June 30, 2020 and December 31, 2019.

	Level 1	Level 2	Level 3
June 30, 2020			
Assets:			
Cash and cash equivalents	$ 39,446	$ —	$ —
Marketable securities	—	47,789	—
Total assets at fair value	$ 39,446	$ 47,789	$ —

	Level 1	Level 2	Level 3
December 31, 2019			
Assets:			
Cash and cash equivalents	$ 34,479	$ —	$ —
Total assets at fair value	$ 34,479	$ —	$ —

There were no transfers between Level 1, 2 or 3 during 2020 or 2019.

4. Marketable Securities

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

		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
June 30, 2020				
U.S. government obligations (maturing in one year or less)	$ 4,073	$ —	$ —	$ 4,073
Corporate debt securities (maturing in one year or less)	43,706	10		43,716
Total marketable securities	$ 47,779	$ 10	$ —	$ 47,789

The Company holds investment-grade marketable securities, and none were in a continuous unrealized loss position for more than twelve months as of June 30, 2020. Marketable securities include $0.2 million of accrued interest at June 30, 2020.

5. **Prepaid Expenses**

Prepaid expenses consist of the following:

	June 30, 2020	December 31, 2019
Prepaid insurance	$ 1,289	$ 656
Other	238	184
Total prepaid expenses	$ 1,527	$ 840

6. **Accrued Liabilities**

Accrued liabilities consist of the following:

	June 30, 2020	December 31, 2019
Employee bonuses	$ 674	$ 1,437
Accrued professional fees and other	616	367
Total accrued liabilities	$ 1,290	$ 1,804

7. **Leases**

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The Company adopted ASU No. 2016-02 on January 1, 2019. The Company recorded a lease asset and lease liability of approximately $0.3 million on its balance sheet as of January 1, 2019, with no material impact on its statement of operations.

The Company has no finance leases and one operating lease for office space in Princeton, NJ. Operating lease expense was $48 and $96 for the three and six months ended June 30, 2020.

Operating cash flows used for operating leases during the three and six months ended June 30, 2020 were $46 and $90, respectively. As of June 30, 2020, the weighted-average remaining lease term was 0.42 years and the weighted average discount rate was 21.2%.

Future minimum lease payments under non-cancellable leases as of June 30, 2020 were as follows:

Remainder of 2020	$ 86
Total	$ 86
Less: Interest	(4)
Present value of lease liability	$ 82

8. **Credit Agreement and Guaranty**

On February 10, 2020 (the “Closing Date”), the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party (“Perceptive”), for a senior secured term loan credit facility of up to $35.0 million, (the “Perceptive Credit Agreement”). A first tranche of $5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15.0 million was funded as a result of the approval of Twirla by the FDA. Another $15.0 million tranche will be available to the Company based on the achievement of certain revenue milestones.

The facility will mature on February 10, 2024 (“Maturity Date”). The Company is scheduled to make interest-only payments on the loans under the Perceptive Credit Agreement until February 10, 2023. Thereafter, the

Company is required to make monthly principal payments in an amount equal to 1.50% of the principal amount of the outstanding loans until February 10, 2024.

Borrowings under the Perceptive Credit Agreement will accrue interest at an annual rate equal to the London Interbank Offered Rate for one-month deposits ("LIBOR") plus 10.25%, provided that LIBOR shall not be less than 1.5%. The rate of interest in effect as of the Closing Date and at June 30, 2020 was 11.75%. Upon the occurrence and during the continuance of any event of default under the Perceptive Credit Agreement, the interest rate automatically increases by 3.0% per annum.

The Company may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment fee of 10.0% if such prepayment occurs on or prior to February 10, 2021; 8.0% if such prepayment occurs after February 10, 2021 and on or prior to February 10, 2022; 4.0% if such prepayment occurs after February 10, 2022 and on or prior to February 10, 2023; and 2.0% if such prepayment occurs after February 10, 2023 and prior to February 10, 2024.

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

The Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restrict or limit the ability of the Company to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's business activities; make certain investments or restricted payments (each as defined in the Perceptive Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting the Company's ability to make loan repayments under the Perceptive Credit Agreement. In addition, 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 March 31, 2021, report revenues for the trailing 12-month period that exceed the amounts set forth in the Perceptive Credit Agreement, which range from $3.8 million for the fiscal quarter ending March 31, 2021 to $93.5 million for the fiscal quarter ending December 31, 2023. At June 30, 2020, the Company was in compliance with all of the covenants contained in the Perceptive Credit Agreement.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 1,400,000 shares of the Company's common stock (together, the "Perceptive Warrants"). The first warrant is exercisable for 700,000 shares of common stock at an exercise price of $3.74 per share. The second warrant is exercisable for 700,000 shares of common stock at an exercise price of $4.67 per share. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections. The Perceptive Warrants are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of the Company's common stock as a result of the exercise. The Perceptive Warrants expire on February 10, 2027.

The Company allocated the proceeds of $20.0 million in accordance with ASC 470 based on the relative fair values of the debt and warrants. The relative fair value of the 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 Company's warrants issued to Perceptive include (i) volatility (70.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 3-year life), (iii) strike prices of $3.74 and $4.67 for the common stock warrants, (iv) fair value of common stock ($4.01) and (v) expected life (7 years). The fair value of the 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.

	June 30, 2020
Notes payable	$ 20,000
Debt issuance costs	(967)
Warrant discount	(3,258)
Long-term debt	$ 15,775

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 $303 and $404 for the three and six months ended June 30, 2020.

9**. Stockholders' Equity**

Shelf Registration Statement

On November 2, 2018, 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 $100.0 million (the "2018 Shelf Registration Statement"). On November 14, 2018, the 2018 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 2018 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

Public Offerings

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

In August 2019, the Company completed a public offering of 14,526,315 shares of its common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $12.7 million.

Private Placement

In March 2019, the Company completed a private placement of 8,426,750 shares of common stock at $0.93 per share. Proceeds from the Company's private placement, net of offering costs were approximately $7.8 million.

ATM Sales Agreement

In January 2019, the Company entered into a common stock sales agreement (the "Sales Agreement") under which the Company may sell up to an aggregate of $10.0 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 3% of the gross proceeds of any common stock sold under the Sales Agreement. During the three months ended June 30, 2019, the Company issued and sold 992,072 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $1.4 million. During the six months ended June 30, 2019, the Company issued and sold 1,658,046 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $2.2 million. The Company terminated the Sales Agreement on July 31, 2019.

Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 139	$ 159	$ 337	$ 310
General and administrative	700	320	1,123	659
Total	$ 839	$ 479	$ 1,460	$ 969

10. Accumulated Other Comprehensive Income

The change in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the six months ended June 30, 2020 is summarized below:

	Unrealized Gain on Marketable Securities
Balance at December 31, 2019	$ —
Other comprehensive income	10
Balance at June 30, 2020	$ 10

No amounts were classified out of accumulated other comprehensive income during the six months ended June 30, 2020.

11. Income Taxes

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

12. 2019 Retention Plan

In July 2019, the Company adopted a retention plan (the "2019 Retention Plan") for all employees (with the exception of the Chairman and Chief Executive Officer) in order to induce such employees to remain employed by the Company through at least the extended PDUFA goal date of February 14, 2020.

Each employee who participated in the 2019 Retention Plan and remained continuously employed by the Company through the approval of Twirla was to be paid a lump-sum cash payment in an amount determined for each eligible employee by the Compensation Committee at the time of the adoption of the 2019 Retention Plan. If an eligible employee terminated employment prior to the approval for any reason, no such retention payment was payable to the eligible employee. With the approval of Twirla in February, the cash portion of the 2019 Retention Plan in the amount of approximately $0.3 million was expensed and paid to each eligible employee in February 2020.

All employees (with the exception of the Chairman and Chief Executive Officer) who were employed by the Company as of July 3, 2019 were also granted a stock option to purchase the number of shares of common stock as approved by the Compensation Committee, with a per share exercise price of $1.48, representing the closing price of the Company's common stock as reported by Nasdaq on the date of grant. For each option, 50% of the option vested on July 3, 2020 and the remaining 50% will vest on December 31, 2020.

In addition, the vesting schedule for the stock options granted in January 2019 was amended for all employees (with the exception of the Chairman and Chief Executive Officer) holding such options who were employed on July 3, 2019 as follows: 50% of the option vested on January 29, 2020, 25% vested on June 30, 2020 and the remaining 25% will vest on December 31, 2020.

13. Commitments and Contingencies

The Company has several firm purchase commitments, primarily related to the manufacture and supply of Twirla and the supply of a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services. Future firm purchase commitments under these agreements, the last of which ends in 2030, total $16.1 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 into 2021or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company's operations or its financial position. As of June 30, 2020, 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 February 20, 2020. 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, as may be updated by our Quarterly Reports on Form 10-Q and the other reports we file from time to time with the SEC, 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. Twirla® and our potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Twirla, our first and only approved product, is a once-weekly prescription combination hormonal contraceptive patch. Twirla is designed using our proprietary transdermal patch technology, called Skinfusion®, designed with properties to optimize patch adhesion and patient wearability, which may help support compliance while, for the first time, delivering a dose of estrogen consistent with commonly prescribed combined hormonal contraceptives, or CHCs. We believe there is an unmet market need for a contraceptive patch that is designed to deliver approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient dosage form that may support compliance in a non-invasive fashion.

Twirla was approved for sale in the United States on February 14, 2020 as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. Based on the observed relationship between efficacy and BMI in a Phase 3 clinical trial, Twirla's limitation of use instructs healthcare providers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2 because compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs.

As part of Twirla's approval, the FDA is requiring us to conduct a long-term prospective, observational post-marketing study comparing the risks for VTE and ATE in new users of Twirla to new users of other CHCs. The FDA's requirement for Twirla is similar to another post-marketing study requirement for a recently approved CHC. The final study report for the Twirla post-marketing study is scheduled to be submitted to the FDA in November 2032, with interim safety data reporting to the FDA due in November 2026. We have also agreed to a small post-marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla. The PMC study is similar to residual drug studies requested of patch developers in the FDA's November 2019 draft guidance

entitled “Transdermal and Topical Delivery Systems—Product Development and Quality Considerations.” We are evaluating the design and cost of these post-marketing studies.

With the approval of Twirla we are now focused on our transition from a clinical development stage company to a commercial company. We plan to continue the implementation of our commercialization plan for Twirla and to manage the growth of our company. Our near-term plan for the commercialization of Twirla includes:

Activity	Expected Timing
Conduct activities to obtain coverage and reimbursement of Twirla from third-party payors in the United States.	On-going
Hiring of contract sales force	Initial hires began in Second Quarter 2020 and will continue through the Third Quarter 2020.
Complete validation of the commercial manufacturing process consistent with our approved marketing application	Second Half 2020 with first shipment of product in the Fourth Quarter 2020.

Our short-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. To that end, we completed the pre-validation process and began our validation of the commercial manufacturing process in the first half of 2020. We plan to manufacture three validation batches of Twirla and complete the process in the second half of 2020. We intend to ship product to wholesalers in the fourth quarter of 2020. At the same time, we will prepare for the availability of commercial product supply. We also expect to explore the advancement of our existing pipeline and its possible expansion through business development activities.

In the first quarter of 2020, we began the pre-validation work on our commercial manufacturing process for Twirla, and entered into an agreement with our third-party logistics provider for Twirla distribution services.

In the second quarter of 2020, we continued to execute on our plan to engage with third party payors to gain coverage and reimbursement for Twirla, completed production of the planned manufacturing pre-validation batch of Twirla and began the validation process. On April 30, 2020, we entered into a definitive agreement with our contract manufacturer, Corium, for the commercial manufacture and supply of Twirla. In addition, on April 30, 2020, we entered into an agreement with inVentiv Commercial Services, a Syneos Health group company, or inVentiv, to provide a contract sales force and related sales services for Twirla. We have started hiring and training an initial sales team, which we estimate to be in the range of 70 to 100 persons. We continue to monitor the current public health crisis and evaluate with our partner inVentiv the exact size and specific implementation plan for our sales team, including the use of remote detailing services.

A summary of our current priorities are as follows:

- Successfully complete the validation process for the commercial manufacturing of Twirla;
- Obtain coverage and reimbursement for Twirla in the United States from third-party payors;
- Implement our commercialization plans for Twirla to ensure a successful launch in the United States, including building a sales and marketing team and implementing a healthcare compliance program;
- Establish a supply chain for Twirla that will support commercialization across the United States at launch;
- Complete the design and protocol of the FDA-required post-marketing long-term observational study comparing risks for VTE and ATE in new users of Twirla to new users of other CHCs;
- Explore the advancement of our existing pipeline and its possible expansion through business development activities.

It should be noted that current public health threats could adversely affect our ongoing or planned business operations. In particular, the World Health Organization has declared the outbreak of a novel strain of coronavirus, now referred to as COVID-19, a pandemic resulting in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, restrictions on public gatherings, and stay at home

orders. The effect of these orders, government imposed quarantines and measures we have taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt our business and could delay our commercialization timeline. 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. While it is unknown how long these conditions will last and what the complete effect will be on the Company, to date, we have been able to continue to execute our plans according to the related timelines. We will continue to closely monitor events as they develop and evaluate alternative, mitigating measures we can implement if needed.

Financial Overview

Since our inception in 1997, we have devoted substantial resources to developing and seeking regulatory approval for Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We incurred research and development expenses of $9.9 million, $9.8 million and $14.4 million during the years ended December 31, 2019, 2018 and 2017, respectively. We incurred research and development expenses of $3.7 million and $1.8 million for the three months ended June 30, 2020 and 2019, respectively. We incurred research and development expenses of $6.8 million and $4.7 million for the six months ended June 30, 2020 and 2019, respectively. While we anticipate that a portion of our operating expenses will continue to be related to research and development based on the pre-validation manufacturing activities related to Twirla, and as we conduct our Phase 4 study and plan the development of our pipeline, we expect our operating expenses to substantially shift towards commercialization. A substantial amount of our resources are currently dedicated to completing manufacturing validation and commercializing Twirla.

Moving forward, we plan to monitor our spending closely. We expect operating expenses for the full year 2020 to be in the range of $52.0 million to $56.0 million, with general and administrative expenses accounting for approximately 70% of the spending as we build out our commercial infrastructure. Included in operating expense is $2.5 million to $3.0 million of non-cash stock compensation expense. Based on conversations with suppliers and our current expectations, net revenue in the fourth quarter of 2020, reflecting the initial launch of Twirla, is expected to be in the range of $1.0 million to $2.0 million. Based on our current business plan and our ability to launch Twirla, we believe that our cash, cash equivalents and marketable securities as of June 30, 2020, will be sufficient to meet our projected operating requirements through the end of 2021. 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 funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of June 30, 2020 and December 31, 2019, we had $87.2 million and $34.5 million in cash, cash equivalents and marketable securities, respectively.

In January 2019, we entered into a common stock sales agreement, or the 2019 ATM Agreement, under which we were authorized to sell up to an aggregate of $10.0 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 3% of the gross proceeds of any common stock sold under this agreement. During the year ended December 31, 2019, we issued and sold a total of 1,801,528 shares of common stock under the 2019 ATM Agreement resulting in net proceeds of approximately $2.5 million. We terminated the 2019 ATM Agreement on July 31, 2019.

In March 2019, we completed a private placement of 8,426,750 shares of common stock at $0.93 per share. Proceeds from the private placement, net of offering costs, were approximately $7.8 million.

In August 2019, we completed a public offering of 14,526,315 shares of common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $12.7 million.

In November 2019, we entered into a second ATM Agreement, or the Second 2019 ATM Agreement, under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $20.0 million from time to time. We agreed to pay a commission of 3% of the gross proceeds from the sales of our

common stock under the Second 2019 ATM Agreement. In the year ended December 31, 2019, we issued and sold 10,440,908 shares of common stock under the Second 2019 ATM Agreement, representing all the capacity of Second ATM Agreement, resulting in net proceeds of approximately $19.3 million.

In February 2020, we entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, or Perceptive, for a senior secured term loan facility of up to $35 million, which we refer to as the Perceptive Credit Agreement. A first tranche of $5 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15 million was funded as a result of the approval of Twirla by the FDA. Another $15 million tranche will be available upon the achievement of certain revenue milestones. The facility will be interest only until the third anniversary of the closing date.

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

We have not generated any revenue and have never been profitable for any year. Our net loss was $18.6 million, $19.8 million and $28.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. Our net loss was $10.8 million and $3.5 million for the three months ended June 30, 2020 and 2019, respectively. Our net loss was $18.7 million and $8.2 million for the six months ended June 30, 2020 and 2019, respectively. We expect to incur increased expenses and increasing operating losses for the foreseeable future as we commercialize Twirla. This includes completing the qualification and validation of our commercial manufacturing process, initiating pre-launch commercial activities, commercially launching Twirla, advancing our other potential product candidates and expanding our research and development programs.

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 complete the validation of Corium's commercial manufacturing line for Twirla and be capable of supplying projected commercial quantities of Twirla. We expect to incur significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing, distribution, medical affairs and compliance functions.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. In the future, we may generate revenue from product sales, license fees, milestone payments and 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 complete the development of Twirla or any other potential 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, will be adversely affected.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities. Research and development expenses consist primarily of costs incurred for the development of Twirla and other current and future potential product candidates, and include:

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

- costs associated with equipment scale-up required for commercial production.

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

Research and development activities are central to our business model and to date, our research and development expenses have related primarily to the development of Twirla. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Twirla.

For the three months ended June 30, 2020 and 2019, our research and development expenses were approximately $3.7 million and $1.8 million, respectively. For the six months ended June 30, 2020 and 2019, our research and development expenses were approximately $6.8 million and $4.7 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended June 30, (In thousands)		Six months ended June 30, (In thousands)	
	2020	2019	2020	2019
Clinical development	$ 451	$ 83	$ 628	$ 1,581
Regulatory	105	429	334	690
Personnel related	368	449	860	940
Manufacturing—commercialization	2,598	659	4,666	1,139
Stock-based compensation	139	159	337	310
Total research and development expenses	$ 3,661	$ 1,779	$ 6,825	$ 4,660

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 other 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 product candidates that obtain regulatory approval.

The duration, costs and timing of clinical trials and development of our other potential product candidates in addition to conducting required post-marketing studies for Twirla will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, obtaining additional capital, and significant and changing government regulation. For the foreseeable future, we expect the current public health crisis to have an effect on the conduct of clinical trials. In addition, the probability of success for the development of any of our product candidates 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, as well as an assessment of each product candidate's commercial potential. Substantially all of our resources are currently dedicated to commercializing Twirla.

General and Administrative Expenses

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

For the three months ended June 30, 2020 and 2019, our general and administrative expenses totaled approximately $6.4 million and $1.8 million, respectively. For the six months ended June 30, 2020 and 2019, our general and administrative expenses totaled approximately $10.8 million and $3.6 million, respectively. With the recent approval of Twirla, we intend to commercialize Twirla in the United States through a contract sales force. We anticipate that our general and administrative expenses will increase in the future with the commercialization of Twirla. These increases will likely include increased selling and marketing costs, including payroll and operating costs, related to the commercial launch of Twirla, legal and accounting services, stock registration and printing fees, addition of new personnel to support compliance and communication needs, increased insurance premiums, outside consultants and investor relations.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

	Three Months Ended June 30,		
	2020	2019	Change
Operating expenses:			
Research and development	$ 3,661	$ 1,779	$ 1,882
General and administrative	6,378	1,768	4,610
Total operating expenses	10,039	3,547	6,492
Other income (expense)			
Interest income	115	63	52
Interest expense	(902)	—	(902)
Total other income (expense), net	(787)	63	(850)
Loss before benefit from income taxes	(10,826)	(3,484)	(7,342)
Net loss	$ (10,826)	$ (3,484)	$ (7,342)

Research and development expenses. Research and development expenses increased by $1.9 million, or 106%, from $1.8 million for the three months ended June 30, 2019 to $3.7 million for the three months ended June 30, 2020. This increase in research and development expenses was primarily due to the following:

- an increase in manufacturing commercialization expenses of $1.9 million for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019. This increase reflects costs to complete manufacturing development, process improvements, and pre-validation work for the commercial manufacturing of Twirla by Corium, our contract manufacturer.

General and administrative expenses. General and administrative expenses increased by $4.6 million, or 261%, from $1.8 million for the three months ended June 30, 2019 to $6.4 million for the three months ended June 30, 2020. This increase in general and administrative expense was primarily due to:

- an increase in commercial development expense of $3.2 million for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019. This increase relates to the resumption of our pre-

commercialization activities such as brand building, advocacy, market research and consulting. It also includes the initial costs for our contract sales force;

- an increase in salaries and wages of $0.3 million, due to increased headcount for the three months ended June 30, 2020;
- an increase in professional fee expense of $0.5 million primarily related to recruiting fees and increased use of financial consultants;
- an increase in stock compensation expense of $0.4 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019. This increase is primarily the result of new hires and higher stock prices associated with 2020 stock option grants as compared to 2019 stock option grants; and
- an increase in D&O insurance of $0.1 million for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019.

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

Interest expense. Interest expense is attributable to our term loan with Perceptive for the three months ended June 30, 2020. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense increased by $0.9 million, from $0 for the three months ended June 30, 2019 to $0.9 million for the three months ended June 30, 2020.

Comparison of the Six Months Ended June 30, 2020 and 2019

	Six Months Ended June 30,		
	2020	2019	Change
	(In thousands)		
Operating expenses:			
Research and development	$ 6,825	$ 4,660	$ 2,165
General and administrative	10,831	3,594	7,237
Total operating expenses	17,656	8,254	9,402
Other income (expense)			
Interest income	247	101	146
Interest expense	(1,300)	—	(1,300)
Total other income (expense), net	(1,053)	101	(1,154)
Loss before benefit from income taxes	(18,709)	(8,153)	(10,556)
Benefit from income taxes	—	477	(477)
Net loss	$ (18,709)	$ (8,153)	$ (10,556)

Research and development expenses. Research and development expenses increased by $2.2 million, or 46.5%, from $4.7 million for the six months ended June 30, 2019 to $6.8 million for the six months ended June 30, 2020. This increase in research and development expenses was primarily due to the following:

- an increase in manufacturing commercialization expenses of $3.5 million for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. This increase reflects costs to complete manufacturing development, process improvements, and pre-validation work for the commercial manufacturing of Twirla by Corium, our contract manufacturer;

- a decrease in clinical development expenses of $1.0 million for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. This decrease is primarily related to decreased costs associated with the comparative wear study of Twirla and Xulane, which was initiated and completed during the six months ended June 30, 2019; and

- a decrease in regulatory expenses of $0.4 million for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. This decrease is primarily related to decreased costs associated with preparation for the FDA advisory committee meeting in the fourth quarter of 2019.

General and administrative expenses. General and administrative expenses increased by $7.2 million, or 201%, from $3.6 million for the six months ended June 30, 2019 to $10.8 million for the six months ended June 30, 2020. This increase in general and administrative expense was primarily due to:

- an increase in commercial development expense of $4.8 million for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. This increase relates to the resumption of our pre-commercialization activities such as brand building, advocacy, market research and consulting. It also includes the initial costs for our contract sales force;

- an increase in salaries and wages of $0.6 million, due to increased headcount and retention bonuses expensed and paid in the six months ended June 30, 2020;

- an increase in professional fee expense of $0.7 million primarily related to recruiting fees and increased use of financial consultants;

- an increase in stock compensation expense of $0.5 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. This increase is primarily the result of new hires and higher stock prices associated with 2020 stock option grants as compared to 2019 stock option grants; and

- an increase in D&O insurance of $0.2 million for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019.

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

Interest expense. Interest expense is attributable to our term loan with Perceptive for the six months ended June 30, 2020. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense increased by $1.3 million, from $0 for the six months ended June 30, 2019 to $1.3 million for the six months ended June 30, 2020.

Liquidity and Capital Resources

At June 30, 2020, we had cash, cash equivalents and marketable securities totaling $87.2 million. We invest a portion of our cash equivalents and marketable securities in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

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

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (14,649)	$ (7,339)
Net cash used in investing activities	(48,044)	—
Net cash provided by financing activities	67,660	10,074
Net increase in cash and cash equivalents	$ 4,967	$ 2,735

Operating Activities

We have incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as our lead product candidate, Twirla, was being developed. Net cash used in operating activities was $14.6 million for the six months ended June 30, 2020 and consisted primarily of a net loss of $18.7 million, offset by non-cash stock-based compensation expense of $1.5 million, $0.5 million of other non-cash charges, and a net increase in operating assets and liabilities of $2.1 million. Net cash used in operating activities was $7.3 million for the six months ended June 30, 2019 and consisted primarily of a net loss of $8.2 million, which was offset by non-cash stock-based compensation expense of $1.0 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2020 and 2019 was $48.0 million and $0, respectively. Cash used in investing activities for the six months ended June 30, 2020 primarily represents purchases of marketable securities totaling $47.8 million.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2020 was $67.7 million which primarily represented net proceeds of $48.4 million received from the issuance of 17,250,000 shares of our common stock through a public offering, and proceeds of $20.0 million from the Perceptive term loan. These proceeds were partially offset by debt financing costs of $1.0 million. Net cash provided by financing activities for the six months ended June 30, 2019 was $10.1 million which primarily represented net proceeds of $7.8 million received from the issuance of 8,426,750 shares of our common stock in a private placement and net proceeds of approximately $2.2 million from the sale of 1,658,046 shares of our common stock through an ATM sales program.

Funding Requirements and Other Liquidity Matters

Based on our current business plan and ability to get Twirla launched, we believe that our cash, cash equivalents and marketable securities as of June 30, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. As we have limited funding capacity remaining under our 2018 Shelf Registration Statement, we are currently evaluating financing alternatives to meet our future cash needs. Specifically, we plan to file a new universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, and debt securities. 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 expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- establish a sales and marketing infrastructure to commercialize Twirla in the United States;
- continue the validation process related to Corium’s manufacturing facility in preparation for commercial operations;
- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Contractual Obligations and Commitments

In April 2020, we entered into a Manufacturing and Commercialization Agreement (“the Commercialization Agreement”) with Corium, Inc. for the manufacture and supply of Twirla. Under the terms of the Commercialization Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The

Commercialization Agreement includes a fixed price per unit for two years depending on annual purchase volume and quarterly minimum purchase amounts. As of June 30, 2020, the amount committed for purchases through 2020 is $5.0 million.

In April 2020, we entered into a project agreement (the "Project Agreement") with inVentiv Commercial Services, LLC ("inVentiv") under which inVentiv will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services and training services with respect to Twirla to the Company in exchange for an up-front implementation fee and a fixed annual fee. The Project Agreement has an initial term of two years from the date of the first activity undertaken by inVentiv to detail Twirla (the "Deployment Date") unless earlier extended upon the mutual written agreement of the Parties. We may terminate the Project Agreement for any reason upon timely notice after the first anniversary of the Deployment Date; provided, however, that if we terminate the Project Agreement prior to the eighteen month anniversary of the Deployment Date, we will be obligated to pay inVentiv a termination fee, the amount of which varies depending on the date of termination. As of June 30, 2020, the minimum amount committed totals $11.1 million.

The following table summarizes our contractual obligations and commitments as of June 30, 2020 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(In thousands)		
Long-term Debt	$ 20,000	$ —	$ 1,500	$ 18,500	$ —
Operating Lease	87	87	—	—	—
Purchase Obligations	16,099	14,055	2,044		
Total	$ 36,186	$ 14,142	$ 3,544	$ 18,500	$ —

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey, which is set to expire in November 2020, however we currently plan to enter into an extension for this location through May 31, 2021. We are currently seeking new facilities or considering expanding existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Shelf Registration Statement

On November 2, 2018, 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 $100.0 million, which we refer to as the 2018 Shelf Registration Statement. On November 14, 2018, the 2018 Shelf Registration Statement was declared effective by the SEC.

On January 23, 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $10.0 million of shares of our common stock. In the year ended December 31, 2019, we sold a total of 1,801,528 shares of our common stock under the ATM program resulting in net proceeds of approximately $2.5 million.

In August 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering a public offering of 14,526,315 shares of common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses, were approximately $12.7 million.

On November 8, 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $20.0 million of shares of our common stock. In the year ended December 31, 2019, we sold a total of 10,440,908 shares of our common stock under this ATM program, representing all the capacity, resulting in net proceeds of approximately $19.3 million.

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

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

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

We had cash, cash equivalents and marketable securities of $87.2 million and $34.5 million at June 30, 2020 and December 31, 2019, respectively, consisting primarily of funds in cash, money market accounts and corporate and government debt securities. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows are subject to fluctuations due to changes in interest rates. We do not believe that we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a 1% unfavorable change in interest rates would not have a material effect on interest expense for the six months ended June 30, 2020.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the six months ended June 30, 2020.

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 factors should be considered in addition to our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2019:

Risks Related to our Business Operations and Industry

The ongoing outbreak of the novel strain of coronavirus, or COVID-19, or other similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including on our anticipated commercial launch of Twirla®.

In December 2019, a novel strain of coronavirus (SARS-CoV-2), now referred to as COVID-19, surfaced in Wuhan, China. Since then, the virus has spread globally to multiple countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive on many aspects of society, and it has resulted in and will likely continue to result in significant disruptions to global business activities and capital markets around the world.

As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely affect our business, including our plans to clinically develop and commercialize our products. We may not be able to meet expectations with respect to our anticipated commercial launch of Twirla, our first approved product, which we plan to begin manufacturing on a commercial scale in the second half of 2020. For example, global business interruptions resulting from COVID-19 may adversely impact our third-party manufacturer, Corium, whom we rely upon for the manufacture of Twirla, as well as its suppliers of raw materials. As a result, we may not be able to obtain sufficient quantities of Twirla, which could impair our ability to commercialize Twirla and conduct the post-marketing studies requested by the U.S. Food and Drug Administration, or the FDA, in connection with the approval of Twirla. In addition, if there are continued or future disruptions, our third-party manufacturers may not be able to supply our other potential product candidates, which would adversely affect our research and development activities.

Further, many jurisdictions have implemented travel restrictions and expansive social distancing orders. These measures may have a material adverse impact on the third-party consultants who assist us with our sales and marketing functions, as well as on our ability to develop our own sales and marketing infrastructure. For example, such social distancing orders could limit the ability of sales representatives to interact with healthcare providers and also restrict the ability of patients to interact with their healthcare providers. This could negatively affect our ability to commercialize Twirla as well as market our other potential product candidates.

Delays in the ability to manufacture commercial supplies of Twirla and to implement a sales force for Twirla could also adversely affect our financial position. Based on our current business plan and ability to get Twirla launched, we believe that our cash, cash equivalents and marketable securities as of June 30, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. If the COVID-19 outbreak 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. However, significant delays in the timelines to manufacture commercial supply of Twirla, and/or the ability to implement a salesforce that can engage with healthcare providers could delay, or even prevent, our ability to generate revenue, which in turn could require us to raise additional capital if the revisions to our commercial plans are inadequate or management determines that it is necessary.

Additionally, certain of our clinical activities, including the post-marketing studies requested by the FDA in connection with the approval of Twirla may be delayed or interrupted, compromising our ability to maintain regulatory approval for Twirla and our future ability to obtain marketing approval for our other potential product candidates. Any of these factors could significantly impair our ability to generate revenue in the future and to attain and maintain profitability.

We are continuing to monitor and assess the real and potential effects of the COVID-19 pandemic on our business, including with respect to our expected timing for commercialization of Twirla. However, the ultimate extent to which COVID-19 impacts our business will depend upon future developments which are highly uncertain and cannot be accurately predicted at this time, such as the ultimate geographic spread of the virus, the severity of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or mitigate its impact, and the effectiveness of actions taken in the United States and other countries to treat the disease.

Item 6. Exhibits.

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

Exhibit Index

Exhibit Number	Description of Document
10.1*	Project Agreement, dated April 30, 2020, by and between the Registrant and inVentiv Commercial Services, LLC.
10.2*	Master Service Agreement, dated October 11. 2017, by and between the Registrant and inVentiv Commercial Services, LLC.
10.3	First Amendment to Master Service Agreement, dated April 30, 2020, by and between the Registrant and inVentiv Commercial Services, LLC.
10.4*	Manufacturing and Commercialization Agreement, dated April 30, 2020, by and between the Registrant and Corium, Inc.
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	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders' Equity, (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.

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

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 11, 2020

Agile Therapeutics, Inc.

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

Date: August 11, 2020

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

Exhibit 10.1

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

PROJECT AGREEMENT
(DETAILING – FIELD TEAM AND TELESOLUTIONS)

This Project Agreement (this "Project Agreement") is made as of April 30, 2020 (the "Effective Date") by and between inVentiv Commercial Services, LLC, a Syneos Health™ group company, with an office located at 500 Atrium Drive, Somerset, NJ 08873 ("Syneos Health") and Agile Therapeutics, Inc. with an office located at 100 Poor Farm Road, Princeton, New Jersey 08540 ("Client"). Client and Syneos Health may each be referred to herein as a "Party" and collectively, the "Parties".

RECITALS

A. Client and Syneos Health have entered into a Master Service Agreement dated as of October 11, 2017 (the "MSA").

B. Client and Syneos Health desire to enter into this Project Agreement pursuant to which Syneos Health shall provide Syneos Health sales representatives, district managers and telesolutions agents to provide detailing services as set forth more fully in Exhibit A and B attached hereto.

1. Interpretation and Construction

(a) The Parties confirm that the MSA shall govern the relationship between the Parties. Unless otherwise specifically set forth herein, in the event of a conflict or inconsistency between the terms and conditions set forth in the MSA and the terms and conditions set forth in this Project Agreement, the terms and conditions set forth in this Project Agreement shall take precedence, govern and control.

(b) The Parties hereby acknowledge that the terms set forth in the MSA are incorporated herein by reference, as if fully set forth at length therein.

2. The Services

A description of the detailing services (the "Detailing Services") is set forth on Exhibit A attached hereto and made a part hereof. A description of sales operations, implementation and on-going services for the field and telesolutions team (the "Sales Operations Services") is set forth on Exhibit A-1 attached hereto and made a part hereof. A description of the telesolutions services (the "Telesolutions Services") is set forth on Exhibit B attached hereto and made a part hereof. A description of the compliance services (the "Compliance Services") is set forth on Exhibit C attached hereto and made a part hereof. A description of the sample accountability services (the "SA Services") is set forth on Exhibit D attached hereto and made a part hereof. A description of the training services (the "Training Services") is set forth on Exhibit E attached hereto and made a part hereof (the Training Services, Compliance Services, Sales Operations Services and, collectively with the Detailing Services, the "Services").

3. The Term

This Project Agreement shall be in effect as of the Effective Date and shall remain in effect until the second anniversary of the Deployment Date (as defined in Exhibit A), unless extended as provided herein (the "Term") or unless earlier terminated as set forth below. The period from the Effective Date through the day prior to the one year anniversary of the Deployment Date shall be referred to herein as "Year One," and the period from the one year anniversary of the Deployment Date through the day prior to the second anniversary of the Deployment Date shall be referred to herein as "Year Two." The Term may be extended for additional periods of one (1) year (each an "Additional Term") upon the mutual written agreement of the Parties not less than [***] before the end of the Term or any Additional Term.

4. Termination

(a) Notwithstanding Section 12(a)(iii) of the MSA, either Party may terminate this Project Agreement by providing the other Party with [***] prior written notice; provided, however, that such termination by Client may not occur [***], and if such termination by Client occurs [***], Client shall pay Syneos Health a termination fee based on the actual date of termination according to the following table schedule:

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

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

[***]	[***]

(b) In the case of termination of this Project Agreement by Client (except for termination by Client pursuant to Section 12(a) (ii),(iii) or (iv) of the MSA), a Scale Down, or at the end of the Term (or any Additional Term), Client shall (in addition to all other payment obligations under this Project Agreement) promptly pay (or if paid by Syneos Health, promptly reimburse) Syneos Health for: the amount due any lessor or rental agent of the fleet vehicles ("Fleet Vehicles") and information technology equipment (i.e. laptops and iPads) ("IT Equipment") leased or owned by Syneos Health and provided to members of the Sales Team (as defined in Exhibit A) or the Telesolutions Team (as defined in Exhibit B) (collectively, the "Project Team"), for any early termination of the lease or rental agreement. Client may elect to:

(i) either, (i) transfer the IT Equipment to Client and pay an amount equal to the net book value (if any) of the IT Equipment on the books of Syneos Health at the time of the transfer event, or, (ii) dispose of the IT Equipment and pay Syneos Health the net loss on such IT Equipment. Net loss is calculated as the remaining net book value of such IT Equipment, plus any amounts due by Syneos Health in connection with the lease or rental termination and costs associated with the storage and disposal of said IT Equipment.

(ii) dispose of the Fleet Vehicles and pay Syneos Health the net loss on such Fleet Vehicles. Net loss is calculated the difference between the remaining net book value of such Fleet Vehicles and the actual net price received by Syneos Health for the disposal of such Fleet Vehicles, plus any amounts due by Syneos Health in connection with the lease or rental termination and costs associated with the transportation, storage, and disposal of said Fleet Vehicles.

(c) Notwithstanding Section 4(a) of this Project Agreement, Client may immediately terminate this Project Agreement upon prior written notice to Syneos Health, in the event that the United States Food and Drug Administration (the "FDA")has caused the withdrawal from the market of the Product, and such withdrawal causes or will cause this Project Agreement and/or Client's commercialization of the Product to no longer be commercially viable (such commercial viability to be mutually determined by the Parties in good faith); provided, however Client shall pay Syneos Health for all fees and expenses under this Project Agreement incurred through the effective date of such termination.

(d) In the event of a change of control, or assignment to a successor in interest in accordance with Section 14(b) of the Agreement, the assignee or successor in interest may terminate this Project Agreement by providing Syneos Health with [***] prior written notice; provided however, that if such termination by assignee or successor in interest occurs [***], assignee shall pay for all fees and noncancelable expenses under this Project Agreement incurred through the effective date of such termination and assignee shall pay a termination fee for each Sales Representative and Telesolutions Agent allocated hereunder in accordance with the below table schedule:

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

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

5. Conversion

(a) Notwithstanding Section 7 of the MSA, during the Term (or any Additional Term), Client may solicit, employ or retain the Syneos Health Sales Representative(s), DM(s) or Telesolutions Agent(s) performing Services hereunder (each a "Conversion") upon [***] prior written notice to Syneos Health. In the event of a Conversion, Client may elect to either:

(i) backfill the position subject to such Conversion as to maintain the number of Syneos Health Sales Representatives and DMs as outlined in Exhibit A and Telesolutions Agent as outlined in Exhibit B and pay Syneos Health a recruitment fee for replacement/backfill per the table below; or

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

(ii) Scale Down the respective position pursuant to the terms of Section I(c)(ii) of Exhibit F and pay Syneos Health the Conversion Fee outlined in the below table based on the actual date of such Conversion.

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

(iii) The Parties shall meet to agree upon Project Team composition in the event of conversion.

(b) Client understands and agrees that Syneos Health cannot guarantee that the Syneos Health Sales Representative, DM or Telesolutions Agent will agree to participate in a Conversion.

(c) In the event Client implements a Conversion, the Parties agree that any and all training materials created by Syneos Health, without the use of any Client Confidential Information, and made available to the Syneos Health Sales Representative(s), DM(s) or Telesolutions Agent(s) will be immediately returned to Syneos Health, it being understood and agreed that the Syneos Health proprietary training modules constitute valuable and proprietary information of Syneos Health and are subject to the confidentiality obligations set forth in Section 6 of the MSA. Within [***] of implementing a Conversion, Client shall return to Syneos Health any originals and copies of Syneos Health proprietary training modules, which had been in the possession of the converted Syneos Health Sales Representative, DM or

Telesolutions Agent.

6. Fees

Set forth on Exhibit F are the fees to be paid by Client to Syneos Health for the performance of the Services.

WHEREFORE, the parties hereto have caused this Project Agreement to be executed by their duly authorized representatives on the day and year first above written.

AGILE THERAPEUTICS, INC.	**INVENTIV COMMERCIAL SERVICES, LLC**
By: _____	By: _____
Name:	Name:
Title:	Title:
Date:	Date:

EXHIBIT A
THE DETAILING SERVICES

Syneos Health will provide Client with a field force that shall consist of [***] full-time sales representatives (the "Representatives") consisting of up to [***] senior representatives (the "SR. Reps" and collectively with the Representatives, the "Syneos Health Sales Representatives" or "Sales Representatives") who shall detail Client's Product by making Calls pursuant to a Call Plan on Targets in two waves of deployment as defined in the below table.

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

The Sales Representatives will be managed by up to [***] district managers (the "DMs") who will also be Syneos Health employees. Syneos shall also provide [***] national sales director (the "NSD"). The Sales Representatives, DMs and NSD may be referred to collectively herein as the "Sales Team". For purposes of clarity, the Implementation Fees and Fixed Monthly Fees outlined in Section I(a) and (b) of Exhibit F includes the headcount for Wave One, the Telesolutions Agents, Sales Representatives, and the DMs. The Fees associated with the Wave Two headcount shall be handled as a Scale Up pursuant to Section I(c)(i) of Exhibit F. Syneos Health shall adjust the Fixed Monthly Fee prior to the initial fill of any Project Team member, pro-rated for any partial months, according to the Fixed Monthly Fee table outlined in Exhibit F, Section I(c)(i).

In the event that the Parties desire to increase the type and / or number of Sales Team members providing Services under this Project Agreement they may do so by utilizing a Sales Team Member Request Form (the "Request Form") in a format that is substantially similar to the one attached hereto as Attachment 1. The details set forth in the Request Form shall be mutually agreed upon by the Parties. For clarification, the Request Form may not be used in those situations where it is the intent of the Parties to amend terms and conditions of this Project Agreement other than those specific items set forth on the Request Form.

I. ADDITIONAL DEFINED TERMS

(a) "Call" means the activity undertaken by a Sales Representative to detail the Product, further described as a face-to-face presentation by a in Sales Representative to a Target and will include providing the Product Literature (as directed by Client).

(b) "Call Plan" means a plan jointly designed by Client and Syneos Health, which is intended to enhance the efficiency and effectiveness of the Sales Team in making Calls. The Call Plan will be maintained by Syneos Health at its offices with a copy of such Call Plan maintained by Client at its offices, and may be amended or reconfigured from time to time solely at Client's written request (limited quarterly updates are included in the current fee) with Client paying Syneos Health a fee pursuant to the Standard Pricing Table outlined in Exhibit A-1, Section 3.1.1(d)(5), as agreed upon in writing, for the performance of such amendment or reconfiguration services. Client may add products to the call plan, which may be either products owned by the Client or those for which the client has entered into a co-promotion agreement without having an impact on the monthly fees. If a Call Plan requires

amending or reconfiguration a Change of Scope document would be executed by both Parties and the Standard Pricing Table see Exhibit A, Section 3.1.1(d)(5) would apply as applicable.

(c) "Deployment Date" means the date of the first Call by a Syneos Health Sales Representative, which is anticipated by the Parties to be on or about [***]. Notwithstanding the date set forth herein, the Deployment Date will be the actual date of the first Call by a Syneos Health Sales Representative.

(d) "Healthcare Professional" or "HCP" means a person, other than an individual patient, including, without limitation, any medical or health care professional or entity in a position to purchase, lease, recommend, use, influence or arrange for the purchase or lease of, or prescribe the Products with whom Syneos Health Sales Representatives come in contact with in connection with providing the Services hereunder.

(e) "Product" shall mean **Twirla®**.

(f) "Product Literature" shall mean promotional, informative and other written information concerning the Product. All Product Literature shall be prepared and provided by Client. The Syneos Health Sales Representatives shall utilize the Product Literature when making Calls.

(g) "Sales Team Hire Date" means the date the first Syneos Health Sales Representative is assigned to the Sales Team.

(h) "Targets" mean the licensed practitioners who are identified by Client as potential prescription writers and/or customers for the Product as provided by Client to Syneos Health.

II. HIRE STATUS, FLEET, TRAINING AND MEETINGS

(a) Hire Status—Generally. Upon completion and approval by the parties of the field alignment and profile (including approval of the final number of Sales Team members), Syneos Health will commence recruiting and hiring activities for the Sales Team members. In the event that Syneos Health receives notification to commence recruiting and hiring activities with respect to a position or territory, and that position or territory is subsequently cancelled by Client at any time after [***] from the date of such notification, then Client shall pay a cancellation fee to Syneos Health in the amount of [***] for each such cancelled position or territory.

(b) Hire Status—Provisioning. Syneos Health shall provide following:

(i) Salary, benefits, and incentive compensation as agreed by Client to the Sales Team members.

(ii) Fleet Vehicles and fleet management services for the Sales Representatives include the following:

(1) Coordination of department of motor vehicle ("DMV") checks and confirmation of completion for all employees in Fleet Vehicles

(2) Management of vendor involvement for accidents, fuel cards, and insurance

(3) Coordination of delivery of bridge rentals or Fleet Vehicles dependent upon background and DMV check completion, timeline of deployment and vehicle availability

(4) Recommendations for snow belt vehicles as applicable for project

(5) Ordering new vehicles or transfer of existing surplus vehicles dependent upon team size, availability and Client budget

(6) Timely pick-up of fleet vehicles through third-party vendor for terminations and leaves of absence ("LOAs") as appropriate

(iii) The above stated fleet management services shall assume the following:

(1) Timely notification of territory and district locations for vehicle placement

(iv) Human resources management services for the Sales Team to include, but not be limited to, the following:

(1) Creation, distribution, and tracking of offer letters and onboarding documents

(2) Distribution of emails from background and drug screening vendors to complete required data for background screening and drug screen

(3) Tracking of background and drug screening results (follow-up may be required)

(4) New hire orientation

(5) Works with project lead coordination on investigations of policy non-compliance, background and other performance issues

(6) Coordination with leave and benefits administration as required

(7) Delivery of termination notices, participation in notification calls regarding downsizing and conversions

(v) Human resources management services assume the following:

(1) Timely completion of background vendor required information through its link for new hires

(2) Information regarding vacation, incentive compensation, expectations are available for inclusion in the offer letters

(vi) Information technology hardware for the Sales Representatives to include iPads and laptop computers (including sales force automation software) and printers.

(vii) CRM and operational support for the Sales Representatives as further described in Exhibit A-1.

(c) Training - The training responsibilities of the Parties are as follows:

(i) Syneos Health shall be responsible for training members of the Sales Team pursuant to Exhibit E.

(ii) Client shall be responsible for training members of the Sales Team concerning all Product specific information including Product complaint handling procedures, applicable specific Client health care compliance policies and Client customer service policies and procedures, orientation to Client's business, compliance with Applicable Law, and adverse event reporting policies and procedures. The Parties agree to work together to mutually determine if, when, and at what cost additional training shall be provided to members of the Sales Team.

(d) All expenses associated with Plan of Action (POA) meetings and national training meetings shall be pre-approved by Client and be paid for by Client as a pass-through expense or direct billed to Client.

(e) Syneos Health will be responsible for providing credit cards to any Syneos Health Sales Team member as requested by Client who establishes credit-worthiness in accordance with standards established by Syneos Health's corporate credit card provider. Client and Syneos Health shall establish appropriate limitations on the amount of available credit. In the event a Syneos Health Sales Representative is unable to establish credit worthiness, Client shall determine if it nevertheless desires to have a credit card issued to such Syneos Health Sales Representative. All credit card expenses shall be submitted and processed through the Syneos Health expense reimbursement system. In the event of a default on a credit card invoice by any Syneos Health Sales Representative (i.e., the expenses/receipts are not input into the Concur system), Client shall nevertheless reimburse Syneos Health for all business related expenses properly incurred by such field personnel in accordance with the Project Agreement which are substantiated through credit card statement documentation, and not otherwise entered in the expense management system.

III. PERFORMANCE

If Client believes in good faith that the performance of any Syneos Health Sales Team member is unsatisfactory or is not in compliance with the provisions of this Project Agreement, Client shall notify Syneos Health and Syneos Health shall promptly address the performance or conduct of such person in accordance with its internal human resource policies. In the event that Client determines in good faith that a Syneos Health Sales Team member has violated any applicable law, regulation or policy, Client shall notify Syneos Health in writing. Syneos Health shall promptly address the issue and take all reasonable and appropriate action (including but not limited to termination of such employee). No such action shall be contrary to Syneos Health's internal human resource policies and procedures, provided such human resource policies and procedures are in compliance with all Applicable Laws. If, despite any foregoing action by Syneos Health, Client is still reasonably unsatisfied with the performance of

any Syneos Health Sales Team member, Client may request the removal of such Syneos Health Sales Team member by promptly notifying Syneos Health in writing, and Syneos Health shall remove the Syneos Health Sales Team member from the provision of Services hereunder. Any action taken pursuant to this Section III will be in accordance with Syneos Health's internal human resource policies and procedure and the Applicable Laws governing employees. Syneos Health shall promptly notify Client if it becomes aware that any Sales Team member has violated or is alleged to have violated any applicable law, regulation or policy.

IV CALLS AND TARGETS

The Syneos Health Sales Team shall provide Product Literature and Product samples (as needed) when making Calls as directed and approved by Client. Client is solely responsible for the content, production and distribution (to the Syneos Health Sales Representatives) of the Product Literature. Each Syneos Health Sales Representative shall record information concerning each Call, including but not limited to Product sample distribution, and concerning the profile of each individual Target (or other physician called upon) on whom the Syneos Health Sales Representative calls. Client shall permit Syneos Health to access and use all Target, sales and Call-related data that supports or is associated with the Services that are performed in accordance with this Project Agreement (the "Data"). The Data shall be used by Syneos Health for the purpose of evaluating the performance of its Sales Team members; and, provided that Syneos Health de-identifies all Client and Product specific components of the Data, for business development and analytics purposes.

V. THE PRODUCTS

The Product shall be promoted by Syneos Health under trademarks owned by or licensed to Client and are Products which Client has all lawful authority necessary to market and sell the Products in all geographic areas where the Products are to be promoted under this Project Agreement. This Project Agreement does not constitute a grant to Syneos Health of any property right or interest in the Products or the trademarks owned by or licensed to Client. Syneos Health recognizes the validity of and the title of Client to all its owned or licensed trademarks, trade names and trade dress in any country in connection with the Products, whether registered or not. Client represents to Syneos Health that neither those trademarks, trade names and trade address nor the promotion of the Products by Syneos Health infringes on any intellectual property right of any other person or entity.

VI. HIRING PROFILE

In selecting Sales Team members, Syneos Health will use the preferred hiring profile approved by Client. Syneos Health will take reasonable steps to confirm the accuracy of information concerning background and experience received from applicants for positions of Sales Team members. Syneos Health shall not knowingly employ or otherwise retain, or permit to be retained as a Sales Team member, a practicing physician or a person affiliated on a professional level with or employed by any physician, physician practice or other healthcare professional or provider or a person who is in a position to unduly influence the purchase of the Products.

VII. BACKGROUND CHECKS

Syneos Health shall be responsible for performing drug testing and background checks of all

Sales Team members. Syneos Health represents and warrants that it will complete or cause to be completed a thorough background check of all Sales Team members. This will include, Criminal Check, Social Security Check, Drug Screen, Motor Vehicle Record Check, Education Check, Past Employer Check. Syneos Health further represents and warrants that it will perform or cause to be performed background checks to confirm that no Sales Representative:

a. is an excluded person on the Office of Inspector General's List of Excluded Individuals/Entities and is not on the General Services Administration Excluded Parties List (as of the date the background check is performed);

b. is, so far as it is aware, an unfit or an improper individual for the performance of the Services;

c. is, so far as it is aware, engaged in any fraudulent or unlawful activity, or other inappropriate conduct as measured by the other requirements of this Project Agreement.

Syneos Health shall institute prompt corrective or disciplinary action against any Sales Team member who fails to meet the requirements set forth in this Exhibit A. Syneos Health further agrees to cooperate and comply with all investigations by or on behalf of Client with respect to wrongdoing, or alleged or suspected wrongdoing, in respect of any obligations of Syneos Health or any Sales Team members under this Project Agreement.

VIII. REPRESENTATIONS AND UNDERTAKINGS

(a) [***].

(b) Client represents that:

(i) it recognizes that for Syneos Health to comply with its obligations hereunder, it shall need the good faith cooperation of Client to provide Syneos Health with the necessary materials and assistance required to enable Syneos Health to perform the Services;

(ii) the Services being provided by Syneos Health are in furtherance of Client's program of marketing and promoting the Products and as such, Client is responsible for ensuring, and further, Client represents and warrants, that the Client's program being implemented by Syneos Health pursuant to the terms hereof (but not the implementation thereof by Syneos Health), strictly adheres to all applicable state and federal statutes, laws, ordinances, and the rules and regulations of all governmental and regulatory authorities, including but not limited to, the Federal Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act;

(iii) it shall ensure that none of its employees add, delete or modify claims of efficacy or safety of the Products, nor makes any changes (including but not limited to, underlining or otherwise highlighting any language or adding any notes thereto) in the Product Literature, during the training on the Products or during any communications with Syneos Health employees;

(iv) it shall ensure that none of its employees working with the Sales Team or in connection with the Services, directly or indirectly instruct any Syneos Health employee to pay, offer or authorize payment of anything of substantial value (either in the form of compensation, gift, contribution or otherwise) to any person or entity in a position to order, recommend or purchase the Products contrary to any law; and

(v) neither it nor any of its employees directly or indirectly instruct any Syneos Health employee to make any representations or warranties relating to the Products that conflict, or are inconsistent with, applicable laws or the Food and Drug Administration approved labeling for the Products.

(iv) Client shall:

A. provide Syneos Health Sales Team members with all Product Literature and arrange for the provision of Product samples (as applicable).

B. inform Syneos Health promptly of any changes which Client believes are necessary or appropriate in the Product Literature or in information concerning the Products in order to be in compliance with all applicable federal and state law, regulations and administrative guidance.

C. Arrange for a timely and appropriate response to any inquiry concerning a Product communicated to Syneos Health from any licensed practitioner and communicated by Syneos Health to Client.

EXHIBIT A-1
FIELD OPERATIONS SERVICES (SALES TEAMS)

1.0 Executive Summary

This Exhibit A-1 describes the scope of work, deliverables, and assumptions for field operations initial implementation and ongoing annual support for the Project (as defined in Section 3.1.1(a)). Any changes to the assumptions, deliverables, or scope of work described in this Exhibit A-1, or any new work request(s), will follow Section 3.1.1(d), Change Control Process of this Exhibit A-1.

2.0 Scope of Services

The following service areas are part of field operations initial implementation and ongoing annual support:

- Operations Management
- Customer Relationship Management (CRM)
- Customer Master Source Data & Validation
- Travel and Expense Management
- Transparency Reporting
- Data Management
- Analytics and Reporting
- Targeting, Alignment and Call Plan Administration
- Incentive Compensation Management
- Field Support Services
- Technology Training Services
- LMS System Support
- Quality Management and Assurance

3.0 Scope of Work Definition

3.1 Operations Management

3.1.1 As part of operations management, Syneos Health will provide the following:

(a) Project Management. Syneos Health will provide a fully integrated project management approach for the implementation of the operations services (the "Project") including the following:

(1) Leadership of Project kick-off meeting to include review of scope, timelines, and assumptions for each functional area, Sales Team member introduction, and status reporting formats and meetings.

(2) Integration of all Project activity, timelines, and deliverables across all functional areas into a consolidated Project schedule.

(3) Leadership, facilitation, and documentation of all meetings, including meeting notes and action items.

(4) Management of the Project schedule including task management, escalation of issues, risk identification, and interdependencies through Project documentation including:

(i) Issue tracker;

(ii) Milestone tracker; and

(iii) Action item tracker.

(5) Project status meetings and Project status reporting, including weekly status reports and plan reviews with the Client.

(6) Project close-out and lessons learned session to include any information that can be applied to the ongoing operational support of the Client after the initial implementation is complete.

(7) Project management implementation deliverables including the following:

(i) Weekly implementation schedule identifying Project activities and target completion dates.

(ii) Weekly implementation log of risks, actions, issues, and key decisions ("RAID").

(b) Technical Operations Management. Technical operations Project implementation deliverables include the following:

(1) Ongoing communication plan;

(2) Technical operations deliverables document identifying standard deliverables and key business rules – delivered within six (6) weeks of the first day in the field;

(3) Monthly technical operations status report;

(4) Monthly operation leadership meeting and supporting documents; and

(5) Quarterly business review meeting and supporting documents.

(c) Field Administrative Management. Syneos Health will oversee all field administrative tasks, including the following activities:

(1) Field Administrative Management—Implementation.

(i) Project set up and roster management using Syneos Health's proprietary master roster system;

(ii) Onboarding of new hires, including all aspects of administrative systems and processes (e.g., travel, CRM system, business cards, welcome memo, conference call accounts, fleet coordination, credentialing, licensure);

(iii) Meeting planning logistics for national and POA meetings;

(iv) Venue sourcing, hotel sourcing/booking, meal and events arrangements, ground transportation set up, flight arrangements, travel letter development, and budget tracking for national and POA meetings;

(v) One (1) resource for on-site meeting support available, as needed;

(vi) Training development and coordination;

- Identify and coordinate Syneos Health/Client courses for LMS upload
- Coordinate presenters/training schedules & agendas
- LMS course completion monitoring
- Post launch mastery training plan development

(vii) Team Expense Travel and Budget Policy development.

(2) Field Administrative Management—Ongoing Support.

(i) Roster management and distribution;

(ii) Continuation of meeting planning logistics, as described above, either with Client vendor(s) or as a stand-alone offering;

(iii) Monitoring Project parameters and managing eligibility and payout of incentive compensation and awards within approved Project guidelines;

(iv) Coordinate, route, track, and report operational initiatives, questions, or directives across all of the internal administrative departments, as well as external vendors and Client home office;

(v) Review of monthly invoicing and budgets for adherence to Project P&L;

(vi) Coordination with sample management and fulfillment vendor (if applicable);

(vii) Coordination with Syneos Health compliance on HCP expense monitoring and reporting;

(viii) Onboarding of backfill new hires to include all aspects of administrative systems and processes;

(ix) Coordination of communication to the field;

(x) Ad hoc reporting (e.g., turnover/vacancy reports, budget tracker);

(xi) Monthly field employee roster audits; and

(xii) Payroll processing;

(xiii) Review and ensure all field expense reporting is completed, to include HCP reporting;

(xiv) Field communication to include the following for the team conference call:

- FAQ development with HR and business lead
- Communication script
- Project exit check list and acknowledgement

(xv) Monitor return of Syneos Health property;

(xvi) Monitor return of Client property (i.e., samples, marketing materials, etc.);

(xvii) Coordination with fleet department on return of vehicle (if applicable); and

(xviii) Deactivations of all Project specific accounts (i.e., conference call/WebEx, etc.).

(d) Change Control Process. During the Term of this Project Agreement, the Parties may mutually agree to alter the Field Operations Services outlined in this Exhibit A-1. Such changes will be addressed as follows:

(1) Assess the impact of scope changes on Project schedules, resources and pricing;

(2) Provide a formal vehicle for approval to proceed with any changes to the Project Agreement;

(3) Provide a Project audit record of all material changes to the original Project Agreement; and

(4) If requirements arise that are outside the scope of this Exhibit A-1, a Change of Scope document (or an amendment to the Project Agreement, as applicable) will be submitted for Client approval following the below process:

(i) Client requests additional requirements for new functionality or deliverables outside the scope of work provided herein.

(ii) Syneos Health reviews change, meets with Client and internal team members to understand and scope Client expectations regarding business need, timelines, and other deliverable expectations.

(iii) Syneos Health provides Change of Scope (or Amendment or new Project Agreement, as applicable) document, which outlines work effort, timeline and pricing impacts of the change. Pricing will be determined based on standard rates provided below.

(iv) Client accepts proposal and signs Change of Scope (or Amendment or new Project Agreement, as applicable) document which authorizes work to begin on the change request.

(5) Standard Pricing Table.

Role	Price/HR
Software Development	[***]
CRM Configuration	[***]
Data Management	[***]
Alignment/Call Planning	[***]
Incentive Comp Modeling/Design	[***]
Analytics & Reporting	[***]
Project Management/Business Analysis/Solution Design	[***]
Testing	[***]
IC Administration	[***]
Training (Content/Delivery)	[***]
Hardware/Help Desk	[***]

3.2 Customer Relationship Management ("CRM")

3.2.1 CRM; Client Configuration and Available Functionality. Syneos Health will provide a CRM application. Additionally, within its CRM application, Syneos Health will set-up a single, Client-specific, dedicated CRM environment configured specifically to the Client's business rules (the "Client Configuration"). The core functionalities within the Client Configuration are as follows, and will be configured by Syneos Health upon selection by Client:

(a) Customer profile management across account types (individuals and organizations);

(b) Call recording, reporting, and loading of Call plans;

(c) Closed-Loop Marketing ("CLM"), loading and presentation of digital media as part of integrated call record;

(d) Sample management and recording of samples and physician signature capture as part of integrated call record, including Prescription Drug Marketing Act (PDMA), CFR Part 11 Validation, if requested by Client;

(e) Medical Inquiry Request Form ("MIRF") including physician signature capture;

(f) Field Coaching Report (FCR) configuration;

(g) Pre-established reports and dashboards to enable field and field management performance (online only); and

(h) iPad/online platform options including online/home office PC, field tablet PC, and iPad to support mobility needs and improved customer interaction.

3.2.2 CRM; Client Configuration Development and Implementation. CRM implementation will be led using an agile development approach including the following deliverables:

Project Deliverable	Definition
Initial Requirements	Demonstration of the Client Configuration; and discussion of Client needs and business environment to support the general usage and end-user experience; will include accounts, functions, Call types, products, customer profile maintenance, etc.
Alpha Review	First iteration of the Client configuration based on requirements gathered in the Initial Requirements session. Detailed demonstration of the Client Configuration for more in-depth review of Client requirements.
Configuration Requirements Document ("CRD")	After the Alpha Review, Syneos Health will provide the Client with a draft CRD document which summarizes all end-user system requirements taken from both the Initial Requirements and Alpha Review sessions. The CRD will form a basis for the final Client Configuration specifications, risk assessment, testing, training, and validation (if applicable).
Beta Review	The final phase of the Client requirements will be a Beta Review, which will allow for any changes to the Client Configuration system requirements for final testing and production readiness.
CRD Sign-Off	Any changes or additions to the Client Configuration requirements during the Beta Review will be incorporated into the final CRD and submitted to the Client after the Beta Review session for final approval and signature.

3.2.3 Client Configuration Assumptions. The scope of the Client Configuration CRM delivery and associated timelines for the Project assumes the following:

(a) Necessary Client members are available for the Initial Requirements, Alpha Review, and Beta Review meetings (each typically 3 hours), based on the weeks assumed in the agreed upon Project plan (Alpha Review/Beta Review may be done via WebEx);

(b) Sign-off of documentation within 5 days of delivery by necessary Client members;

(c) No customization of code outside of CRM provided configuration capabilities;

(d) Use of standard MIRF functionality and data extracts to medical information;

(e) Client Configuration/CRM does not include Adverse Events/Pharmacovigilance ("AE") reporting or recording. An alert is setup in the CRM system to remind field users of the appropriate number/process to communicate to HCPs;

(f) Linking to company or external web-based systems within CRM tab structure;

(g) Access to Syneos Health Veeva Vault for Client approved content including: CLM presentations and approved email templates. Alternatively, Syneos Health Veeva Vault may be setup to attach directly to Client internal Veeva Vault system in cases where Client is using Veeva Vault for internal Medical, Legal, Review ("MLR"). Syneos Health Veeva Vault is not used for internal Client MLR usage, only for field delivery of approved content;

(h) Sample management functionality, if required, and data feeds for sample shipments, SLN validation, and sample product information as determined by Client requirements;

(i) Inclusion of sales data within standard Veeva reporting functionality (online only);

(j) Field Coaching Report originates from manager, not representative, including data entry only. Form will not be pre-populated with any data from any source;

(k) Call history within the Sales Force Automation ("SFA") system not to exceed 15 months (5 Quarters) without purchasing additional data storage from Salesforce.com;

(l) External access for Client home office administrators can be granted with change control processes in place to ensure integrity of Syneos Health production environment, with additional license costs as dictated by home office license pricing in contract; and

(m) Ongoing support for CRM system including tier 2/technical support for escalated calls from field support desk, and home office support needs;

3.3 Customer Master Source Data and Validation

3.3.1 Veeva Network and Veeva OpenData Validation.

(a) Syneos Health shall provide a near real-time customer validation process leveraging the integration of Veeva Network and Veeva OpenData. This combination gives direct access to Veeva OpenData for adding and changing of HCP and HCO data, which allows for field users to search, add, and immediately pull-down HCPs/HCOs industry standard identifiers and compliance information, such as SLN and DEA, upon adding the new prescriber, as opposed to waiting the standard 2-3 weeks for weekly data exports and validation.

(b) Client and Syneos Health's targeting and alignment team will also have access to Veeva OpenData for sales or marketing research, such as to identify initial target universe, ongoing target adjustments, new product or market evaluations, etc.

(c) The Veeva Network service includes the following:

(1) Configuration and support for utilizing Veeva OpenData and the Veeva Network to allow for this Customer Master Data solution to control the universe in the CRM system and to provide for data stewardship services via Veeva OpenData provided controls.

(2) Data change requests can be submitted by field users to the Veeva OpenData data stewards, which increases efficiency and decreases timelines associated with routine action request processing for universe changes discovered by the field.

(3) The Veeva Network account search will allow for the field to search the Veeva OpenData Customer Master Data for any HCP or HCO that meets the search criteria, and provides the ability to add that HCP or HCO to their Veeva CRM territory. The information included is pre-validated by Veeva OpenData so an eligible HCP can be sampled immediately. Additionally, all valid address information known for that account will be brought down with the HCP or HCO selected.

(d) The Veeva OpenData service includes access to the following data set:

(1) Licensed field and home office users have access to entire customer universe (HCPs, HCOs, addresses, affiliations) in the Veeva OpenData customer universe.

(2) Usage of compliance data scrub – for industry standard identifiers SLN, NPI, DEA #s for initial and ongoing data validation.

(3) Usage of data hygiene scrub – for HCP demographic data such as address, specialty etc. for initial data validation.

(4) Access to email address data is not included in standard offering but may be available on a per record basis for marketing initiatives as needed and is recommended for usage if Client is implementing enhanced approved email functionality (not included in base CRM license).

3.4 Travel and Expense Management

3.4.1 Travel & Expense Set-Up and Ongoing Services. Syneos Health shall leverage its then current travel and expense ("T&E") management system application (and solution provider) (collectively, the "T&E Management Solution"), currently Concur, for capture and reimbursement of all expenses incurred by Syneos Health employees recruited for the Client's Project, and for HCP data capture necessary for transparency reporting. The T&E Management Solution assumes the following:

(a) Required Client members are identified and available for requirements gathering;

(b) Client's requirements align with the standard baseline Concur configuration, (i.e. able to utilize existing expense types, approval workflow, etc., without customization);

(c) Completion of Configuration Request document for Project set-up based on Client spend limits and business rules;

(d) Acceptance of Syneos Health universe for HCP selection utilizing Medpro Concur Connect;

(e) Ongoing support for Concur T&E management system including tier 2/technical support for escalated calls from field support desk;

(f) Changes to or additional audit rules may be requested post-deployment;

(g) On-going roster management as teams expand or re-align (including territory and manager changes);

(h) Information on areas such as Amex cards, mileage rates, report approvers, etc. are communicated and decided on at onset of implementation based on Client business rules;

(i) T&E management system setup and support is only provided for Syneos Health employees. If any Client employees are supported, Client will be responsible for the deployment of the T&E management system and capture of any HCP meal spend, etc. for the Client employees;

(j) Coordination of Learning Management System ("LMS") Project set-up and communication of system access and viewing of Concur module to new hires/end users;

(k) Inclusion of Expense Management in Technology Training sessions; and

(l) Tracking of completed Concur module review in LMS per user.

3.4.2 Travel & Expense Deliverables. The T&E management system application work stream will be managed by the Operations Manager, the Concur system subject matter expert, and the compliance lead, and will include the following deliverables:

Project Deliverable	**Definition**
T&E Guidelines	General Syneos Health guidelines provided to assist the Client in developing their T&E program; this can be reviewed and modified by Client as required.
Compliance Business Rules Document	Detailed document describing all compliance business rules associated with the Client Project. A draft will be provided with Syneos Health's base business rules and guidance with review and modifications as needed, and approval by Syneos Health and Client.
ERD (Expense Requirements Document)	Detailed document describing standard Concur functionality and Client-specific business rules based on requirements gathering and configuration request. Following internal review, final document will be reviewed and approved by Syneos Health and Client.
Training Documentation	Training documentation provided to field users and management with guidance on T&E management system application and compliance business rules and usage.

3.5 Transparency Reporting

3.5.1 Background. H.R. 3590, Section 6002: "Transparency Reports and Reporting of Physician Ownership or Investment Interests," also referred to as the "National Physician Payment Transparency Program" a/k/a the "OPEN PAYMENTS" or "Sunshine Act" and H.R. 3590, Section 6004: "Prescription Drug Sample Transparency," requires certain data collection and reporting regarding payments or transfers of value and drug sample distribution to physicians.

3.5.2 Data Management. Syneos Health will provide the following data management services to Client:

(a) Regular reports of HCP-related meal expenses in Syneos Health's standard format;

(b) Regular reports Syneos Health's standard format of items of value non-sample items left with HCPs;

(c) Syneos Health will run full-cycle system testing and support UAT testing; and

(d) All reports will be clearly defined in terms of layout, content and delivery in the Data Requirements Document.

Syneos Health will work with Client in the data requirements process to confirm the file format, data elements, file delivery process and frequency to meet Client specifications for transparency reporting and Client System Integration. Syneos Health's Monitoring and Auditing processes for transparency reporting is detailed in Exhibit C, below.

3.6 Data Management

3.6.1 Generally.

(a) Syneos Health will provide data loads and data integration services for standard data imports and exports. Data management services includes data flowing to and from the Veeva CRM application, including Client data sources, third parties (i.e. sales data), or service partners. The data management team will work with the Veeva CRM, and analytics and reporting tools, to ensure that all Client business rules and data requirements are understood and planned for in the overall implementation plan.

(b) A full description of all data files and formats for data interfaces will be provided in the Data Requirements Document ("DRD"), which will be included as part of the Project Plan with necessary approvals from the Client and Project leads. The DRD will also include a Production Schedule, for ongoing data management services.

3.6.2 Data Loads, Imports and Extracts—Standard. The Project assumes use of standard data loads and file formats for all initial and ongoing data support as provided below:

(a) Standard initial data loads shall use agreed upon Syneos Health/Client formats including:

(1) Territory hierarchy;

(2) Customer universe, alignments, and Targets/Call plans;

(3) Product information; and

(4) Call history (if required).

(b) Standard reoccurring data imports shall be conducted at set frequencies and in agreed upon formats within five (5) business days of receipt as needed for the following:

(1) Prescriber/account sales data (weekly & monthly);

(2) Prescriber payer data (weekly & monthly);

(3) Call Plan/Targets (quarterly); and

(4) Customer universe updates—validation responses (weekly).

(c) Standard reoccurring data extracts shall be provided at set frequencies to either home office or third-party vendors as needed for processing to include:

(1) Call/activity data (weekly or monthly – Syneos Health to provide within 5 business days from the end of the cycle);

(2) Medical inquiries (daily);

(3) Sample activity (weekly or monthly – Syneos Health to provide within 5 business days from the end of the cycle);

(4) Extracts supporting Transparency Reporting in Section 3.5 (monthly or quarterly);

(i) DME Spend data from Concur;

(ii) Items of value, open payments reports;

(iii) Hand-carry sample reports for ACA 6004 (Knipper clients only); and

(5) Customer Universe Validation Requests (weekly – Syneos Health to provide within 5 business days from the end of the cycle).

(d) Standard data maintenance services will be provided for the ongoing support of the systems and data at fixed frequencies as defined below to include:

(1) State license validation process to reduce field impact in sampling (weekly);

(2) PDRP flagging on accounts (monthly);

(3) Routine merging of accounts (quarterly);

(4) Setup of integration between Veeva CRM and data warehouse, which allows roster, Territory hierarchy and Product management to be seamless (daily);

(5) Processing of action requests (Client data changes) (quarterly);

(6) Time off Territory and holiday updates (monthly);

(7) Ongoing maintenance of sales and payer data (weekly or monthly based on sales data provider availability);

(8) Training database setup and management (quarterly);

(9) Tier 2/technical support for data issues routed from the Field Support Desk (daily);

(10) Customer sales data extracts for IC (as defined in Section 3.10) processing (monthly); and

(11) Customer sales data and Call/activity extracts for A&R processing (monthly).

3.6.3 Assumptions. The scope of the data management delivery and associated timelines for the Project assumes the following:

Project Deliverable	**Definition**
Initial Requirements	Discussion of client needs regarding data loads, extracts, and imports and finalization of Project plan and scope based on SOW assumptions and change management process
Third Party Agreements (TPA)	Syneos Health will secure, in coordination with Client, any rights and licenses that Syneos Health needs from external vendors such as sales data companies which require TPA for data services to be provided
DRD (Data Requirements Document)	Syneos Health will provide the Client with a DRD document which summarizes all data loads, imports, and extracts, as well as any business rules, frequencies, and formats associated with the data services to be provided as part of implementation and ongoing data management services, the DRD draft will be reviewed, modified as needed, and signed by the Client to confirm Project deliverables
Test Files	The Client or third parties will provide needed test files in specified formats and agreed dates in the Project plan based on the implementation schedule
Final Production Files	The Client or third parties will provide final production files in specified formats and agreed dates in the Project plan based on the implementation schedule

3.6.4 Non-Standard; Changes. Any additional data feeds not included in the standards as defined above, or changes to data exchanges or maintenance subsequent to the approved DRD will follow the change control process and rate schedule set forth in Sections 3.1 and 3.1.1(d) respectively.

3.7 Analytics and Reporting

3.7.1 Veeva CRM Dashboard Reporting.

(a) Reporting Generally; User Types. The Project assumes general field activity reporting will be provided in the Veeva CRM Dashboard Reporting environment utilizing Syneos Health's pre-configured reporting tools to optimize field performance and implementation setup time. Syneos Health reporting will be provided for the following user types aggregated based on the user type's span of control:

(1) Representative (Territory level);

(2) Field Management (regional level); and

(3) Home Office (national level).

3.7.2 Veeva Report Configuration and Templates.

(a) Syneos Health will configure the reporting tools to include Client specific fields and terminology, where applicable, within Veeva and SalesForce.com guidelines. Veeva requirements, development, and deployment will follow the requirements and format as provided in the Veeva CRD as stated in Section 3.2, and may include the following: field activity, including the following: Call activity, Call plan adherence, sample activity, CLM utilization, synchronization monitoring, manager exceptions, and/or administration.

(b) Report Templates. The Veeva template field reporting package is designed to drive sales behavior in the following ways:

(1) Evaluation of prescriber sales for pre-Call planning from account summary report;

(2) Measure that the most valuable drivers of sales were detailed and sampled in accordance with the recommended Call plan - account/physician –

(i) Average Calls per day –reviews Call activity against Target or segmentation;

(ii) Reach and frequency can be found on analytics tab;

(iii) Call plan information can be found on the Call plan tab; and

(iv) Call Plan Analysis Report can be found on the analytics tab.

(3) Measure the impact of detailing and sampling on sales –

(i) Effort vs. results report can be found on the analytics tab.

(4) Examine the landscape for the product to identify top sales accounts and potential –

(i) Territory sales analysis—reviews trends in Client Product and competitive landscape; can be found on analytics tab;

(ii) Territory payer analysis –examines payer information; can be found on analytics tab; and

(iii) Territory comparison report—compares sales performance at the Territory level for all territories within span of control; can be found on analytics tab.

(5) Report Template Table.

Template Reports	Base Assumptions	Standard Frequency
Account Summary	Prescriber based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client
Activity/ Administrative	1. Reviews key territory and/or district performance indicators with drill down details for: a. Interactions b. Detailing c. Sampling 2. Review key territory and/or district administrative metrics with drill down details 3. Any information collected within a check box or drop down list into the Veeva systems can be aggregated into a dashboard element. 4. Text box information can be rolled into a report but not the dashboard. 5. Dashboards can have up to 20 measurement elements 6. All Dashboard elements are pictorials which aggregate data from an underlying report	Real time as of last synchronization and refresh

Template Reports	Base Assumptions	Standard Frequency
	7. All pictorials are flexible but limited to two dimensions 8. Color selection is not an option 9. Filters can be applied to comparable data 10. Reports can be filtered by user level (Field, Management, Home Office) 11. Other Reportable Activity: a. System Utilization b. Pending Interaction (Exception/incomplete information) c. Time off Territory d. Synchronization Reports e. Interaction by Date and Time f. Field Action Requests 12. Account Demographics a. Target/Non-Target b. Account Type (practitioner, pharmacy, staff, etc.) c. Specialty d. Segmentation e. Custom Profile Attributes 13. Closed Loop Marketing (CLM) a. Slide Utilization as % of Calls b. View Duration c. Ranking of Slides by View count and Average Duration d. Viewer Reaction (Positive, Neutral, Negative)	
Reach and Frequency	Adapted to specific activity measurements and goals within set up matrix (calls, targets only, reach, frequency, sample distribution)	Real Time as of last synchronization and refresh
Average Calls Per Day	Average Calls Per Day versus goal	Real Time as of last synchronization and refresh
Territory Sales Analysis	1. Adapted to specific product/market definition 2. Monthly prescriber-based product level prescription data; Up to 3 promoted products	At same frequency as sales data (aka prescription data) delivery to Client
Territory Comparison (Mgmt supplement)	1. Adapted to specific product/market definition 2. Monthly prescriber-based product level prescription data; Up to 3 promoted products	At same frequency as sales data (aka prescription data) delivery to Client

Template Reports	Base Assumptions	Standard Frequency
	3. Comparison of sales data amongst the assigned span of control	
Territory Payer Analysis	1. Monthly payer-based product level prescription data 2. Analysis of the prescriber payer 3. Top payers 4. Comparison of payer market products	At same frequency as sales data (aka prescription data) delivery to Client
Effort vs. Results aka Impact Report	1. Adapted to specific product/market definition 2. Up to 3 promoted products 3. Monthly prescriber-based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client

3.7.3 Custom Analysis & Insights.

Additional work-effort will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

3.8 Targeting, Alignment and Call Plan Administration

3.8.1 Generally. Syneos Health will provide targeting and sales force alignment services for optimization of key targets. The goal of these services is to:

(a) Optimize geographic coverage on the most valuable Targets while balancing Territory workload;

(b) Target list generation based on business-specific workload parameters including the incorporation of any segmentation, detailing and frequency provided; and

(c) Identification of uncovered white space geography.

3.8.2 Deliverables.

(a) Metropolitan Statistical Area (MSA) overview;

(b) Alignment summary including coverage of top targets;

(c) Uncovered geography summary;

(d) Mapping at territory, district and national levels;

(e) Zip-Terr;

(f) Span of control; and

(g) Target list.

3.8.3 Assumptions.

(a) The scope assumes the following:

(1) Alignment will be created utilizing Syneos Health's preferred alignment software;

(2) Territory workload parameters and Project assumptions are agreed upon before work starts;

(3) All third-party agreements are signed off on before work starts;

(4) If third-party data purchased by Syneos Health will be passed through to Client;

(5) Client will supply physician level universe which will include best address. Any workload specific data points will be mutually agreed upon by the Parties (i.e., Rx, Deciles, etc.);

(6) One (1) per-deployment interactive alignment session for the field managers for minor geographic tweaks; and

(7) Quarterly Target or Call plan updates will be managed through the Veeva Action Request process, with timing provided for call plan updates that represent [***] changes in territories, geographies or segmentation. This will be done for alignment and Target updates each quarter, with District Manager/Sales Management reviews, per the agreed upon process between Client and Syneos Health. Additional work-effort will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

(b) Items not included in the assumptions:

(1) Major realignments or re-targeting exceeding [***] changes in territories, geography, or segmentation such as new Target strategy, expansions, or down-sizing; and

(2) Additional mapping and data analysis.

3.9 Incentive Compensation Management

3.9.1 Generally. Syneos Health incentive compensation management will design and /or implement an annual incentive compensation ("IC") plan and administer quarterly payouts. Syneos Health IC personnel will facilitate an IC assessment meeting to ascertain scope of work, IC plan parameters, data availability, budget, IC plan goals and incentive compensation culture. Sessions will be led by Syneos Health IC employees experienced in the discipline of IC plan design and field performance measurements. The

assessment sessions are strategically structured to aid in the IC plan design, consisting of metrics aligned to business strategy. After the IC plan design has been approved by the parties, the Syneos Health incentive compensation department will implement, manage and administer IC plan.

3.9.2 Standard IC Services are inclusive of the following:

(a) Post the launch year, which will include at least one full year from the date of launch, a single annual IC plan for each Client team (i.e. Sales and Sales Managers) for the covered field employees, with no more than two (2) Plan Updates (as defined herein) per year. A "Plan Update" is defined as a change, which does not alter the IC plan structure thus resulting in an amendment to the IC plan. Changes to IC plan structure, which require a new set of modeling, design work, and/or plan communication documentation are considered a "New Plan," and may be subject to a separate Statement of Work ("SOW").

(b) The components of an IC plan will include the following:

(1) Plan concept presentation deck;

(2) Formal plan document with electronic signature;

(i) Inclusive of:

- Plan design measurements
- Business rules
- Data crediting
- Calculations
- Participation rules
- Terms and Conditions

(ii) IC Plan document will be reviewed by the following:

- Syneos Health Sales Leadership
- Syneos Health Human Resources
- Syneos Health Corporate Compensation
- Syneos Health Authorized Legal

(3) Monthly spreadsheet ("IC Grid") of calculated results (dependent on data availability and IC plan design);

(4) Monthly field scorecards (dependent on data availability and IC plan design);

(5) Quarterly payout administration in accordance with the Syneos Health payroll calendar;

(6) A single contest/special performance for field force per year to include:

(i) Contest Concept Presentation Deck;

(ii) Formal Plan Document with electronic signature;

(iii) Single payout administration in accordance with the Syneos Health payroll calendar; and

(iv) Single contest grid and/or scorecard of contest results.

(7) A single annual President's Club contest/trip to include:

(i) Results published in conjunction with the monthly IC reporting process.

(8) Additional services and changes will be subject to the Change Control Process and subject to an amendment.

3.9.3 IC Plan Deliverables and Timelines.

(a) Design Phase.

Category	Description	Duration/Timeline
IC Plan Meeting(s)	Initial Meeting to discuss: · Corporate Philosophy · Sales Goals/Objectives · Sales/Marketing Strategy · Business Rules · Data Inputs · Eligibility Requirements	1 day – initial meeting; subsequent follow-up meetings may be held to discuss pending topics or matters requiring further discussion from initial meeting. Maximum timeline 3 weeks
IC Modeling	Based on inputs derived from initial IC meeting(s), Syneos Health will create/provide IC deck illustrating: · Recommended IC plan(s) · Payout Scenarios/Distribution	· 1 week to provide recommendation · 1 week for feedback/follow-up · Additional time may be needed if data is required for modeling

Field Communication	IC Plan communication includes: · PowerPoint deck (Management Team & Sales force) · Word/PDF document (for IC plan participants/acknowledgement)	3 weeks (maximum) once IC plan has been finalized.

(b) Implementation Phase.

Category	Description	Duration/Timeline
IC Plan Programming	· Data Process Setup · SQL Programming · User Interface Setup · Report/Scorecard Programming · KPI/MBO Programming (if applicable) · Acknowledgement Portal Setup · Administration Portal Setup · Programming QC & Testing · Validation & QC of IC plan programming (independent of Programming QC) · Minor changes (cosmetic, etc.)	Maximum of 3 weeks after receipt of initial sales data file in final format

(c) Maintenance/Management Phase.

Category	Description	Duration/Timeline
Plan Administration	IC plan processing · Report Generation o Payout Grid/Summary o Scorecard o Management Summary · IC plan QC · Report Distribution · Roster Management	4 weeks after receipt of monthly sales data file

	· Eligibility; LOA; PIP; New Hire · IC Portal Maintenance · Acknowledgment · Administration	

As IC is a passthrough expense to Client, Syneos Health encourages Client input on IC plan design. In instances where Client has given input into the IC plan design or when Syneos Health implements an IC plan design created by Client, Client acknowledges and agrees that it shall use best efforts to timely approve such IC plan design. The foregoing notwithstanding, in the event field force goals, dependent data, Client requested input, and/or plan documentation are not approved by Client and/or acknowledged by the field force within forty-five (45) calendar days into the then current IC plan period, Syneos Health reserves the right to implement either the IC plan which was utilized in the prior IC period or an Syneos Health standard best practice IC plan, and Client acknowledges that by engaging Syneos Health to perform incentive compensation management, Client is expressly consenting to the foregoing.

3.10 Field Support Services

3.10.1 Help Desk. The Syneos Health field support service desk supports Syneos Health systems and operational processes for field user readiness and performance.

(a) Field support service desk hours are Monday through Friday, 8am-10pm, Eastern Standard Time

(b) Standard Syneos Health metrics and KPIs for call and ticket resolution

(c) Field Support can be reached via telephone or via email

(d) Knowledge base will be supplied for field support service desk based on Client business rules and system configuration

(e) Standard monthly reporting will be provided along with post-rollout daily monitoring reporting for 2 weeks following each field deployment

3.10.2 Asset Management.

(a) Syneos Health will provide asset management services ranging from hardware procurement, to configuration and deployment, and includes tracking IT assets throughout the life of the Project. Syneos Health maintains a suite of standard Windows images and custom images available as needed. Client hardware is asset tagged, scanned and secured in a locked area with restricted access for designated IT personnel.

(b) Standard hardware platform includes:

(1) Field laptop with carrying case

(2) Apple iPad with cover

(3) Printer

(c) Users are given Syneos Health-hosted email boxes with the option to configure with Client-like domains/addresses to give the look and feel of a Client employee.

(d) All Client launches include a [***] spare pool of hardware to be used as replacements in the event of breakage or theft/loss. Repairs/replacements are shipped out to the end-users within 48 hours of receipt of broken hardware.

(e) Passcode-protected iPads are deployed using our mobile device management software with remote-wipe capabilities for added security. App packaging and deployment capabilities are available. For clients opting for iPads with data plans, we can activate with one of the major carriers prior to shipment and then maintain that data plan throughout the life of the contract.

3.11 Technology Training Services

3.11.1 Generally. Syneos Health will provide technology training services for the Sales Team. The technology training services format follows Syneos Health's core training content and facilitation approach. Training delivery assumes the following structure:

(a) Pre-learning home study training (e-modules)

(b) Face-to-face training (up to 1 day)

(c) Post-training mastery (up to 2 hours WebEx)

3.11.2 Content. The training content will include key Syneos Health supported field hardware and applications including the following topics: iPad basics, Concur T&E, HCP Spend Capture, Veeva CRM, Veeva Analytics & Dashboards, and Customer Maintenance. New hire training will be delivered using the same content developed for implementation and offered at the frequency of **one class per quarter**, with the preferred Client format of either WebEx or face-to-face delivery. Additional training is offered as needed following the Change of Scope process in Section 3.1.1(d) of this Exhibit A-1.

3.12 Learning Management System (LMS)

Syneos Health will supply Client with our standard LMS system for the delivery and tracking of all online training. Standard LMS reporting will be provided to internal Syneos Health leadership and Client for communication of training completion and verification of required compliance training. The LMS can contain a combination of Syneos Health and Client-created content to enable its use across all product, selling skills, soft skills, and compliance training and service as a central repository for all training records.

Standard LMS Service Levels are indicated in the below table:

Standard SLA Agreement - Content Load*	
Task/Request	**Timeline**
Simple PDF Load	1-2 days
Simple SCORM Load	2-4 days
Simple Assessment	2-3 days
Registrations/Assignments for existing activities and users	24 hours
Add Additional users (upon notice)	End of next business day
Transcripts	24 hours
Complex Assessment	3-5 days
Complex Course with Assessment	5-7 days
High Stakes/Large Assessment	5-7 days

3.13 Quality Management and Assurance

3.13.1 Quality Management System (QMS). All Client implementations are managed via an approved set of Standard Operating Procedures (SOPs) which are part of Syneos Health's Quality Management System (QMS) under the Head of Quality Assurance. Key processes such as project governance, document control, CRM implementation and training are required for assigned operations personnel. Other SOPs such as Change Control, security and access control, asset provisioning, and CRM end-user training are additional required training for implementation teams, which are also delivered and tracked within Syneos Health's Learning Management System (LMS).

3.13.2 System Validation (Sampling Only). When required by sampling, formal Computer System Validation (CSV) is conducted by professional validation resources following Syneos Health's System Validation SOP. The work is driven by the approved Configuration Requirements Document (CRD), and includes a Validation Plan, Operational Qualification, Performance Qualification, Test Evidence (typically screen shots), Deviation Reports, Traceability Matrix and a Validation Summary Report.

4.0 Operations Services Termination and Data/System Conversion

Syneos Health will retain all documented business requirements, system configurations, and data collected during the term of the Project Agreement. If the Client wishes to convert the field team pursuant to the Project Agreement, Client may have the option to continue on with Syneos Health-provided operations services to limit the disruption of field operations and leverage custom built systems, business rules and data integration. In such a case, a separate agreement will be established to confirm the scope and fees for any stand-alone operations services required. Alternatively, the parties may agree to convert the pre-built CRM configuration utilized for Client, for a fee mutually agreed to by the parties, to cover the migration of data, requirements documentation, and transfer of CRM configuration ownership, training on Client configuration settings and administration, as well as the Project management of the operations conversion, all to ensure a successful migration. Additionally, if the Client does not want to migrate the Syneos Health CRM configuration, the option may be made for Syneos Health to transfer Client data, business rules documentation, current data production schedules, and custom reporting formats for a fee mutually agreed to by the parties. If Syneos Health provides any migration or materials, Client is solely responsible for the system knowledge and performance post-conversion. Syneos Health may provide additional services based on the standard rates provided in the Change Control 3.1.1(d) of this Exhibit A-1.

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EXHIBIT B
TELESOLUTIONS SERVICES

Syneos Health will provide Agile with [***] full time telesolutions agents (the "Telesolutions Agents") who shall detail Agile's Product by making Calls pursuant to a Call Plan on Targets. The Telesolutions Agents shall be managed by [***] shared Call Center Manager, allocated at [***] (the "CCM"). The Telesolutions Agents and CCM may be referred to collectively herein as the "Telesolutions Team."

In the event that the Parties desire to increase the type and / or number of Telesolutions Agents providing Services under this SOW they may do so by utilizing a Project Team Member Request Form (the "Request Form") in a format that is substantially similar to the one attached hereto as Attachment 1. The details set forth in the Request Form shall be mutually agreed upon by the Parties. For clarification, the Request Form may not be used in those situations where it is the intent of the Parties to amend terms and conditions of this SOW other than those specific items set forth on the Request Form.

I. DEFINITIONS

(a) "Telesolutions Agent(s)" mean the full-time tele-solutions personnel who are Syneos Health employees hired, trained and assigned to provide the Telesolutions Services.

(b) "Call" means the telecommunication-based discussion with an HCP (as defined in subsection (e) below).

(c) "Call Plan" means a plan jointly designed by Client and Syneos Health, which is intended to enhance the efficiency and effectiveness of the Telesolutions Agents in making Calls. The Call Plan will be maintained by Syneos Health at its offices with a copy of such Call Plan maintained by Client at its offices, and may be amended or reconfigured from time to time solely at Client's written request (limited quarterly updates are included in the current fee), with Client paying Syneos Health a fee according to the Standard Pricing Table outlined in Exhibit A-1, as agreed upon in writing, for the performance of such amendment or reconfiguration services.

(d) "Client Material" means all Client provided written, printed or graphic material, intended for use by the Telesolutions Team including call script / guide, visual aids, file cards, literature, clinical studies, reprints, drug information updates and any other promotional support items that Client deems necessary or desirable.

(e) "Go-Live Date" means the date of the first Call by a Telesolutions Agent.

(f) "Healthcare Professional" or "HCP" means a person, other than an individual patient, including, without limitation, any medical or health care professional or entity in a position to purchase, lease, recommend, use, influence or arrange for the purchase or lease of, or prescribe the Products who are contacted by Agents or who contact Syneos Health via the assigned project toll free number with inquiries regarding the Client's Product (as defined in subsection (g) below).

(g) "Product" shall mean **Twirla®**.

(h) "Targets" means the HCPs who are identified by Client as potential prescription writers and/or customers for the Product as provided by Client to Syneos Health.

(i) "Telesolutions Team Hire Date" shall mean the date that the first Telesolutions Agent is allocated to the Telesolutions Team.

II. TELESOLUTIONS ACTIVITIES

Syneos Health shall be responsible for performing the following telesolutions activities as related to Agile's Product:

(a) Syneos Health will provide the following:

(i) Third party data (phone number append, where applicable) purchased by Syneos Health in accordance with the business rules document will be billed to Agile as a pass-through expense.

(ii) Standard Call activity reports will be provided to Agile on a weekly basis, focused on the Key Performance Indicators (the "KPIs") determined for the project including successful qualification and scheduling metrics based on total target population provided. The metrics and reporting layout will be defined, documented, and agreed upon during implementation in line with the business rules document.

(iii) Coverage of up to [***] unique HCP Target records for the [***] Level 2 Telesolutions Agent

(iv) Configuration of the Service Cloud CRM, including telephony integration.

1. includes up to [***] question/answer survey configuration, email and SMS templates (each);

2. AE process configuration using client specified form;

3. call recording configuration (as determined applicable by client regulatory requirements); and

4. call cycle configuration+IVR integration.

(v) Development of an Agile approved Interactive Voice Response (IVR)/inbound Call flow which will facilitate automated transfers of callers to the appropriate team for handling, based on the reason for their Call.

(vi) Syneos Health will support inbound customer service for HCPs returning calls and looking for more information. HCPs will be offered Product details and the opportunity to request the follow up Product information email.

(vii) Documentation, configuration and implementation of the initiative level business rules document and data load of HCP, office and territory data.

(viii) Setup of follow up email templates (up to a maximum of [***] forms) which can be triggered as follow up to a phone interaction, with opt-in from the recipient.

(ix) Setup of follow up fax template (up to a maximum of [***] forms) which can be triggered as follow up to a phone interaction, with opt-in from the recipient. Faxing template will be configured to support DTP sampling, as needed, and will be integrated with requirements of the sample fulfillment vendor.

(x) Updates to the target list and agent assignments on a quarterly basis.

(xi) Integration with sample fulfillment vendor and mailhouse (distribution of any hard copy materials). Any additional fulfillment integration or vendors may require additional work effort and scope with incremental setup and ongoing support fees.

(xii) Agile approval of call guide must be received at least [***] prior to beginning telesolutions outreach.

(xiii) A training plan that incorporates all Syneos Health required training, including tele-solution standard operating procedures and system training.

(xiv) Append phone numbers to entire universe at initial load – target HCP/ HCP office data needs to be provided [***] prior to the Go- Live Date if the phone append is required and [***] prior to go live if viable, current phone number data is included in the file.

(xv) Load Target universe with unique physician identifier that will link the record back to Agile systems.

(xvi) Standard Call activity reports will be provided to Agile on a weekly basis, focused on the KPIs determined for the project including successful qualification and scheduling metrics based on total target population provided. The metrics and reporting layout will be defined, documented,

and agreed upon during implementation in line with the business rules document.

(xvii) Agile will provide a direct contact that is responsible for development of HTML files that can be used to load to the CRM for email follow up communications. The project assumes setup of up to [***] template emails with HTML files to be provided by third party.

(xviii) Ongoing CRM Configuration modifications will be supported to provide continuous improvement of the program – including call outcome tags, detailed data capture requirements, call cycling plans. Syneos team will provide up to [***] per month of Business Solutions design, CRM Configuration changes and Testing.

(xix) Outbound Calls will consist of a touch point in [***] call cycles (each, a "Call Cycle") over a twelve (12) month period, with up to [***] attempts per Call Cycle to reach a decision maker at each Target record, with the following assumptions. The call prioritization and cycling to match this frequency will be configured in the Salesforce.com CRM.

1. The number of Calls per day to a primary care office is approximately [***];

2. The Total Office Call consists of messaging a clinical staff member (i.e., physician assistant(s) (PAs), nurse practitioner(s) (NPs), registered nurse(s) (RNs), medical assistant(s) (MAs), and certified medical assistant and registered nurse(s) (CMA and RNs);

(xx) The goal will be to reach decision makers in the Target's offices to drive awareness of the benefits and key features of the Product. Syneos Health will track data resulting from the discussions in a manner agreed to between the Parties. The program details are further described as follows:

1. Outbound Calls to Targets in 'whitespace' (geographies which are not covered by a field-based representative) and/or territories with physical access restrictions, "low frequency" field covered Targets and other targets disseminated by Agile from time to time who have no field coverage. Outbound Calls will focus on providing Product information, Product Literature, raising awareness of the benefits, key features and availability of the Product.

III. STATUS, TRAINING AND MEETINGS

(a) Hire Status—Generally. Upon completion and approval of the field alignment and profile, Syneos Health will commence recruiting and hiring activities for the Telesolutions Agent. In the event that Syneos Health receives notification to commence recruiting and hiring activities with respect to a position or territory, and that position or territory is subsequently cancelled by Client at any time after [***] from the date of such notification, then Client shall pay a cancellation fee to Syneos Health in the amount of [***] for each such cancelled position or territory.

(b) Hire Status—Provisioning. Syneos Health shall provide the Telesolutions Agent with the following:

(i) Salary, benefits, and incentive compensation payments as agreed by Client.

(ii) Human resources management services to include, but not be limited to, the following:

(1) Creation, distribution, and tracking of offer letters and onboarding documents

(2) Distribution of emails from background and drug screening vendors to complete required data for background screening and drug screen

(3) Tracking of background and drug screening results (follow-up may be required)

(4) New hire orientation

(5) Works with project lead coordination on investigations of policy non-compliance, background and other performance issues

(6) Coordination with leave and benefits administration as required

(7) Delivery of termination notices, participation in notification calls regarding downsizing and conversions

(i) Human resources management services assume the following:

(8) Timely completion of background vendor required information through its link for new hires

(9) Information regarding vacation, and incentive compensation expectations are available for inclusion in the offer letters

(10) Information technology hardware to include iPads and laptop computers (including sales force automation software) and printers.

(c) Training - The training responsibilities of the Parties are as follows:

(i) Syneos Health shall be responsible for training members of the Telesolutions Team concerning: Syneos Health human resource policies, procedures and administration and other applicable Syneos Health internal human resource and general compliance policies and procedures.

(ii) Client shall be responsible for training members of the Telesolutions Team concerning all Product specific information including Product complaint handling procedures, applicable specific Client health care compliance policies and Client customer service policies and procedures, orientation to Client's business, compliance with Applicable Law, and adverse event reporting policies and procedures. The Parties agree to work together to mutually determine if, when, and at what cost additional training shall be provided to members of the Telesolutions Team.

III. PERFORMANCE

If Client believes in good faith that the performance of any Telesolutions Agent is unsatisfactory or is not in compliance with the provisions of this Project Agreement, Client shall notify Syneos Health and Syneos Health shall promptly address the performance or conduct of such person in accordance with its internal human resource policies. In the event that Client determines in good faith that a Telesolutions Agent has violated any applicable law, regulation or policy, Client shall notify Syneos Health (in writing). Syneos Health shall promptly address the issue and take all reasonable and appropriate action (including but not limited to termination of such employee). No such action shall be contrary to Syneos Health's internal human resource policies and procedures, provided such human resource policies and procedures are in compliance with all Applicable Laws. If, despite any foregoing action by Syneos Health, Client is still reasonably unsatisfied with the performance of any Telesolutions Agent, Client may request the removal of such Telesolutions Agent by promptly notifying Syneos Health in writing, and Syneos Health shall remove the Telesolutions Agent from the provision of Services hereunder. Any action taken pursuant to this Section III will be in accordance with Syneos Health's internal human resource policies and procedure and the Applicable Laws governing employees. Syneos Health shall promptly notify Client if it becomes aware that any Telesolutions Agent has violated or is alleged to have violated any applicable law, regulation or policy.

IV. CALLS AND TARGETS

The Telesolutions Agent shall provide Client Material when making Calls as directed and approved by Client. Client is solely responsible for the content, production and distribution (to the Telesolutions Agent) of the Client Material. Each Telesolutions Agent shall record information concerning each Call, including but not limited to Product sample distribution, and concerning the profile of each individual Target (or other physician called upon) on whom the Telesolutions Agent calls. Client shall permit Syneos Health to access and use all Targets, sales and Call-related data that supports or is associated with the Services that are performed in accordance with this Project Agreement (the "Data"). The Data shall be used by Syneos Health

for the purpose of evaluating the performance of its Telesolutions Team members; and, provided that Syneos Health de-identifies all Client and Product specific components of the Data, for business development and analytics purposes.

V. THE PRODUCTS

The Product shall be promoted by Syneos Health under trademarks owned by or licensed to Client and are Products which Client has all lawful authority necessary to market and sell the Products in all geographic areas where the Products are to be promoted under this Project Agreement. This Project Agreement does not constitute a grant to Syneos Health of any property right or interest in the Products or the trademarks owned by or licensed to Client. Syneos Health recognizes the validity of and the title of Client to all its owned or licensed trademarks, trade names and trade dress in any country in connection with the Products, whether registered or not. Client represents to Syneos Health that neither those trademarks, trade names and trade address nor the promotion of the Products by Syneos Health infringes on any intellectual property right of any other person or entity.

VI. HIRING PROFILE

In selecting the Telesolutions Agent, Syneos Health will use the preferred hiring profile approved by Client. Syneos Health will take reasonable steps to confirm the accuracy of information concerning background and experience received from applicants for positions of Telesolutions Agents. Syneos Health shall not knowingly employ or otherwise retain, or permit to be retained as an Telesolutions Agent, a practicing physician or a person affiliated on a professional level with or employed by any physician, physician practice or other healthcare professional or provider or a person who is in a position to unduly influence the purchase of the Products.

VII. BACKGROUND CHECKS

Syneos Health shall be responsible for performing drug testing and background checks of all Telesolutions Agents. Syneos Health represents and warrants that it will complete or cause to be completed a thorough background check of all Telesolutions Agents. This will include, Criminal Check, Social Security Check, Drug Screen, Motor Vehicle Record Check, Education Check, Past Employer Check. Syneos Health further represents and warrants that it will perform or cause to be performed background checks to confirm that no Telesolutions Agent:

a. is an excluded person on the Office of Inspector General's List of Excluded Individuals/Entities and is not on the General Services Administration Excluded Parties List (as of the date the background check is performed);

b. is, so far as it is aware, an unfit or an improper individual for the performance of the Services;

c. is, so far as it is aware, engaged in any fraudulent or unlawful activity, or other inappropriate conduct as measured by the other requirements of this Project Agreement.

Syneos Health shall institute prompt corrective or disciplinary action against any Telesolutions Agent who fails to meet the requirements set forth in this Exhibit B. Syneos Health further agrees to cooperate and comply with all investigations by or on behalf of Client with respect to wrongdoing, or alleged or suspected wrongdoing, in respect of any obligations of Syneos Health or any Telesolutions Agent under this Project Agreement.

VIII. REPRESENTATIONS AND UNDERTAKINGS

(a) [***]

(b) Client represents that:

(i) it recognizes that for Syneos Health to comply with its obligations hereunder, it shall need the good faith cooperation of Client to provide Syneos Health with the necessary materials and assistance required to enable Syneos Health to perform the Services;

(ii) the Services being provided by Syneos Health are in furtherance of Client's program of marketing and promoting the Products and as such, Client is responsible for ensuring, and further, Client represents and warrants, that the Client's program being implemented by Syneos Health pursuant to the terms hereof (but not the implementation thereof by Syneos Health), strictly adheres to all applicable state and federal statutes, laws, ordinances, and the rules and regulations of all governmental and regulatory authorities, including but not limited to, the Federal Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act;

(iii) it shall ensure that none of its employees add, delete or modify claims of efficacy or safety of the Products, nor makes any changes (including but not limited to, underlining or otherwise highlighting any language or adding any notes thereto) in the Client Material, during the training on the Products or during any communications with Syneos Health employees;

(iv) it shall ensure that none of its employees working with the Telesolutions Team or in connection with the Services, directly or indirectly instruct any Syneos Health employee to pay, offer or authorize payment of anything of substantial value (either in the form of compensation, gift, contribution or otherwise) to any person or entity in a position to order, recommend or purchase the Products contrary to any law; and

(v) neither it nor any of its employees directly or indirectly instruct any Syneos Health employee to make any representations or warranties relating to the Products that conflict, or are inconsistent with applicable laws or the Food and Drug Administration approved labeling for the Products.

(iv) Client shall:

D. provide Telesolutions Agents with all Client Material.

E. inform Syneos Health promptly of any changes which Client

believes are necessary or appropriate in the Client Material or in information concerning the Products in order to be in compliance with all applicable federal and state law, regulations and administrative guidance.

F. arrange for a timely and appropriate response to any inquiry concerning a Product communicated to Syneos Health from any licensed practitioner and communicated by Syneos Health to Client.

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EXHIBIT C
COMMERCIAL COMPLIANCE SERVICES

1.0 Executive Summary

This Exhibit C describes the work required for the initial implementation and ongoing services of the Selling Solutions Commercial Compliance Services. Any changes to the assumptions, deliverables, or scope of work described in this document or any new work requests will follow the procedure set forth in Section 3.1.1(d) (Change Control Process) of Exhibit A-1.

2.0 Scope of Services

This Exhibit C defines the work related to the following service areas for the initial implementation and the ongoing services of the Selling Solutions Commercial Compliance teams within the following areas:

- Compliance Services
- Monitoring & Auditing

3.0 Compliance Services

Syneos Health will provide compliance services that comply with applicable laws and regulations and are aligned with the philosophy and requirements of OIG's Compliance Program Guidance in correlation with the following activities.

3.1 Pre-Launch Activities

(a) Initial interaction and fact finding with clients.

(b) Development and consultation in regards to the implementation of client specific compliance business rules.

(c) Creation of all training materials, (home study on Learning Management System) and live training modules.

(d) Work with and post specific policies required by the client.

3.2 Launch Activities

(a) Loading and testing of all on-line training to be conducted during home study, as well as assessments to test knowledge and competency. All tracking and reporting of results from the training.

(b) Live training to be conducted at launch meetings, POA's at client site's or in-house.

3.3 Ongoing Activities

(a) Training for all new hires/backfill for replacement personnel or expansions at client site's or in-house.

(b) Continual monitoring and updating if guidelines, laws, state requirements, or client business rules change during the course of the year.

(c) Corporate Integrity Agreement (CIA) obligations, additional training requirements, debarment screening of personnel, and annual certification of personnel and reporting to the client.

(d) Updates and assistance in supplying the necessary oversight and training at POA meetings during the year.

(e) Compliance/Representative ride-along program to monitor the field personnel in regards to their compliance requirements as agreed to by the client (Optional).

3.4 Enforcement and Monitoring

(a) Syneos Health adheres to an "Open Door Policy" and encourages employees to discuss issues and or concerns of misconduct with their manager or other senior personnel, Human Resources, or a member of the Compliance team.

(b) Syneos Health maintains and also encourages and supports a 24 hour anonymous hotline 7 days a week if the person making the report requires or wishes to remain anonymous.

(c) Syneos Health has an investigation process in place so as to ensure continuity in enforcement, and transparency with our personnel and clients so proper adjudication is achieved.

4.0 Monitoring & Auditing

Syneos Health uses the industry standard T&E system, Concur, to capture all expense reimbursement and HCP meal spend.
The Compliance Monitoring & Auditing team will assume the following:

(a) Standard Concur HCP expense fields and set-up are used for projects;

(b) Post Manager Compliance Audit of expense reports that contain HCP meal spend for appropriateness and adherence to Client policy on Interactions with Healthcare Professionals; and

(c) Ensure accountability for problem identification, oversight, follow-up, and resolution generated by the audit findings.

EXHIBIT D
SAMPLE ACCOUNTABILITY SERVICES

1.0 Scope of Services

Syneos Health will provide management of third party sample accountability services ("SA") in compliance with the Prescription Drug Marketing Act (PDMA) regulations for the field sales organization.

2.0 Sample Accountability Services

2.1 Implementation

Sample Accountability will be managed and monitored through a third party sample accountability vendor, through a PDMA compliant Inventory Management System. During the set up stages there will be requirements gathering, QA/validation, unit and integration testing with technical documentation prior to production deployment.

(a) Development will include:

(1) Interface to map from third party Sample Accountability system and Veeva CRM;

(2) Qualification of the CRM/ Sample Accountability deployment with Client specific configuration;

(3) Testing and documentation and validation of the system interfaces;

(4) File layouts - formatting will be received in designated format;

(5) Sample data extract for Annual Federal Reporting – Provided to Client in Syneos Health standard format;

(6) Business Rules and Policy and Procedure Handbook development based on client's specific rules;

(7) Sample Accountability form development (PACF) utilized for disbursement corrections;

(8) Signature verification letter development; and

(9) Set up of individual representative files to store all Sample Accountability activity and documentation on training, storage locations and reconciliations

(10) PDMA training – Initial training with documentation testing through Syneos Health LMS system

(11) Significant Loss Threshold (SLT) Analysis provided by a third party as required

(12) Development of a 1-hour PDMA/Sample Accountability training slide deck (Client Specific) to be delivered to representatives through live training, either on site or via WebEx

2.2 On-Going Sample Accountability Services

Sample Accountability will assume monthly representative inventories will be taken with quarterly reconciliations. Quarterly reconciliations will monitor and compare inventory levels based on the representative's transactional activity during the quarter. A standard suite of reports will be utilized throughout the quarter to monitor the representative's activity and to detect areas of concern prior to the end of the quarter.

(a) The quarterly reconciliation process will include:

(1) Generation/emailing of Sample Inventory Reconciliation report to sales representatives based on field conducted inventory counts;

(2) Representative assistance in reconciliation of inventory variances over established significant loss thresholds;

(3) Reporting of sample reconciliation results to Client home office, based on the FDA reporting model of initial 5 day reporting and 30 day final reporting; and

(4) Syneos Health's Sample Management and Compliance Department (SM&C) oversight of the reconciliation process

2.3 General Sample Management Administration

(a) Standard reports will be provided as agreed upon in the implementation phase of the project

(b) Physician Signature Audit Service will include an agreed upon percentage of letters sent monthly to practitioners to verify signatures. This audit is to detect possible abuse with capturing fraudulent signatures. Negative responses are reported to Client as defined in the Client's business rules

(c) Tracking of PDMA and Sample Management Training – Files will be maintained for each representative

(d) Field Audits – Random, For Cause, Closeouts and Annual

(e) Sample Accountability Help Desk Support

(f) Ongoing PDMA/Sample Accountability training annually and as needed – New hire/retraining

(g) Monitoring of non-compliant representatives through monthly trending reports

(h) Maintenance/tracking of representative sample storage locations – Stored in representatives individual files

(i) Maintenance of product name, description, lot numbers, expiry dates as pertains to Representative sampling activity

2.4 Additional Ad Hoc Services:

(a) FDA and State reporting by third party Sample Accountability vendor

EXHIBIT E
TRAINING SERVICES

5.0 Executive Summary

This Exhibit E describes the work required for the initial implementation and ongoing operation of the Training Services to support the Project Team by Syneos Health Learning Solutions

6.0 Scope of Services

Syneos Health will provide training services for the Syneos Health Field Team employees; to include, in addition to any Client-provided content, the following Syneos Health content:

- Syneos Health Administrative Training
- Syneos Health Technology & Operational Training
- Syneos Health Policies
- Selling Skills Training (customization to be scoped separately)
- Fleet (as applicable)
- Syneos Health University (Home Study e-Courses only)
- Pharmaceutical Institute LLC; d/b/a Syneos Health Learning Solutions, Catalog of e-Courses), in the following categories:
  - Therapeutic Essentials (i.e., Disease State e-Courses)
  - Managed Markets Excellence (i.e., Market Access e-Courses)
  - Understanding Pharma (i.e., Industry Background e-Courses)
- Skillsoft Business and Leadership Skills Catalog of e-Courses Only)

Syneos Health will leverage its internal Learning Management System (LMS) to consolidate the training curriculum and training records which allows for tracking and reporting of certification internally and to client.

EXHIBIT F
COMPENSATION - FIXED FEES, VARIABLE FEES AND PASS-THROUGH COSTS

I. FIXED FEES

The Fixed Fees provided in this Exhibit F are based on per position headcount as follows:

Position	Headcount
Sales Team	
Sales Representatives	[***]
DMs	[***]
Telesolutions Team	
Telesolutions Agents	[***]

The Fixed Fees will be proportionally modified based on the final headcount.

(a) Implementation Fee

(i) Client has paid, or shall pay, [***] pursuant to the Initial Service Agreement (the "ISA") by and between Client and Syneos Health dated as of March 30, 2020, which will be applied as a credit against the Implementation Fee invoice.

(ii) Client shall pay Syneos Health an Implementation Fee of [***] associated with performance of the Services for the Sales Team.

(ii) Client shall pay Syneos Health an Implementation Fee of [***] associated with performance of the Services for the Telesolutions Agents.

(b) Fixed Monthly Fees

(i) Commencing on the Sales Team Hire Date, Client shall pay Syneos Health a Fixed Monthly Fee as follows:

PERIOD	SALES TEAM FIXED MONTHLY FEE
Year One	[***]
Year Two	[***]

(ii) Commencing on the Telesolutions Team Hire Date, Client shall pay Syneos Health a Fixed Monthly Fee as follows:

PERIOD	TELESOLUTIONS TEAM FIXED MONTHLY FEE
Year One	[***]
Year Two	[***]

Syneos Health shall adjust the Fixed Monthly Fee prior to the initial fill of any Syneos Health Sales Representative, DM or Telesolutions Agent, prorated for any partial months, according to the Fixed Monthly Fee table outlined in subsection (c)(i), below.

The Implementation Fee and/or Fixed Monthly Fee set forth above are based upon the assumptions set forth in the recruitment/training timeline agrees to by the Parties. In the event that the assumptions set forth in the recruitment/training timeline are changed, the Implementation Fee and/or Fixed Monthly Fee shall be re-calculated and agreed-upon by the Parties.

(c) Scale Up/Down

(i) Client may increase the number of Representatives, SR. Reps, Telesolutions Agents or DMs above the number outlined in Exhibit A and B (a "Scale Up") upon written notification to Syneos Health. In the event of a Scale Up, Client shall pay to Syneos Health an additional Implementation Fee and Fixed Monthly Fee as follows:

Position	Implementation Fee
Per Representative	[***]
Per SR. Rep	[***]
Per Telesolutions Agent	[***]
Per DM	[***]

Position	Fixed Monthly Fee (Year One)	Fixed Monthly Fee (Year Two)
Per Representative	[***]	[***]
Per SR. Rep	[***]	[***]
Per Telesolutions Agent	[***]	[***]
Per DM	[***]	[***]

(ii) Client may decrease the number of Representatives, SR. Reps, Telesolutions Agents or DMs below the number outlined in Exhibit A and B (a "Scale Down") upon [***] prior written notice to Syneos Health; provided, however, that the Client may not perform a Scale Down prior to the [***] anniversary of the Deployment Date. In the event of a Scale Down, Syneos Health shall reduce the Fixed Monthly Fee as follows:

Position	Fixed Monthly Fee (Year Two)
Per Representative	[***]
Per SR. Rep	[***]
Per Telesolutions Agent	[***]
Per DM	[***]

(iii) The Parties shall meet to agree upon Project Team composition in the event of a Scale Up/Scale Down.

(d) Salary Reconciliation

The parties agree that the Fixed Monthly Fees set forth in Section I(b), above, are based on the annual salary per the below table (the "Annual Salary").

Position	Salary (Year One)	Salary (Year Two)
Per Representative	[***]	[***]
Per SR. Rep	[***]	[***]
Per Telesolutions Agent	[***]	[***]
Per DM	[***]	[***]

Syneos Health and Client will reconcile actual salaries and payroll taxes at [***] (pricing assumption), excluding incentive compensation, measured by actual days worked, for each Syneos Health Sales Representative, DM and Telesolutions Agent in such calendar month against an amount equal to the appropriate percentage of the Annual Salary. The parties agree that the Annual Salary does not include incentive compensation for the Syneos Health Sales Representatives, DMs or Telesolutions Agents (plus the applicable employer portion of taxes). If any review shows that Syneos Health's actual annual salary per Syneos Health Sales Representative, DMs or Telesolutions Agent is below the Annual Salary, then Syneos Health shall issue a credit for the entire amount of such difference to Client. If any review shows that Syneos Health's actual salary per Syneos Health Sales Representative, DMs or Telesolutions Agent is above the Annual Salary, then Syneos Health shall bill the difference to Client.

(e) Vacancy Credit

Syneos Health agrees to fill vacant territories as requested by Client. Syneos Health will continue to invoice Client the amounts set forth above as Fixed Monthly Fee during any such vacancy period. Syneos Health will provide a monthly credit to Client, prorated for the number of business days per month that a territory is vacant, for each vacant territory, including leaves of absence lasting longer than [***], until such territory is filled, as set forth in the following table:

Monthly Vacancy Credit*	Year One	Year Two
Per Representative	[***]	[***]
Per SR. Rep	[***]	[***]
Per Telesolutions Agent	[***]	[***]
Per DM	[***]	[***]

*Within the month a territory becomes vacant.

Monthly Vacancy Credit*	Year One	Year Two
Per Representative	[***]	[***]
Per SR. Rep	[***]	[***]
Per Telesolutions Agent	[***]	[***]
Per DM	[***]	[***]

*Subsequent months of vacancy.

(f) Backfill Recruiting

Client agrees to pay Syneos Health a fee, per the table below, for recruiting and onboarding costs associated with any backfill for a vacant territory, provided that Client shall only pay such fee in the event that such territory becomes vacant [***] after the applicable hire date.

Position	Backfill Recruiting Fee
Per Sales Representative	[***]
Per SR. Rep	[***]
Per Telesolutions Agent	[***]
Per DM	[***]

II. VARIABLE FEES

(i) Client shall pay Syneos Health the following monthly fees per Client employee receiving operations support (Veeva and LMS Licenses) commencing on the date a Client employee is provided such support.

Position	Monthly Fee (Year One)	Monthly Fee (Year Two)
Veeva License Only Per Client User	[***]	[***]
LMS License Only Per Client User	[***]	[***]

(ii) Client shall pay Syneos Health an annual fee of [***] for each Client employee to have access to a list of Client programs on the LMS System (same environment as the Syneos Health Project Team – i.e., no customization per view set-up) commencing on the date a Client employee is provided such support.

(iii) Syneos Health shall invoice Client the following Variable Fees associated with the Telesolutions Team as incurred.

Additional Services	Variable Fee
Phone Append Access (up to 13,000 Records)	[***]
Phone Append Access, per Record (After 13,000 Records)	[***]
Phone Append Transfer (up to 650 Records)	[***]
Phone Append Transfer, per Record (After 650 Records)	[***]
Outbound Fax, per page	[***]
E-mail, each	[***]

III. PASS-THROUGH COSTS

In addition to the Fixed Fees, certain expenses will be charged to Client on a pass-through basis. These expenses will be billed to Client at actual cost. Pass-through costs include:

- Incentive compensation payments for the Syneos Health Sales Representatives, Telesolutions Agents and DMs (plus applicable employer portion of taxes at [***])
- Travel expenses (e.g. transportation, lodging, meals etc.)
- Costs for all meetings, including but not limited to POA Meetings
- Marketing expenses and costs (e.g. Lunch & Learns, etc.)
- Sales TRx data and any third party data acquisition expenses
- Syneos Health Sales Representative product storage units
- Data plan overages
- Interview expenses (including turnover recruiting)
- Business cards

- Managers' severance
- Licensing and credentialing expenses
- Shipping, freight, and postage of samples (if incurred)
- Other expenses which have been approved by Client.

IV. INCENTIVE FEES

(a) Included in the Fixed Monthly Fees (set forth in Section I(b)(i), above) is Syneos Health's management fee, a portion of which (the "Incentive Fee") is subject to Syneos Health's achievement of certain performance objectives (the "Performance Objectives") which will be mutually agreed upon by the Parties.

(b) The monthly Incentive Fee for the annual period from the Deployment Date through the end of Year One is equal to [***] and the monthly Incentive Fee during Year Two is equal to [***].

(c) In the event of a Scale Up or Scale Down, the monthly Incentive Fee shall be adjusted by [***] per Syneos Health Sales Representative from the Deployment Date through the end of Year One, and [***] per Syneos Health Sales Representative during Year Two.

(d) In the event of termination of this Project Agreement by the Client, effective as of the date of notification of such termination from the Client, the Performance Objectives shall no longer be applicable and the outstanding incentive fees will be earned at [***]; unless Project Agreement is terminated due to material breach by Syneos Health in accordance with Section 12(ii) of the MSA.

V. SERVICE CREDITS

Syneos Health shall issue to Client annual service credits of [***] per Syneos Health Sales Representative and Telesolutions Agent (estimated to be [***] in Year One and [***] in Year Two). Credits shall be earned at a rate of [***] per month per Syneos Health Sales Representative and Telesolutions Agent territory, for which a fee has been paid, commencing on the Deployment Date. Client may use all expected credits at any time during the Term and shall repay Syneos Health at the end of the Term for any credits used, but never accrued. The service credits shall be used to purchase additional services from Syneos Health's Affiliates. The term Affiliate means, with respect to any entity, any other entity directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with such entity. As used in this definition, the term "control" (including "controlled by" or "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through ownership of voting securities, as trustee, by contract or otherwise. For purposes of clarity, Client shall not be permitted to apply the credits against any of the fees or costs associated with Services provided under this Work Order or any others services provided by Syneos Health, it being understood that the credits are applicable only for services provided by a Syneos Health Affiliate. The credits shall be valid until expiration or termination of this Work Order. Syneos Health shall not provide any form of refund, rebate or any other form of monetary incentive to Client in lieu of the credits.

VI. INVOICES; BILLING TERMS

The Implementation Fees outlined in Section I(a), above, shall be invoiced to Client upon execution of the Project Agreement. [***] of Sales Team Fixed Monthly Fee and [***] of Agents Fixed Monthly Fee (the "Advanced Fees") shall be paid by Client to Syneos Health which will be invoiced to the Client [***] prior to the sales representative hire date. The Advanced Fees shall be held as a deposit and credited to Client upon expiration or termination of the Project Agreement. Thereafter, commencing on the Sales Team Hire Date and Telesolutions Agent Hire Date, Client will be billed monthly in advance the amounts stated above as the Fixed Monthly Fees. Pass-through Costs will be billed to Client at actual cost as incurred by Syneos Health.

Invoices are due in accordance with Section 5 of the MSA. All invoices shall include the following:

- A/P Email
- A/P Telephone
- A/P Mailing Address
- A/P E-invoice System
- Other Contacts to be Included on Submission of Invoice
- Accountant

Payment to Syneos Health may be made by the following method:

- ACH Payment (Preferred Method)
  [***]
  ACH # [***]
  Account # [***]

  Advice transmittals should be directed to [***].

In the event Client will be issuing purchase orders for payment of Syneos Health invoices, Client shall issue such purchase orders within [***] following the execution of this Project Agreement. A purchase order shall include the following:

- PO Number
- PO Contact Name
- PO Contact E-mail
- PO Contact Telephone

  Purchase Orders should be directed to [***].

The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Project Agreement provides the terms and conditions governing the relationship between the Parties.

ATTACHMENT 1

PROJECT TEAM MEMBER REQUEST FORM

This Request for Additional Project Team members is issued pursuant to the Master Services Agreement between Syneos Health Commercial Services, LLC ("Syneos Health") and Agile Therapeutics, Inc. ("Client") dated and the Project Agreement issued thereunder dated _____.

PART 1	**To be completed by Client** **Attach any relevant, helpful information**
NUMBER AND TYPE OF PROJECT TEAM PERSONNEL REQUESTED	
TERRITORY LOCATION(S)	
REQUESTED HIRE DATE	
DEPLOYMENT DATE	
AUTHORIZED CLIENT REPRESENTATIVE SUBMITTING REQUEST	Signature: _____ Name: Title: Date: Phone: Fax:
PART 2	**To Be Completed by Syneos Health**
NEW PROJECT TEAM MEMBER DETAILS (the fees set forth below are per Project Team member added): Implementation Fee $_____ Added Fixed Monthly Fee: $_____ Target Start Date: _____	Request is Accepted, and Recruitment shall begin immediately upon Client approval of New Representative Details: _____ (sign and date) Syneos Health Contact Person: Phone:
	New Project Team member accepted and customer understands that recruiting will begin immediately: (sign and date) Client Contact Person: Phone:

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

MASTER SERVICE AGREEMENT

This Master Service Agreement (this "Agreement") is made as of October 11, 2017 (the "Effective Date") by and between inVentiv Commercial Services, LLC, a New Jersey limited liability company with an office located at 500 Atrium Drive, Somerset, NJ 08873 ("inVentiv") and Agile Therapeutics, Inc., a Delaware corporation with an office located at 101 Poor Farm Road, Princeton, New Jersey 08540 ("Client"). Client and inVentiv may each be referred to herein as a "Party" and collectively, the "Parties".

RECITALS

A. inVentiv and its Affiliates (as defined herein) offer a wide range of services and offerings to clients in the pharmaceutical and biotechnology arena.

B. Client hereby engages inVentiv, and inVentiv hereby accepts such engagement, to provide various types of services pursuant to the terms hereof and each separate project agreement in the form attached hereto as Exhibit A (each a "Project Agreement") to be executed by the Parties. Client and inVentiv shall enter into a Project Agreement for each program they wish to be governed by the terms and conditions of this Agreement.

1. Interpretation and Construction

(a) The Parties desire for the terms and conditions set forth in this Agreement to govern the relationship between the Parties. Unless otherwise specifically set forth in a Project Agreement, in the event of a conflict or inconsistency between the terms and conditions set forth in this Agreement and the terms and conditions set forth in a Project Agreement, the terms and conditions set forth in this Agreement shall take precedence, govern and control. Terms in a Project Agreement that supplement the terms of this Agreement will be read together with their related terms and not be deemed "conflicting".

(b) The Parties hereby acknowledge that the terms set forth in this Agreement shall be incorporated by reference into each Project Agreement, as if fully set forth at length therein.

(c) The Parties acknowledge that in addition to inVentiv, certain of inVentiv's Affiliates may provide certain services to Client and may directly enter into a Project Agreement with Client, subject to Client's prior written consent, pursuant to which such inVentiv Affiliate shall provide certain services to Client, as set forth in detail in said executed Project Agreement. The Parties acknowledge and agree that variation may exist in the form Project Agreement depending upon the inVentiv Affiliate and the nature and type of services provided. In such event, the Project Agreement shall confirm that this Agreement shall govern the relationship between Client and the particular inVentiv Affiliate, and such parties agree to be bound by the terms set forth herein. Client agrees that inVentiv acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of any inVentiv Affiliate under any

circumstances in connection with any Project Agreement that is not signed by inVentiv. Further, each inVentiv Affiliate acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of inVentiv or any other inVentiv Affiliate under any circumstances in connection with this Agreement or any Project Agreement that is not signed by that inVentiv Affiliate.

(d) As set forth above, the term "Affiliate" means, with respect to any entity, any other entity directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with such entity. As used in this definition, the term "control" (including "controlled by" or "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through ownership of voting securities, as trustee, by contract or otherwise.

2. <u>The Services</u>

(a) Client shall retain inVentiv to provide services as set forth in one or more Project Agreements (hereinafter the "Services").

(b) Client has no obligation to inVentiv for Services under this Agreement in the absence of an executed Project Agreement covering such Services.

(c) Each Project Agreement shall allocate responsibility for project management and quality assurance activities necessary to perform the Services. inVentiv will provide regular updates as to the progress of the Services at a frequency and in a manner designated by the Parties in the Project Agreement.

3. <u>Representations and Warranties of the Parties</u>

(a) inVentiv represents, warrants and covenants that:

(i) it shall perform the Services in a professional, workmanlike manner, in accordance with good industry practice, in accordance with all applicable policies and procedures, and in accordance with those specifications, timelines, and any other qualitative or quantitative standards which inVentiv and Client agree to (in writing);

(ii) it shall maintain in full force and effect all necessary licenses, permits, approvals (or waivers) and authorizations required by law to carry out its obligations under this Agreement and any Project Agreement;

(iii) the execution, delivery and performance of this Agreement by inVentiv and the consummation of the transaction(s) contemplated hereby has been duly authorized by all requisite corporate action; that the Agreement constitutes the legal, valid, and binding obligation of inVentiv, enforceable in accordance with its terms (except to the extent enforcement is limited by bankruptcy, insolvency, reorganization or other laws affecting creditors' rights generally and by general principles of equity); and that this Agreement and performance hereunder does not violate or constitute a breach under any organizational document of inVentiv or any contract,

other form of agreement, or judgment or order to which inVentiv is a party or by which it is bound;

(iv) the personnel assigned to perform Services rendered under this Agreement and any Project Agreement shall be capable professionally and duly qualified to perform the Services hereunder and in each Project Agreement;

(v) it is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement and any Project Agreement and that during the term of this Agreement and any Project Agreement, it will not enter into any agreement to provide services which would in any way prevent it from performing the Services;

(vi) the Services shall be provided in compliance with all applicable statutes, federal and state laws, ordinances, rules or regulations of any governmental or regulatory authority including (but not limited to), as applicable, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code on Interactions with Healthcare Professionals, the Accreditation Council for Continuing Medical Education requirements for continuing medical education, the American Medical Association Ethical Guidelines on Gifts to Physicians from Industry, the Federal Food, Drug and Cosmetic Act ("FDCA"), the Medicare/Medicaid anti-kickback statute, the Prescription Drug Marketing Act ("PDMA"), the Health Insurance Portability and Accountability Act ("HIPAA") and The Health Information Technology for Economic and Clinical Health ("HITECH") Act, and similar state laws, rules and regulations (collectively, "Applicable Law");

(viii) any Services or work performed or Deliverables (defined below) provided under this Agreement or any Project Agreement, or any portion thereof, do not infringe, misappropriate, or otherwise violate any intellectual property rights of any third party; and no third party has asserted or is asserting, a claim of any of the foregoing. However, the foregoing will not apply if the applicable infringement, misappropriation, or violation is caused by Client's unauthorized use or modification of any work or Deliverables

(b) Client represents, warrants and covenants that:

(i) the execution, delivery and performance of this Agreement by Client and the consummation of the transaction(s) contemplated hereby has been duly authorized by all requisite corporate action; that the Agreement constitutes the legal, valid, and binding obligation of Client, enforceable in accordance with its terms (except to the extent enforcement is limited by bankruptcy, insolvency, reorganization or other laws affecting creditors' rights generally and by general principles of equity); and that this Agreement and performance hereunder does not violate or constitute a breach under any organizational document of Client or any contract, other form of agreement, or judgment or order to which Client is a party or by which it is bound;

(ii) Client shall apply the degree of skill and care necessary, and will act in good faith to provide inVentiv with the necessary materials, information, product training, and assistance required to enable inVentiv to perform the Services in compliance with all Applicable

Law. Certain Client obligations and responsibilities unique to a specific Project Agreement shall be specified within that Project Agreement;

(iii) Client shall ensure all content (product or otherwise), materials, documentation and information provided by it to inVentiv are in compliance with all Applicable Laws when provided or made available to inVentiv;

(iv) Client shall provide any and all necessary training regarding the Client product(s) and shall be responsible for all costs and expenses of such training, including pre-approved inVentiv personnel travel, lodging, meals, and other reasonable miscellaneous expenses directly related to such training;

(v) Client's products shall be promoted under trademarks owned by or licensed to Client and are products which are either owned by Client and/or as to which Client has all lawful authority necessary to market and sell the products. Client represents and warrants that its trademarks, trade names and trade dress do not infringe on any intellectual property or product marketing rights of any other person or entity. Client further represents and warrants that the promotion of any Client product by inVentiv does not infringe on any intellectual property or product marketing rights of any other person or entity;

(vi) Client is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement and any Project Agreement and that during the term of this Agreement and any Project Agreement, it will not enter into any agreement which would in any way prevent or restrict inVentiv from performing the Services; and

(vii) Client is solely responsible for reviewing and approving all Client's product promotional materials and literature created pursuant to or provided for use under this Agreement and/or Project Agreement and for ensuring all such materials comply with Applicable Law; and

(viii) Client shall notify inVentiv in the event it is subject to or becomes subject to a Federally Mandated Corporate Integrity Agreement (CIA) or other compliance obligations which require inVentiv to provide Client with data, training, analysis, oversight or certifications that are not contemplated by the Services described herein. In such event, the Parties shall mutually agree on an appropriate allocation of costs and expenses associated with inVentiv's provision of such CIA related data, training, analysis, oversight or certifications not included in the scope of Services provided under this Agreement or any related Project Agreement.

4. **Independent Contractors; inVentiv Personnel**

Except as may otherwise be provided in a Project Agreement:

(a) inVentiv and its directors, officers, employees, independent contractors, and any persons providing Services under the Agreement and any Project Agreement are at all times independent contractors with respect to Client. Persons provided by inVentiv to perform Services shall not be deemed employees of Client. Neither this Agreement nor the Services to be rendered hereunder

shall for any purpose whatsoever or in any way or manner create any employer-employee relationship between inVentiv, its directors, officers, employees and any persons providing Services under the Agreement and Client. inVentiv may utilize independent contractors in connection with its performance of the Services only with Client's prior written approval; provided, further, that inVentiv will remain fully responsible for the conduct of its independent contractors. For purposes of this Agreement, the parties agree that Client's prior written consent is not required for inVentiv to use third party contractors in inVentiv's general business operations and the underlying support services supporting such general business operations (for example, IT services and/or internal software, equipment, CRM, etc.) which may be used in the provision of Services.

(b) inVentiv is, and at all times shall remain, solely responsible for the human resource and performance management functions of all inVentiv personnel provided to perform the Services. inVentiv shall be solely responsible and liable for all disciplinary, probationary and termination actions taken by it, and for the formulation, content and dissemination of all employment policies and rules (including written disciplinary, probationary and termination policies) applicable to its employees, agents and contractors (individually, a "inVentiv Employee" and collectively, "inVentiv Employees").

(c) inVentiv shall obtain and maintain worker's compensation insurance and other insurances required for inVentiv Employees performing the Services and acknowledges that Client does not, and shall not obtain or maintain such insurances, all of which shall be inVentiv's sole responsibility.

(d) Except as otherwise set out in this Agreement or in a Project Agreement, Client shall have no responsibility to inVentiv or any inVentiv Employee for any compensation, expense reimbursements or benefits (including, without limitation, vacation and holiday remuneration, healthcare coverage or insurance, life insurance, pension or profit-sharing benefits and disability benefits), payroll-related or withholding taxes, or any governmental charges or benefits (including, without limitation, unemployment and disability insurance contributions or benefits and workers compensation contributions or benefits) that may be imposed upon or be related to the performance by inVentiv or its employees, agents or contractors of the obligations under this Agreement or any Project Agreement, all of which shall be the sole responsibility of inVentiv. To clarify, Client will not withhold any income tax or payroll tax of any kind on behalf of inVentiv.

(e) Any request by Client for removal of a inVentiv employee assigned to provide Service(s) shall be made in writing, supported by the Client's reasons for requesting the removal and documentation of the inVentiv staff member's actions and/or behavior that support the request. All employment decisions regarding an inVentiv employee shall be made solely and exclusively by inVentiv and is subject to compliance at all times with inVentiv's human resource policies and procedures.

5. inVentiv Compensation

(a) In consideration of the performance of the Services, Client shall pay inVentiv the

fees, costs and expenses (collectively, the "Fees") as set forth in each Project Agreement. inVentiv shall bill Client as set forth in each Project Agreement and invoices shall be sent by inVentiv to Client on a monthly basis for the Fees for Services.

(b) In addition to the Fees set forth in a Project Agreement, certain necessary and reasonable expenses will be charged to Client on a pass-through basis. These expenses will be billed to Client at actual cost incurred by inVentiv. Pass-through costs specific to a particular Service shall be set forth in the applicable Project Agreement.

(c) Payments are due upon Client's receipt of each applicable invoice from inVentiv. If any invoice amount is not paid within [***] of Client's receipt, inVentiv reserves the right, following [***] prior written notice, to impose a [***] on all amounts not paid when due. In the event that a third party supplier of inVentiv requires expedited payment from inVentiv, Client will pay inVentiv for such expenses on the same terms that inVentiv is required to pay its third party supplier; provided, however, that inVentiv must provide Client with such terms in writing, and, whenever reasonably possible in advance, with as much notice as possible.

(d) Client may withhold payment of any invoiced amounts it may dispute in good faith; provided, however, that if there is an undisputed portion of the invoice, such payment must be made when due. The Parties will work in good faith to resolve any such disputes, but in no event later than [***] from notice of the dispute. During such good faith resolution period and subject to Section 12(a)(ii), such billing disputes shall not be cause for non-performance under this Agreement or any Project Agreement.

(e) In the event Client will be issuing purchase orders for payment of inVentiv invoices, Client shall issue such purchase orders in a timely manner in accordance with the terms and conditions set forth herein. The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Agreement provides the terms and conditions governing the relationship between the Parties.

(f) Taxes. Upon mutual agreement of the Parties, inVentiv shall invoice Client and Client shall reimburse inVentiv for any taxes actually paid by inVentiv that are properly imposed upon inVentiv by any governmental agency as a result of this Agreement or any Project Agreement (excluding any taxes based on inVentiv's income) that are the responsibility of the Client. The Parties will cooperate to minimize mutual tax exposure.

6. <u>Confidentiality</u>

(a) During the performance of the Services contemplated by this Agreement, each Party may learn confidential, proprietary, and/or trade secret information of the other Party ("Confidential Information"). The Party disclosing Confidential Information shall be referred to as the "Disclosing Party" and the Party receiving Confidential Information shall be referred to as the "Receiving Party."

(b) Confidential Information means any information, unknown to the general public, which is disclosed, made available, or created by the Disclosing Party to the Receiving Party under this Agreement. Confidential Information includes, without limitation, the terms set forth

in this Agreement, technical, trade secret, commercial and financial information about either Party's (i) research or development; (ii) marketing plans or techniques, contacts or customers; (iii) organization or operations; (iv) business development plans (i.e., licensing, supply, acquisitions, divestitures or combined marketing); (v) products, licenses, trademarks, patents, other types of intellectual property or any other contractual rights or interests (including without limitation processes, procedures and business practices involving trade secrets or special know-how), (vi) pricing and financial information, and (vii) in the case of inVentiv, the names and contact information (i.e. phone number, address and e-mail address) of the inVentiv Employees.

(c) The Receiving Party shall neither use nor disclose Confidential Information received from the Disclosing Party for any purpose other than as specifically allowed by this Agreement. Confidential Information disclosed to a Receiving Party will be held in confidence by the Receiving Party, using at least the same standard of care the Receiving Party uses with respect to its own information of a similar nature, but in no event less than a reasonable standard of care and will not be disclosed to others or used, except solely for the purposes agreed in this Agreement or any Project Agreement, without the prior written approval of the Disclosing Party. Each party will advise its Permitted Representatives of the requirements of this Agreement and direct each of them to comply therewith. Each party is responsible for any breach of this Agreement by its Permitted Representatives. Receiving Party agrees to use the Confidential Information received hereunder solely for the purpose of this Agreement and any Project Agreement and further agrees to limit dissemination of Confidential Information to those of its Permitted Representatives who have a need to know for purposes of performing its obligations under this Agreement and each applicable Project Agreement and who are bound by an obligation (written or oral) of non-disclosure with Receiving Party. Each party will maintain reasonable safeguards, policies and procedures to protect Confidential Information against unauthorized use, disclosure, alteration, or destruction. As used herein, "Permitted Representatives" means a Party and its Affiliates and their respective officers, employees, directors, agents, third party vendors, independent contractors, consultants, counsel and advisors who need to know the Confidential Information for the purpose of performing obligations in connection with this Agreement or any Project Agreement.

(d) Upon the expiration or termination of this Agreement and receipt of Disclosing Party's written request, Receiving Party, at its option, shall promptly either (a) return to the Disclosing Party all tangible forms of Confidential Information in its possession, including any and all copies and/or derivatives of Confidential Information made by either Party or their employees as well as any writings, drawings, specifications, manuals or other printed or electronically stored material based on or derived from, Confidential Information, or (b) destroy Confidential Information in its possession and deliver to Disclosing Party a certification that such destruction has occurred; provided however, that Receiving Party may retain a copy of any information, including Confidential Information, that the Receiving Party reasonably believes is required to comply with applicable laws or regulations or to effectuate the Purposes of this Agreement. The Receiving Party shall not disclose to third parties any Confidential Information or any reports, recommendations, conclusions or other results of work under this Agreement or any Project Agreement without prior consent of an officer of the Disclosing Party. The obligations set forth in this Section 6, including the obligations of confidentiality and non-use shall be continuing and shall survive the expiration or termination of this Agreement and the Project Agreement and will continue for a period of [***] from the date of such expiration or

termination.

(e) The obligations of confidentiality and non-use set forth herein shall not apply to the following: (i) Confidential Information at or after such time that it is or becomes publicly available through no fault of the Receiving Party; (ii) Confidential Information that is already independently known to the Receiving Party without confidential or proprietary restriction, before disclosure, as shown by prior written records; (iii) Confidential Information at or after such time that it is disclosed to the Receiving Party by a third party with the legal right to do so, and (iv) solely with respect to the specific relevant process, order or request, Confidential Information required to be disclosed pursuant to judicial process (and only to the extent so required), court order or administrative request, provided that the Receiving Party shall so notify the Disclosing Party sufficiently prior to disclosing such Confidential Information as to permit the Disclosing Party to seek a protective order.

7. Restrictions on Solicitation

Except as may otherwise be provided in a Project Agreement:

(a) Neither Party may solicit the employees or independent contractors of the other Party to become employees of, or consultants to, such Party during the Term of this Agreement and any Project Agreement and for a [***] period following the termination of both this Agreement and any Project Agreement. The provisions of this Section 7 shall not apply with respect to either Party's employees or independent contractors who seek employment from the other Party on their own initiative, such as, but not limited to, in response to a general vacancy announcement or advertisement.

(b) Client agrees during the Term of this Agreement and for [***] thereafter not: (i) to provide any contact information (including name, address, phone number or e-mail address) of any inVentiv Employee to any third party which provides or proposes to provide Client with the same services being provided by inVentiv pursuant to a Project Agreement, or (ii) to assist actively in any other way such a third party in employing or retaining such inVentiv Employee.

(c) Each Party shall pay to the other Party (or cause the third party to pay to inVentiv, as the case may be, [***] for each employee of the other Party so employed or retained as liquidated damages for breach of Sections 7(a) or 7(b).).

8. Indemnification

(a) inVentiv shall indemnify and hold Client, its officers, directors and employees harmless from and defend them against any and all third party liabilities, losses, proceedings, suits, actions, damages, claims or expenses of any kind, including court costs and reasonable attorneys' fees (collectively, "Losses") which are caused by: (i) any fraudulent or negligent acts or omissions by or the willful misconduct of inVentiv, its directors, officers, ~~or~~ employees, or independent contractors, (ii) any material breach of this Agreement or any Project Agreement by inVentiv, its directors, officers, employees, or independent contractors, (iii) any breach of the representations, warranties, covenants, and agreements of inVentiv to Client set out in Section 3(a) and Section 6 above.

(b) Client shall indemnify and hold inVentiv, its officers, directors and employees harmless from and defend against any and all Losses which are caused by: (i) any negligent acts or omissions by or the willful misconduct of Client, its directors, officers or employees, (ii) any material breach of this Agreement or any Project Agreement by Client, its directors, officers or employees, (iii) any product liability claims relating to Client products, whether arising out of warranty, negligence, strict liability (including manufacturing, design, warning or instruction claims) or any other product based statutory claim, (iv) any intellectual property infringement claims relating to any trademarks owned by or licensed to Client, and (v) any breach of the representations, warranties, covenants, and agreements of Client to inVentiv set out in Section 3(b) and Section 6 above..

(c) In case any action, proceeding or claim shall be brought against one of the Parties hereto (an "Indemnified Party") based upon any of the above claims and in respect of which indemnity may be sought against the other Party hereto (the "Indemnifying Party") such Indemnified Party shall promptly notify the Indemnifying Party in writing. The failure by an Indemnified Party to notify the Indemnifying Party of such Claim shall not relieve the Indemnifying Party of responsibility under this Section, except to the extent such failure adversely prejudices the ability of the Indemnifying Party to defend such claim. The Indemnifying Party at its expense, with counsel of its own choice, shall defend against, negotiate, settle or otherwise deal with any such claim, provided that the Indemnifying Party shall not enter into any settlement or compromise of any claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party without the Indemnified Party's prior written consent. The Indemnified Party may participate in the defense of any claim with counsel of its own choice and at its own expense. The parties agree to cooperate fully with each other in connection with the defense, negotiation or settlement of any such claims. In the event that the Indemnifying Party does not undertake the defense, compromise or settlement of any claim, the Indemnified Party shall have the right to control the defense or settlement of such claim with counsel of its choosing.

(d) Client shall reimburse inVentiv for all reasonable actual out-of-pocket expenses incurred by inVentiv in connection with responses to subpoenas and other similar legal orders issued to inVentiv in respect to Client's product or the Services performed under this Agreement and the applicable Project Agreement. However, Client shall have no obligation to reimburse inVentiv for any such expenses (and to the extent paid by Client to inVentiv, shall be repaid by inVentiv to Client) arising out of, in connection with or otherwise relating to actions or omissions of inVentiv or its employees, independent contractors, officers, directors, and/or Affiliates that violate this Agreement, any Project Agreement, or Applicable Law.

9. <u>Limitation of Liability</u>

(a) Subject to Section 9(c) below, neither Party shall be liable to the other Party with respect to any subject matter of this Agreement or any Project Agreement under any contract, tort, negligence, strict liability, breach of warranty (express or implied) or other theory for any indirect, incidental, special, punitive, exemplary or consequential damages, nor for any loss of revenues or loss of profits, even if advised of the possibility of such damages.

(b) Subject to Section 9(c) below, each Party's (including its Affiliates) liability, including for claims and Losses, arising out of the Services under a specific Project Agreement shall be limited to [***] (the "Liability Cap"). If [***], the applicable Liability Cap will be [***].

(c) The limitations set out in Sections 9(a) and 9(b) above shall not apply:

(i) to the parties indemnification obligations set forth in Section 8 above; and

(ii) to any claims for liabilities, losses, proceedings, suits, actions, damages, claims or expenses of any kind, including court costs and reasonable attorneys' fees caused by (A) the fraud, gross negligence or willful misconduct of a Party; (B) any violation, infringement or misappropriation of the other Party's intellectual property rights; and (C) either Party's breach of its confidentiality obligations set forth in Section 6 above.

10. Intellectual Property; Ownership

(a) Except as set forth in Sections 10(b) and 10(c) below, all documents, materials, reports and deliverables provided by inVentiv to Client pursuant hereto whether or not patentable, copyrightable, or susceptible to any other form of legal protection which are made, conceived, reduced to practice or authored by inVentiv, or inVentiv's employees, independent contractors, representatives or agents (if any) as a result of the performance of Services, or which are derived from use or possession of Client's Confidential Information (collectively, the "Deliverables") shall be the sole and exclusive property of Client upon full payment of all sums due to inVentiv for each such Deliverable under this Agreement. Notwithstanding the foregoing nothing in this Agreement or any Project Agreement shall be construed to give inVentiv any right, title or interest to any trademarks, patents or other pre-existing intellectual property of Client. For the avoidance of doubt, but subject to Section 10(b) inVentiv will not have any right, title, or interest in any new inventions, developments or improvements inVentiv makes to Client intellectual property or creates using Client Confidential Information during the course of performing under this Agreement and any Project Agreement. Subject to Sections 10(b) and 10(c) below, each Deliverable constituting an original work shall be considered a work made for hire under applicable copyright laws. Subject to Section 10(b) and 10(c) below, inVentiv hereby assigns and agrees to assign to Client all right, title and interest in all worldwide intellectual property rights in the Deliverables, including without limitation, patents, copyrights, and trade secrets. inVentiv agrees to cooperate, at Client's expense, with reasonable all efforts on behalf of Client to identify and perfect all intellectual property rights associated with the Deliverables.

(b) Notwithstanding anything to the contrary set forth herein, to the extent any Deliverable or work made for hire include inVentiv's concepts, ideas, models, know-how, software, methodologies, technology, techniques, procedures, management tools, workshops, manuals, macros, data files, inventions, and other intellectual capital and property that inVentiv has developed, created or acquired prior to, in the course of, or independent of performing Services under this Agreement (the "inVentiv Materials"), inVentiv shall retain exclusive ownership in such inVentiv Materials. Upon full payment of all sums due to inVentiv, inVentiv hereby grants Client a non-exclusive, non-transferable, royalty-free right and license, for Client

to use the inVentiv Materials solely in connection with its use of the Deliverables created by inVentiv in connection with the Services. For the avoidance of doubt, the Parties agree that any source or object code, previously owned or licensed by inVentiv or created hereunder without the use of or reference to any Client Confidential Information, are not a part of the rights provided to Client and may be used by inVentiv on behalf of itself or any of its other clients. Without limiting the foregoing, inVentiv may use such source or object code to create materials that have a substantially similar "look and feel" as the Deliverables for products or services that are directly competitive to products or services for which such Deliverables were created. Provided that inVentiv de-identifies all personal data, Client, and Client product identifying information, inVentiv may use all project data for the purpose of evaluating its performance under this Agreement and for business development and analytics purposes.

(c) Without limiting the general rights of Client as provided in this Section 10, it is understood and agreed that certain promotional material or other Deliverables may contain the intellectual property of third parties pursuant to a license or other arrangement which permits Client to use such intellectual property only in connection with a specific project or campaign, and which would require additional payments for a different or extended use by Client. inVentiv will provide prior written notification to Client of any material conditions or limitations relating to such approvals inVentiv has obtained as part of the approval process for specific projects and campaigns, and Client will be solely responsible for any fees or other charges associated with any use of such third party intellectual property outside the scope of the use contemplated by the applicable project.

(d) If a Deliverable or any portion of a Deliverable is found to infringe on the intellectual property rights of a third party, and provided the infringing portion does not arise from materials provided by Client, inVentiv shall, at no cost to the Client, (A) obtain the right for Client to continue use of the Deliverable; (B) replace or modify the Deliverable to be non-infringing and functionally and operationally equivalent to the applicable Deliverable; or (iii) remove the Deliverable, in which case, it will be inVentiv's responsibility to find an alternative functionally equivalent solution to replace the Deliverable If none of the foregoing is possible within a commercially reasonable time, then Client shall have the immediate right to a refund of all Fees paid with respect to such infringing Deliverable.

11. Term

The Agreement shall be in effect as of the Effective Date and shall remain in effect until the third anniversary of the Effective Date (the "Term") or until such later date as may be set forth in a Project Agreement (it being understood that this Agreement will not terminate in the event the term set forth in a Project Agreement is longer than the term set forth herein). The Parties may extend this Agreement for additional periods of one year each (each an "Additional Term") by mutual written agreement of the Parties.

12. Termination

(a) Except as may otherwise be provided in any Project Agreement, this Agreement and any Project Agreement may be terminated by inVentiv or Client upon giving written notice as

follows:

(i) by inVentiv, if any undisputed payment to inVentiv by Client is not made when due and such payment is not made within [***] from the date of written notice from inVentiv to Client of such nonpayment;

(ii) by either Party, in the event that the other Party has committed a material breach of this Agreement and such breach has not been cured within [***] of receipt of written notice from the non-breaching Party of such breach (provided that, during the [***] cure period for termination due to breach, each Party will continue to perform its obligations under the Agreement);

(iii) by Client, for its convenience, at any time, upon [***] prior written notice to inVentiv; or

(iv) by either Party, in the event the other Party is either debarred from federal contracting or is a "Sanctioned Entity". For purposes hereof, a Sanctioned Entity is an entity that:

(A) Is currently under indictment or prosecution for, or has been convicted (as defined in 42 C.F.R. § 1001.2) of: (1) any offense related to the delivery of an item or service under the Medicare or Medicaid programs or any program funded under Title V or Title XX of the Social Security Act (the Maternal and Child Health Services Program or the Block grants to States for Social Services programs, respectively), (2) a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service, (3) fraud, theft, embezzlement, or other financial misconduct in connection with the delivery of a health care item or service, (4) obstructing an investigation of any crime referred to in (1) through (3) above, or (5) unlawful manufacture, distribution, prescription, or dispensing of a controlled substance; or

(B) Has been required to pay any civil monetary penalty regarding false, fraudulent, or impermissible claims under, or payments to induce a reduction or limitation of health care services to beneficiaries of, any state or federal health care program, or is currently the subject of any investigation or proceeding which may result in such payment; or

(C) Has been excluded from participation in the Medicare, Medicaid, or Maternal and Child Health Services (Title V) program, or any program funded under the Block Grants to States for Social Services (Title II) program~~; or~~.

(b) This Agreement and any Project Agreement shall terminate immediately without notice in the event that the other Party has: (i) become insolvent or has been dissolved or liquidated; (ii) filed or has filed against it, a petition in bankruptcy and such petition is not dismissed within thirty (30) days of the filing; (iii) makes a general assignment for the benefit of creditors; (iv) has a receiver appointed for a substantial portion of its assets; or (v) if this Agreement or any Affiliate Addendum or Project Agreement is deemed rejected pursuant to the provisions of Bankruptcy Code §365(d), as amended, in a case under Bankruptcy Code.

(c) Upon the effective date of such termination, the Parties shall have no further

obligation to each other (other than those set forth in Sections 4, 6, 7, 8, 9, 10 12(d), 13, 14(a), 14(d)-14(f), 14(h), 14(k), and 14(~~h~~l)), except that Client shall pay the amounts set forth or provided for in any Project Agreement through the actual date of termination or completion of the Services being performed under all applicable Project Agreements. For purposes of clarity, in the event this Agreement is terminated or expires prior to the completion of work under any Project Agreement, such Project Agreement shall continue through completion, and this Agreement shall continue to apply to the Project Agreement(s) in full force and effect through completion of such outstanding Services under such Affiliate Addendum and Project Agreement(s).

(d) Client will pay for all fees and out-of-pocket expenses under this Agreement and all applicable Project Agreements incurred through the effective date of termination and any wind down period. Client will be responsible for all reasonable non-cancelable commitments entered into by inVentiv on Client's behalf and for reasonable wind down costs. All expenses or commitments [***] and not set forth in a Project Agreement shall be pre-approved by Client. Upon termination, to the extent applicable and as mutually agreed to by the Parties, inVentiv will give or otherwise transfer to Client, at Client's expense, all property in inVentiv's possession that belongs to and was paid for by Client (excluding archival copies thereof), provided that all invoices with respect to such property have been paid in full.

13. Venue and Jurisdiction

This Agreement shall be construed according to the laws of the State of New Jersey (without reference to any principles regarding conflicts of law) and any action brought by either inVentiv or Client in connection with this Agreement shall be brought in the state or federal courts located in the State of New Jersey.

14. Miscellaneous

(a) Insurance. Each Party undertakes to maintain, as applicable, General Liability insurance of [***] per occurrence/[***] annual aggregate, Workers' Compensation Statutory, Employer's Liability insurance of [***], Automobile Liability insurance of [***] combined single limit each occurrence, Products/Completed Operations and Professional Errors and Omissions Liability insurance of [***] per occurrence/[***] annual aggregate. In addition, Client shall carry Product Liability insurance each in the amount of at least [***]. Limits may be provided with Umbrella/Excess insurance. Insurance companies must have an AM Best Rating of "A-/VII" or better, or an analogous rating by a similar organization if the insurance company is not a United States company. Client's indemnity shall not be capped by its insurance limits. Each Party shall name the other Party as an additional insured on all liability insurance coverage as their interests may appear. In addition, upon written request, each Party will provide the other with evidence of coverage complying with this Section 14. The Parties understand and agree that additional insurance requirements may be set forth in the Project Agreements

(b) Assignment; Binding Effect. Neither inVentiv nor Client may assign or transfer this Agreement or any Project Agreement or any of its rights, duties or obligations hereunder without the other Party's prior written consent; provided, however, that either inVentiv or Client may assign or transfer its rights, duties and obligations as part of an acquisition or purchase of

inVentiv or Client, without the prior written consent of the other Party when: (i) such assignment is to a successor-in-interest to all or substantially all of the ownerships interest or business assets of such Party whether in a merger, sale of stock, sale of assets or other similar transaction; (ii) the successor is a financially capable business entity; and (iii) the successor is not a competitor of the other Party. Any permitted successor or assignee of this Agreement or any Project Agreement and the rights and/or obligations hereunder or thereunder, will in writing (satisfactory in form and substance) to the other Party, expressly assume this Agreement and any existing Project Agreement and the rights and obligations hereunder. If such a writing is not received, any proposed assignment or transfer need not be recognized and shall be null and void.

(c) Force Majeure. Except for Client's payment obligations, noncompliance with the obligations of this Agreement or any Project Agreement due to a state of force majeure, the laws or regulations of any government, regulatory or judicial authority, war, civil commotion, destruction of facilities and materials, fire, flood, earthquake or storm, shortage of materials, failure of public utilities or common carriers, and any other similar causes beyond the reasonable control of the applicable Party, shall not constitute a breach of contract.

(d) Severability. If any provision of this Agreement or any Project Agreement is finally declared or found to be illegal or unenforceable by a court of competent jurisdiction, both Parties shall be relieved of all obligations arising under such provision, but, if capable of performance, the remainder of this Agreement or such Project Agreement shall not be affected by such declaration or finding.

(e) Entire Agreement; Amendment. This Agreement, together with each applicable Project Agreement (including any attachments or exhibits hereunder or thereunder), contains all of the terms and conditions of the agreement between the Parties and constitutes the complete understanding of the Parties with respect thereto. This Agreement and each Project Agreement supersedes all prior arrangements and understandings between the Parties related to the subject matter hereof. No modification, extension or release from any provision hereof shall be affected by mutual agreement, acknowledgment, acceptance of contract documents, or otherwise, unless the same shall be in writing signed by the other Party and specifically described as an amendment or extension of this Agreement or any Project Agreement; provided, however, an email confirmation or other electronic confirmation accepting any modified terms shall be the same as if the Parties have signed in writing and shall be a valid enforceable agreement between the Parties.

(f) Public Announcement. The form and content of any public announcement to be made by one Party regarding this Agreement or any Project Agreement, or the subject matter contained herein, shall be subject to the prior written consent of the other Party (which consent may not be unreasonably withheld), except as may be, in the reasonable opinion of the disclosing Party's legal counsel, required by Applicable Law, including the U.S. Securities Exchange Commission or any stock exchange upon which such Party' securities are listed or to which application for listing has been submitted, in which event the other Party shall endeavor to give the other Party reasonable advance notice, review and comment of any such disclosure, including a copy of the proposed redacted filings, if any. Notwithstanding the above, either Party may, in connection with its general marketing materials and without the consent of the other Party, list the name of the other Party in a non-descriptive fashion in connection with its general marketing

materials; (ii) in a list of the names of other similarly situated third parties that such Party does business with; and (iii) in internal business communications, including communications to Affiliates.

(g) Counterparts. This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Electronically submitted signatures shall have the same force and effect of an original signature.

(h) Notices. Any notices required or permitted under this Agreement shall be given in person or sent by first class, certified mail to:

To Client: **Address:** Agile Therapeutics, Inc. 101 Poor Farm Road Princeton, NJ 08540	**To inVentiv** **Address:** inVentiv Commercial Services, LLC 500 Atrium Drive Somerset, NJ 08873
Attention: Chairman and Chief Executive Officer **Fax: 609-683-1855**	**Attention:** President **Fax:** 732-537-4999
Copy To: Agile Therapeutics, Inc. 101 Poor Farm Road Princeton, NJ 08540 Attn: General Counsel	**Copy To:** inVentiv Commercial Services, LLC 500 Atrium Drive Somerset, NJ 08873 Attn: VCS General Counsel

or to such other address or to such other person as may be designated by written notice given from time to time during the term of this Agreement by one Party to the other.

(i) Cooperation. Each of the Parties shall do, execute and perform and shall procure to be done and perform all such further acts deeds documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Agreement.

(j) Preparation. Except as otherwise expressly provided in this Agreement, each Party shall pay its own expenses and costs incidental to the preparation of this Agreement and to the consummation of the transactions contemplated by this Agreement or each Project Agreement.

(k) Waiver.

(i) No delay or omission by either Party to exercise any right or power it has under this Agreement will impair or be construed as a waiver of such right or power.

(ii) A waiver by either Party of any breach or covenant will not be construed to be a waiver of any succeeding breach or any other covenant.

(iii) No waiver to any provision of this Agreement or any Project Agreement (including any Exhibit or Schedule hereto or thereto), will be valid unless in writing and signed by an authorized representative of the Party against whom enforcement of such waiver is sought.

(l) Interpretation. This Agreement and each Project Agreement shall be governed by the following rules of construction, unless the context requires otherwise: (i) any reference to a Section, Schedule, Exhibit, subsection, clause, subclause, or recital is a reference to a Section, Schedule, Exhibit, subsection, clause, subclause, or recital of this Agreement or the applicable Project Agreement; (ii) any reference to any statute shall be construed as including all statutory provisions consolidating, amending or replacing such statute; (iii) the terms "hereof," "hereby," "hereto," "hereunder" and similar terms shall refer to this Agreement or applicable Project Agreement as a whole; (iv) the word "including" and words of similar import means "including, without limitation" and "including, but not limited to"; (v) the word "may" shall mean "has the right, but not the obligation to do something" and "may not" shall mean "does not have the right to do something"; (vi) the headings contained herein are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement or any Project Agreement; (vii) any reference to "days" means calendar days unless otherwise stated as "Business Days"; (viii) all references to "dollars" or "$" refer to United States dollars; (ix) use of the singular includes the plural and vice versa; and (x) use of the masculine gender includes the feminine and neuter genders and vice versa.

[SIGNATURE PAGE FOLLOWS]

WHEREFORE, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

AGILE THERAPEUTICS, INC.	**INVENTIV COMMERCIAL SERVICES, LLC**
By: _____	By: _____
Title: Chairman and Chief Executive Officer	Title:

Exhibit A
FORM OF PROJECT AGREEMENT

This Project Agreement (the "Project Agreement") made as of _____ ____, 20___ by and between [INVENTIV COMMERCIAL SERVICES, LLC, with its principal office located at 500 Atrium Drive, Somerset, New Jersey 08873 ("inVentiv")] and Agile Therapeutics, Inc., a Delaware corporation with an office located at 100 Poor Farm Road, Princeton, New Jersey 08540 ("Client"). Client and inVentiv may each be referred to herein as a "Party" and collectively, the "Parties".

RECITALS

A. Client and inVentiv have entered into a Master Services Agreement dated as of _____ ___, 2017 (the "Agreement").

B. Client and inVentiv desire to enter into this Project Agreement (this "Project Agreement" or "PA").

1. Interpretation and Construction

(a) The Parties confirm that the Master Service Agreement shall govern the relationship between the Parties. Unless otherwise specifically set forth herein, in the event of a conflict or inconsistency between the terms and conditions set forth in the Master Service Agreement and the terms and conditions set forth in this Project Agreement, the terms and conditions set forth in the Master Service Agreement shall take precedence, govern and control. Terms in a Project Agreement that supplement or refine the terms of this Agreement will be read together with their related terms and not be deemed "conflicting".

(b) The Parties hereby acknowledge that the terms set forth in the Agreement are incorporated herein by reference, as if fully set forth at length herein.

2. The Services

A detailed description of the services (the "Services") is set forth on Exhibit A attached hereto.

3. Term and Termination

[To be determined based on the Services and inVentiv Affiliate].

4. Fees

Set forth on Exhibit B attached hereto is a summary of the cost and fees to be paid by Client to inVentiv for the performance of the Services.

5. **[Miscellaneous]**

[Insert any additional contract terms and project requirements specific to the Services to be provided by inVentiv Affiliate].

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

AGILE THERAPEUTICS, INC.	**INVENTIV COMMERCIAL SERVICES, LLC**
By: _____	By: _____
Title:	Title:

EXHIBIT A
THE SERVICES

EXHIBIT B
FEES AND COSTS

FIRST AMENDMENT TO MASTER SERVICES AGREEMENT

This First Amendment to Master Services Agreement (this "Amendment") dated April 30, 2020 ("Amendment Effective Date") by and between inVentiv Commercial Services, LLC, a Syneos Health™ group company and a New Jersey limited liability company with an office located at 500 Atrium Dive, Somerset, NJ 08873 ("inVentiv") and Agile Therapeutics, Inc., a Delaware corporation with an office located at 101 Poor Farm Road, Princeton, New Jersey 08540 (together with its Affiliates, "Client"). Client and inVentiv may each be referred to herein as a "Party" and collectively, the "Parties".

RECITALS

WHEREAS, inVentiv and Client entered into that certain Master Services Agreement effective as of October 11, 2017 (the "Agreement");

WHEREAS, the Term of the Agreement will expire on October 11, 2020; and

WHEREAS, inVentiv and Client desire amend the Agreement to extend the term of the Agreement as set forth herein.

NOW THEREFORE, in consideration of the above Recitals, the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby understand and agree as follows:

1. **Capitalized Terms**. All capitalized terms used but not otherwise defined in this Amendment shall have the same meaning given to such terms in the Agreement.

2. **Term**: Section 11 is hereby deleted and replaced with the following language:

> "The Agreement shall be in effect as of the Effective Date and shall remain in effect until October 11, 2023 (the "Term") or until such later date as may be set forth in a Project Agreement (it being understood that this Agreement will not terminate in the event the term set forth in a Project Agreement is longer than the term set forth herein). The Parties may extend this Agreement for additional periods of one year each (each an "Additional Term") by mutual written agreement of the Parties."

3. **Miscellaneous**.

   a. Except as specifically amended or modified in this Amendment, each term of the Agreement shall continue to be in full force and effect.

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

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

d. This Amendment shall be governed by and interpreted in accordance with, and any dispute, controversy or claim arising out of or relating to this Amendment shall be resolved in the manner provided in Section 13 of the Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment to the Agreement to be effective as of the Amendment Effective Date.

AGILE THERAPEUTICS, INC.		**INVENTIV COMMERCIAL SERVICES, LLC**	
By:	_____	By:	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____
Date:	_____	Date	_____

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

MANUFACTURING AND COMMERCIALIZATION AGREEMENT

This Manufacturing and Commercialization Agreement (the "Agreement") is entered into as of April 30, 2020 (the "Effective Date") between Corium, Inc., a Delaware corporation having its principal place of business at 235 Constitution Drive, Menlo Park, CA 94025 and its manufacturing operations 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 101 Poor Farm Road, Princeton, NJ 08540, including its Affiliates ("Agile"). Corium and Agile shall be referred to individually as a "Party" and collectively as the "Parties".

ARTICLE 1: DEFINITIONS

For purposes of this Agreement, the following terms shall have the respective meanings set forth below:

1.1 "Act" shall mean the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

1.2 "Affiliate" shall mean, with respect to either Party, a corporation or any other entity that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, that Party, but only for so long as the relationship exists. "Control" shall mean ownership of shares of stock having at least 50% of the voting power entitled to vote for the election of directors in the case of a corporation.

1.3 "Bankruptcy Event" shall mean with respect to a Party, any of the following events: (i) such Party files a voluntary petition for relief under Title 11 of the United States Code (the "Bankruptcy Code"); or (ii) there is filed against such Party an involuntary or ancillary petition for relief under the Bankruptcy Code, and either (x) such petition is not dismissed within sixty (60) days after its filing or (y) an order for relief is entered against such Party in such petition; (iii) an action or proceeding is filed with regard to such Party in any court or with any agency in each case having jurisdiction thereof under any statute or regulation (other than the Bankruptcy Code) of any state or country, which is a petition in bankruptcy or insolvency or for the general reorganization of the Party's financial affairs; or for the appointment of a receiver or trustee over such Party or its assets, and, in the case of a filing against such Party, the action or proceeding is not stayed or dismissed within sixty (60) days after the filing thereof, or (iv) such Party files for dissolution or adopts a plan of liquidation, or (v) such Party makes a general assignment for the benefit of creditors.

1.4 "Calendar Quarter" shall mean any of the three-month periods beginning January 1, April 1, July 1, and October 1 of any calendar year.

1.5 "cGMP" shall mean those Current Good Manufacturing Practices required by the FDA to be followed in connection with the manufacture of pharmaceutical products, as defined from time to time by the Act and related regulations, as amended, or any successor laws or regulations governing the manufacture, handling, storage and control of the Product in the United States.

1.6 "Commercialization" shall mean the activities undertaken to market, promote, sell, and service the Product or have it marketed, promoted, sold or serviced in the Territory.

1.7 "Competing Product" means any transdermal contraceptive product.

1.8 "DSCSA" shall mean Drug Supply Chain Security Act and its implementing regulations.

1.9 "Facility" means any facility at which Manufacture occurs.

1.10 "FDA" shall mean the United States Food and Drug Administration or any successor United States governmental agency performing similar functions with respect to pharmaceutical products.

1.11 "Know-How" means confidential or proprietary information (including but not limited to technical information, formulations, techniques, processes, methods, data, substances and materials) that is reasonably necessary or reasonably useful for the development, Manufacture, or commercialization of a Product.

1.12 "Manufacture" shall mean the manufacturing, processing, testing, release, packaging, storing and other activities undertaken or required to be undertaken by Corium in order to manufacture and supply Agile with the Product.

1.13 "NDA" shall mean the New Drug Application (as defined in Title 21 of the U.S Code of Federal Regulations) submitted to the FDA requesting approval to market the Product.

1.14 "Product" shall mean Agile's proprietary AG 200-15 transdermal delivery system for female contraception whether labeled, packaged and marketed as a brand-name product or an authorized generic of such product.

1.15 "Product Specification" shall mean the manufacturing, testing, labeling, storage and quality control specification for the Product as set forth in the NDA as approved by the FDA and in the USP, plus any additional specifications agreed upon in writing by the Parties.

1.16 [***].

1.17 "Territory" shall mean the entire world.

1.18 "Third Party" shall mean an entity or person other than a Party or an Affiliate of a Party.

1.19 "Third Party Manufacturer" shall mean a Third Party that enters into a manufacture and supply agreement with Corium or Agile for the manufacture and supply of Product pursuant to the terms of this Agreement.

1.20 "Unit" shall mean one (1) patch.

ARTICLE 2: MANUFACTURE OF THE PRODUCT

2.1 Manufacturing Responsibility.

(a) During the Term, Corium shall Manufacture and supply Product to Agile in accordance with this Agreement.

(b) Agile shall purchase exclusively from Corium all of Agile's requirements for the Product for use and distribution in the Territory, except as otherwise provided in Section 2.4. Other than with the prior written agreement of Agile, Corium shall not directly or indirectly develop or supply the Product or any Competing Product to any person or entity other than Agile and its Affiliates.

2.2 Obligations of Corium. Without limiting the foregoing, Corium shall be responsible for, directly or through a Third Party Manufacturer:

(a) maintaining FDA qualifications for the Facility;

(b) maintaining distribution shipping records for the Product;

(c) conducting all testing required by the NDA, cGMPs, the Quality Agreement, and FDA regulations, as amended, including, without limitation, required stability testing of Product Manufactured hereunder; and

(d) Manufacturing Product according to the Product Specification and any guidelines reasonably required and provided by Agile and consistent with the NDA and all applicable FDA and DSCSA regulations, as amended. Agile shall have the exclusive right to define packaging, cartoning, labeling, including package inserts, and all related artwork for containers, subject to Section 3.10.

2.3 Subcontracting Manufacturing. Corium shall be entitled to engage a Third Party Manufacturer to satisfy its Manufacturing commitments pursuant to this Article 2. In such event Corium shall promptly notify Agile, and shall identify and upon Agile's prior written approval (which approval shall not be unreasonably withheld) engage and qualify such Third Party Manufacturer to satisfy such Manufacture commitments. Corium will bear the sole responsibility for entering into a supply agreement for the Product between Corium and such Third Party and shall continue to be responsible to Agile for all the obligations imposed on Corium herein.

2.4 Agile's Manufacturing Right.

(a) Qualification of Second Source. Agile will have the right to Manufacture the Product itself or qualify an Agile Affiliate or one or more Third Party Manufacturer as a second supply of the Product, at Agile's expense; provided, however, that Agile (or its Afffiliate) may Manufacture Product, or obtain Product from a Third Party Manufacturer, only to the extent expressly permitted in Section 2.4(b). In support of such second-source qualification, Agile may provide the Affiliate or Third Party Manufacturer with any data and documentation created under the Agreement that is specific to the Product and reasonably necessary for its Manufacture. Any such disclosure shall be made in confidence and shall, at a minimum, be subject to confidentiality obligations equivalent to those set forth in Article 5.

(b) Second-Source Manufacturing. Agile shall have the right to Manufacture the Product, and/or have the Product Manufactured by an Affiliate or Third Party Manufacturer qualified as a second source as permitted above, only in the event of [***]. Notwithstanding the foregoing, Corium may resume Manufacturing and supplying Product on an exclusive basis if, [***], Corium provides [***].

(c) Technical Support. To facilitate an orderly transfer of the Manufacture of the Product to a qualified second source in the event Agile exercises its rights under Section 2.4(b), Corium shall provide the Affiliate or Third Party Manufacturer with all necessary technical assistance in the form of reasonable consulting services to be provided by Corium personnel at Agile's or the Third Party Manufacturer's facility at Agile's expense. Such consulting services shall not require Corium to divulge any proprietary Know-How or trade secrets unless pursuant to specific licensing, confidentiality, and other terms and conditions reasonably agreed to by Corium in advance.

(d) Supporting License. Corium shall grant to Agile and/or its designated Affiliate or Third Party Manufacturer(s), as directed by Agile, a non-exclusive, non-transferable, non-sublicensable, limited right to [***], but solely to the extent necessary to enable Agile, its Affiliate, and/or such Third Party Manufacturer to manufacture the Product for Agile pursuant to Section 2.4(b). Such license shall be subject to the provisions of Section 6.4 hereof.

2.5 Expiration Dates. Product supplied by Corium shall, at the time of Delivery to Agile, be dated such that the expiration of such Product shall not occur before [***]; provided, however, that Corium shall use commercially reasonable efforts to provide Product to Agile with the longest possible expiration date but in any event no less than [***] from Delivery. In the event that the Product expiration date is [***] from Delivery, Agile shall have the right to reject such Product.

2.6 Quality Control. Corium shall manufacture, test, label, package, and ship all Product, or cause the Product to be manufactured, tested, labeled, packaged, and shipped in accordance with the respective NDA, Product Specifications, cGMP, the Quality Agreement, and the Act, as amended.

2.7 Manufacturing Changes. Corium shall notify Agile in the event it desires to make any changes in the manufacturing process as set forth in the applicable NDA for the Product. No such change shall be made unless Agile authorizes such change in writing. Agile shall be entitled to request changes to the Product Specifications from time to time, subject to approval by Corium which shall not be unreasonably withheld. Corium shall undertake commercially reasonable efforts to make all revisions to the Product Specifications requested by Agile, in accordance with this Section 2.7 and all applicable laws and regulations.

2.8 Manufacturing Capacity and Expansion. No less than [***], Corium and Agile shall review Corium's capacity for Manufacturing Product against Agile's then-current expectations for future Product demand to determine whether there is a need for expanding Corium's Manufacturing capacity. In the event the Parties determine that capacity expansion is required to support Agile's production demands, Corium agrees to make the existing space and supporting infrastructure available to accommodate [***] and the Parties will negotiate in good faith the timing, costs, and expenses associated with such expansion, including the financing thereof, taking into account [***].

2.9 Manufacturing Audit. Agile, either itself or through or with its representatives, shall have the right, once each calendar year, or more often if a reasonable basis exists therefore (such as, by way of example and not limitation, a change in, or material noncompliance with, applicable laws, regulations and governmental guidelines), upon reasonable notice and during normal business hours, to subject the Facilities where Corium Manufactures, or has Manufactured, the Product to a cGMP audit or inspection at Agile's expense for the purpose of ensuring compliance with all requirements of this Agreement, the Quality Agreement and applicable laws and regulations, including cGMPs. Such inspection and auditing shall be permitted upon reasonable notice and during normal business hours, taking into account Corium's manufacturing cycle of the Product.

2.10 Notice of Inspections. Corium shall immediately notify Agile of any inspection of its or any of its Affiliates' Facilities (or of any Facilities of its or their licensees, distributors, contractors, subcontractors or agents) related to the Product or the API by any regulatory agency, including the FDA, shall permit Agile to be onsite during such inspection, and shall send Agile copies of any written reports or correspondence to or from any regulatory agency relating to such inspection. Such reports may exclude any trade secrets of Corium that are unrelated to the activities under this Agreement. Corium shall take Agile's comments regarding the same into good faith consideration. Corium shall promptly notify Agile of any alleged violations or deficiencies relating to the Product as set forth in the Quality Agreement. Corium shall permit the relevant governmental authorities to inspect its Facilities and records in connection with the activities contemplated by this Agreement.

2.11 Quality Agreement. The Parties have separately entered into that certain Quality Agreement, the current version of which was effective September 25, 2015 (as updated from time to time, the "Quality Agreement"), and acknowledge that the manufacture, testing, and quality of the Product are subject, in addition to the terms and conditions of this Agreement, to the terms and conditions of the Quality Agreement. To the extent, if any, that the terms of the Quality Agreement conflict with those of this Agreement, the terms of the Quality Agreement shall control with respect to the matters addressed therein.

2.12 Maintenance of Facility and Equipment.

(a) Except as otherwise approved in writing by Agile, Corium shall Manufacture Product exclusively at its Facility.

(b) Corium shall ensure that any and all licenses, registrations, and regulatory authority approvals required by applicable Law to be obtained in connection with any Facility and equipment used in connection with the Manufacturer of Product by Corium or any subcontractor so as to permit Corium to Manufacture Product and supply it to Agile as contemplated hereunder have been obtained and are in all respects current and in full force and effect.

(c) Corium shall at all times during the Term maintain the Facility and such equipment in a state of repair and operating efficiency consistent with the requirements of the Product Specifications, the NDA, cGMP and applicable laws.

(d) Corium has and will maintain a valid long-term renewable lease to use the Facility for the Manufacture throughout the Term. Corium shall promptly provide Agile with notice of any material change to the lease or other situation impacting Corium's use of the Facility.

(e) Agile owned Equipment. All equipment used in the Manufacture of the Product as set forth on Exhibit C hereto shall be solely owned by Agile. While such equipment is in the Facility, Corium shall, at its cost and expense, safeguard and maintain such equipment in good working order, perform all required upkeep and maintenance on such equipment and not use such equipment for any purpose other than the Manufacture of the Product. Corium shall insure all such equipment to its full replacement value. Corium shall maintain such equipment free and clean of all liens and encumbrances. Agile shall reimburse Corium for all external expenses associated with the non-routine repair and maintenance of such equipment in excess of [***] per calendar year. The Parties will work in good faith to determine which repairs are non-routine.

ARTICLE 3: COMMERCIALIZATION AND SUPPLY.

3.1 Commercialization. Agile shall have the exclusive right, even as to Corium, to Commercialize the Product in the Territory. As determined by Agile in its sole and exclusive discretion, Agile shall use commercially reasonable efforts to Commercialize the Product in the Territory. Agile shall have the sole and exclusive right to establish and control the prices and all other terms and conditions for the sales of the Product in the Territory.

3.2 Regulatory Responsibilities. Agile shall be solely responsible, with Corium's reasonable assistance, for maintaining the NDA for the Product including any necessary periodic reporting requirements. Furthermore, Agile shall be responsible for all adverse event reporting as required by the Act. Agile agrees to perform these activities in conformance with cGMP, the NDA specifications and the Act. Agile shall provide Corium with copies of all material correspondence from or to regulatory authorities in the Territory relating to the maintenance of the NDA.

3.3 Supply. Corium shall supply Agile with its requirements for the Product in the Territory. Corium shall maintain inventory levels for the Product, consistent with its normal practices, giving due consideration to the forecasts submitted by Agile hereunder. Corium shall obtain all raw materials and packaging components necessary for the Manufacture of Products from qualified suppliers in accordance with the Quality Agreement. 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.

3.4 Forecasts.

(a) Agile shall provide Corium with a binding purchase order for [***] within [***] of the Effective Date.

(b) 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, [***].

(c) The total amount of Product actually ordered by Agile in [***] may not be less than [***] or exceed [***] of the [***] and, in any event, must be no less than [***]. No change may be made in the binding Purchase Order or the shipment dates requested therefor without the prior consent of Corium (such consent not to be unreasonably withheld).

3.5 Excess Over Forecast. Quarterly Purchase Orders in excess of [***] of the applicable Firm Forecast require the prior written agreement of Corium, which shall use commercially reasonable efforts to supply the amounts of Product so ordered by Agile.

3.6 Purchase Orders. Agile's Purchase Orders to Corium shall set forth: (i) the quantity or amount of Product ordered, (ii) shipping arrangements, and (iii) the requested delivery date to Agile; provided that the quantity of Product specified in each Purchase Order shall be in whole batch increments. Corium shall not be required to fulfill any Purchase Order requesting a delivery date earlier than [***] after receipt of the Purchase Order or later than [***] after receipt of the Purchase Order. Within [***] of its receipt of any Purchase Order, Corium shall send a written acknowledgement of such receipt to Agile and include in such acknowledgement, if necessary, the fact that Corium is unable to fulfill such Purchase Order and the reason for such inability (without limiting any of Agile's rights or remedies under this Agreement or otherwise). The terms and conditions of this Agreement shall supercede and control any terms and conditions in any form of Purchase Order or any other business forms used by the Parties for the purposes of ordering, acknowledging, invoicing or shipping.

3.7 Delivery. Corium shall deliver Product ordered pursuant to a Purchase Order to Agile, F.O.B. Corium's Facility in the United States, in accordance with the delivery instructions set forth in such Purchase Order. Agile shall arrange for shipment to occur no later than the delivery date set forth in the Purchase Order, unless otherwise agreed to in writing by Corium. Title and risk of loss will pass to Agile when the Product units are delivered to Agile's designated carrier. Agile shall have the right to cancel any Purchase Order, in whole or in part, which is delayed more than [***] from the date of delivery requested by Agile.

3.8 Delays.

a. Corium shall notify Agile promptly, in writing, of any circumstance that may cause a material delay in Manufacturing and supplying Product or a material delay or inability to meet Agile's forecast, stating the estimated period of delay and the reasons therefor. Corium shall use commercially reasonable efforts to avoid or minimize the delay, including, when necessary or at Agile's reasonable request, the expenditure of premium time and shipping by air or other expedited routing. Costs associated with delays directly caused by the actions or inactions of one Party shall be borne by that Party; other costs shall be allocated equitably among the Parties.

b. "Supply Delay" means, solely for purposes of this Section, Corium's failure to deliver [***] of the Product ordered under an accepted Purchase Order due to reasons under the reasonable control of the Corium within [***] of the delivery date. A Supply Delay will not be deemed to occur if (i) such failure is caused by a Force Majeure Event, or (ii) the volume ordered exceeds [***] of the volume set forth in the applicable Firm Forecast (but only in respect of the excess). Beginning [***], in the event of a Supply Delay, Corium shall credit Agile on Product invoices an amount equal to [***].

3.9 Non-Conforming Product. In accordance with and subject to the terms of the Quality Agreement, Agile shall visually inspect the Product units that are delivered by Corium pursuant to this Agreement according to Agile's standard inspection guidelines, prior to their distribution and sale by Agile or sublicensees or distributors. If a shipment of Product, or any portion thereof, is adulterated, damaged, defective or otherwise non-conforming, then Agile shall have the right to reject such shipment, or the portion thereof that fails to so conform, as the case may be, upon written notice to Corium, specifying the grounds for such rejection, within [***] following the date on which Agile receives from Corium the invoice relating to such shipment of Product. If no notice of rejection is given by Agile within such [***] period or with respect to a shipment of Product, then such shipment shall be deemed to have been accepted; provided, however, that any failure to provide a notice of rejection by Agile shall not be deemed to be an acceptance in the event that any reason for rejection exists that could not be discovered during a reasonable visual inspection of such shipment. In the event of any such rejection, [***]. If Corium agrees with Agile's claim, [***]. If Agile and Corium are unable to resolve their differences, then either Agile or Corium may refer the matter to a certified analytical firm of international reputation independent of and acceptable to both Parties for final analysis using a sample from such shipment provided by Agile, which shall be binding on Agile and Corium. The fees and disbursements of such firm shall be paid by the Party whose

contention is rejected by the firm. This Section 3.9 will be applied and interpreted in accordance with the Quality Agreement.

3.10 NDA Specifications. Agile shall comply with the specifications set forth in the NDA, the applicable law, and any written specifications concerning the packaging, labeling, storage, handling, and transportation of the Product. Neither Agile nor any employee or person acting on behalf of Agile shall make any modification to the Product, Product packaging, or labeling of the Product as delivered by Corium.

3.11 Product Recall. Agile shall be entitled to make all decisions with respect to any recall, market withdrawals, or other corrective action related to the Product in accordance with the Quality Agreement, provided that Agile shall consult with Corium and consider Corium's comments in good faith. Corium shall reimburse Agile for reasonable costs incurred by Agile that are directly required to implement a recall or corrective action mandated by FDA if the recall or corrective action arises solely from Corium's gross negligence or willful misconduct; otherwise such costs shall be borne by Agile unless otherwise agreed to in writing by the Parties in good faith.

ARTICLE 4: PAYMENTS

4.1 Commercial Terms. Agile will pay Corium for Product delivered under this Agreement and accepted by Agile in the amounts and according to the schedule and other commercial terms set forth in the attached Exhibit B.

4.2 Manner of Payment. Except as otherwise specified in Exhibit B, all payments under this Agreement will be remitted within [***] after the date of invoice (which will be no earlier than the date of shipment but in any event not later than [***] after the delivery date set forth in the Purchase Order). All payments due hereunder shall be made in United States dollars without any deduction or withholding for or on account of, any taxes, duties, levies, fees or charges except those taxes or duties levied against Corium which are legally required to be withheld by Agile. All taxes levied on account of any payment accruing to Corium under this Agreement which constitutes income to Corium shall be the obligation of Corium, and, if provision is made in law or regulation for withholding, such tax shall be deducted by Agile from any payment then due, Agile shall pay such tax to the proper taxing authority, and receipt for payment of the tax shall be promptly sent to Corium by Agile. However, Corium shall have the right to appeal to the appropriate tax authority any such withholding and payments of any such tax.

4.3 Books of Account; Audit. Each Party shall maintain true and complete books of account containing an accurate record of all data necessary for the proper computation of amounts charged by it and payments due from it under this Agreement. Upon [***] prior written notice, each Party shall have the right, through the independent certified public accountants engaged by the requesting Party, to conduct its regular annual audit, or through a firm of independent public accountants selected by mutual agreement of the Parties, to examine the books and records of the other Party as they relate to this Agreement, at any time within [***] after the date of the payment or charges to which they relate [***] for the purpose of verifying the amount of such payments or charges and the accuracy of such books and

records. Such examination shall be made during normal business hours at the place of business of the Party whose books and records are being examined. The Parties agree that information furnished as a result of any such examination shall be limited to a written statement by such certified public accountants to the effect that they have reviewed the books and records of such Party and either (i) the amounts paid or charged under this Agreement are in conformity with such books and records and the applicable provisions of this Agreement, or (ii) setting forth any required adjustments. The fees and expenses of the accountants performing such verification shall be borne by the Party requesting the examination. If any such examination shows any underpayment or overpayment, or overcharge or undercharge, a correcting payment or refund shall be made within [***] after receipt of the written statement described above providing the non-challenging Party agrees with the findings of the challenging Party. If the non-challenging Party disagrees with the finding of the challenging Party, the Parties will attempt, in good faith, to resolve the difference. If after [***] the Parties fail to settle the difference, the dispute resolution provisions of Section 12.13 will be followed. Notwithstanding the foregoing, if any such examination indicates that there was any underpayment with respect to any [***] of more than [***] of the payment actually due or the amount that should actually have been charged, then the Party whose books are being examined shall bear all costs of the examination.

ARTICLE 5: CONFIDENTIAL INFORMATION

5.1 Definition. “Confidential Information” means: (a) all information related to the Product including, without limitation, documentation, drawings, designs, and specifications; (b) any non-public information of a Party including, without limitation, Know-How and information related to a Party’s technology, techniques, research, designs, finances, accounts, procurement requirements, manufacturing, customer lists, business forecasts, and marketing plans; (c) any other information of a Party that is designated in writing as “Confidential” or “Proprietary” at the time of disclosure or, if disclosed orally or visually, is identified as confidential or proprietary at the time of disclosure; and (d) the specific terms of this Agreement.

5.2 Obligation of Non-Disclosure and Limitation of Use. Except as specifically authorized by this Agreement, each Party shall keep confidential, not disclose to others, and use only for the purposes provided for or permitted under this Agreement, the other Party’s Confidential Information (the “Confidentiality Obligations”). Notwithstanding the foregoing, such information may be (a) disclosed to governmental agencies and others where such Confidential Information is required to be included in regulatory filings permitted under the terms of this Agreement; (b) provided to a Party’s Affiliates, employees, and subcontractors who reasonably require access to such Confidential Information for the performance of this Agreement, but only if provided pursuant to obligations of confidentiality substantially equivalent to those in this Agreement; or (c) disclosed to the extent required by applicable laws or regulations or as ordered by a court or other regulatory body having competent jurisdiction. In each of the foregoing cases, the recipient will use its commercially reasonable efforts to limit the disclosure and maintain confidentiality to the extent possible. In the case of a required disclosure under clause (c) above, the Party required to make the disclosure shall promptly notify the original disclosing Party and shall provide reasonable assistance, if requested by the original disclosing Party, to assist the original disclosing Party in its attempts to prevent or

limit the disclosure. The Confidentiality Obligations shall not apply to any information which is (i) already known to the recipient prior to the date of disclosure as evidenced by its written records made prior to such date; (ii) publicly known prior to or after disclosure other than through unauthorized acts or omissions of the recipient; (iii) disclosed in good faith to the recipient by a Third Party lawfully and contractually entitled to make such disclosure; (iv) developed by or for the receiving Party without the use of any Confidential Information of the disclosing Party, as evidenced by the receiving Party's written records; or (v) made public with the written consent of the Party that owns the information. The disclosing Party has the right to use its own Confidential Information for any purpose, except to the extent specifically restricted herein.

5.3 Duration of Obligation. The Confidentiality Obligations shall remain in force [***].

5.4 Ownership. Ownership of Confidential Information shall remain with the disclosing Party. Nothing herein is intended to transfer the ownership of any Confidential Information.

ARTICLE 6: LICENSE AND OWNERSHIP

6.1 Intellectual Property Ownership. Each Party shall be the sole owner of any inventions (including improvements), Know-How, trademarks, works of authorship, and associated intellectual property rights (collectively "Intellectual Property") that it owned or controlled prior to the effective date of the Agreement ("Background Intellectual Property"). In the case of Agile, that includes Background Intellectual Property relating to the Product and the NDA, except for Background Intellectual Property related to the Manufacture of the Product that is owned by Corium. The Parties will jointly own Intellectual Property jointly developed or invented by employees or contractors of both Parties, except that each Party will solely own any Intellectual Property developed or invented under this Agreement that relates to its Background Intellectual Property.

6.2 Agile License to Corium. Agile hereby grants to Corium an exclusive (except to the extent required by Agile to exercise its rights under Section 2.4), royalty-free, fully paid-up, sublicensable to Third Party Manufacturers, and non-transferable (except to an assignee under Section 12.6) right and license under the NDA and its Intellectual Property to develop, manufacture and supply the Product to Agile pursuant to Corium's obligations under this Agreement.

6.3 Corium License to Agile. Corium hereby grants to Agile a royalty-free, fully paid-up, non-sublicensable, and non-transferable (except to an assignee under Section 12.6) right and license under its Intellectual Property to use, market, sell (directly or through multiple tiers of distribution), offer to sell, import, export and otherwise commercially exploit Product manufactured by Corium or a Third Party Manufacturer in the Territory.

6.4 Effects of Insolvency or Bankruptcy on Licenses. The Parties acknowledge and agree that all rights and licenses to intellectual property granted to a licensee pursuant to this Agreement are, for all purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to

"intellectual property" as defined in the Bankruptcy Code, and that in the event a Party who is a licensor becomes a debtor in bankruptcy, the provisions of Section 365(n) of the Bankruptcy Code shall apply and the other Party shall continue to have rights under such licenses as long as such Party continues to fulfill all of its obligations, including its obligations to pay royalties, under this Agreement, as and to the extent provided in Section 365(n). Each Party, in its capacity as licensor of such rights under this Agreement (as applicable), acknowledges and agrees that the other Party, in its capacity as licensee of such rights under this Agreement (as applicable), shall retain and may fully exercise all of such other Party's rights and elections as and to the extent provided in the Bankruptcy Code.

ARTICLE 7: REPRESENTATIONS AND WARRANTIES

7.1 Mutual Representations and Warranties. Each of Agile and Corium represents and warrants to the other that: (i) such Party has all requisite corporate power to enter into this Agreement, and (ii) neither the execution and delivery by such Party of this Agreement nor the consummation by such Party of the transactions contemplated hereby nor the compliance by such party with any of the provisions hereof will violate any order, writ, injunction, decree, law, statute, rule, regulation, agreement or other restriction applicable to it or require the consent, approval, permission, or authorization of, or qualification of filing with or notice to, any court, arbitrator, or other tribunal or any governmental, administrative, regulatory, or self-regulatory agency or any Third Party, and (iii) this Agreement has been duly executed and delivered by such Party and constitutes the legal, valid and binding agreement of such Party, enforceable against it in accordance to its terms.

7.2 Non-Infringement Warranties. Agile represents and warrants that, to the best of its knowledge as of the Effective Date, no third-party intellectual property rights are or will be infringed or otherwise violated by the Agile Background Intellectual Property or its use in the manner contemplated by this Agreement. Corium represents and warrants that, to the best of its knowledge as of the Effective Date, no third-party intellectual property rights are or will be infringed or otherwise violated by Corium's Background Intellectual Property or its use in the manner contemplated by this Agreement.

7.3 Corium Warranties. Corium represents and warrants that any Product Manufactured by or on behalf of Corium hereunder (i) shall be manufactured in accordance with the Product NDA and the Product Specification, and shall meet the Product Specification for its shelf life as set forth in the NDA; (ii) shall not, at the time of delivery to Agile's designated carrier, be adulterated or misbranded within the meaning of the Act, or any applicable laws in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act, as the Act and laws are constituted and effective at the time of such delivery; and (iii) shall be manufactured in accordance with cGMP and all other similar applicable United States laws and regulations, as amended. Except as set forth in Section 8.1, Agile's sole remedy for breach of the warranty contained in this Section 7.3 shall be the replacement of such non-complying Product.

7.4 Disclaimer. THE WARRANTIES SET FORTH IN SECTION 7.3 ARE CORIUM'S EXCLUSIVE WARRANTIES TO AGILE WITH RESPECT TO THE PRODUCT, AND ARE GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER

WARRANTIES, GUARANTEES, CONDITIONS AND REPRESENTATIONS, EXPRESS OR IMPLIED, CONCERNING THE PRODUCT, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 8: INDEMNIFICATIONS

8.1 Corium Indemnity. Corium shall indemnify, defend and hold harmless Agile and its Affiliates, employees or directors from any and all costs, expenses, damages, judgments and liabilities (including reasonable attorneys' fees and the cost of any recalls) incurred by or rendered against Agile, or its Affiliates, employees or directors in any Third Party claim made or Third Party suit brought based on (i) a breach by Corium of its representations, warranties or other obligations pursuant to this Agreement, or (ii) Corium's negligence, willful misconduct or violation or applicable laws or regulations, (iii) an allegation that Corium's Background Intellectual Property, or any part thereof, infringes or violates any patent, copyright or trademark of a Third Party or misappropriates any trade secret of a Third Party, except to the extent that such claim or suit is based on (i) Agile's breach of its representations, warranties, or other obligations under this Agreement, or its negligence, willful misconduct, or violation of applicable laws and regulations, (ii) any allegation that the Product, or any part thereof, infringes or violates any patent, copyright, trademark, or misappropriates any trade secret (other than misappropriations of which Corium knew or reasonably should have known), or (iii) an action to which Agile provided its written consent. Agile shall give prompt written notice of any such claim or suit, and Corium shall undertake the defense thereof. Agile shall cooperate in such defense, to the extent reasonably requested by Corium, at Corium's expense. Agile shall have the right to participate in such defense, at its own expense, to the extent that in its judgment Agile may be prejudiced thereby. In any claim made or suit brought for which Agile seeks indemnification under this Section 8.1, neither Party shall settle, offer to settle, or admit liability or damages without the prior written consent of the other Party.

8.2 Agile Indemnity. Agile shall indemnify, defend and hold harmless Corium and its Affiliates, employees or directors from any and all costs, expenses, damages, judgments and liabilities (including reasonable attorneys' fees and the cost of any recalls) incurred by or rendered against Corium, or its Affiliates, employees or directors in any Third Party claim made or Third Party suit brought that is based on (i) damages resulting from the clinical testing, use, or sale of the Product, (ii) an allegation that the Product, or any part thereof, infringes or violates any patent, copyright or trademark of a Third Party or misappropriates any trade secret of a Third Party (other than misappropriations of which Corium knew or reasonably should have known), (iii) Agile's breach of representations, warranties, or other obligations pursuant to this Agreement, or (iv) Agile's negligence, willful misconduct, or violation of applicable laws or regulations, except to the extent that such claim or suit is based on Corium's breach of its representations or warranties under this Agreement, negligence, willful misconduct or violation of applicable laws or regulations. Corium shall give prompt written notice of any such claim or suit, and Agile shall undertake the defense thereof. Corium shall cooperate in such defense, to the extent reasonably requested by Corium, at Agile's expense. Corium shall have the right to participate in such defense, at its own expense, to the extent that in its judgment Corium may be prejudiced thereby. In any claim made or suit brought for which Corium seeks indemnification under this Section 8.2, neither Party shall

settle, offer to settle, or admit liability or damages without the prior written consent of the other Party.

8.3 Mitigation. In the event of any occurrence which may result in either Party becoming liable under this Article, each Party shall use commercially reasonable efforts to mitigate the damages that may be payable by the other Party hereunder.

8.4 Insurance Requirements. For the Term and [***] thereafter Corium shall maintain, or cause to be maintained, at its own expense, product-liability, general liability and excess policy insurance in an amount not less than [***] per occurrence. In addition, Agile and Corium shall maintain workers' compensation and property, inventory and business interruption insurance as is commercially reasonable. Upon a Party's written request from time to time, each Party shall furnish to the other Party one or more Certificates of Insurance reflecting coverage under such insurance and shall name such other Party as an additional insured on such policy.

ARTICLE 9: LIMITATION OF LIABILITY

9.1 Limits of Liability. Except for Parties' indemnification obligations under Article 8 or breach of confidentiality obligations under Article 5, in no event, other than as set forth herein, shall either Party be liable to the other Party for special, incidental, consequential or punitive damages, or for costs of procuring substitute products, whether the claim is based upon contract, warranty, tort, negligence, product liability, or strict liability theories or otherwise relates to the failure to perform any obligations set forth herein. Except for Corium's indemnification obligations under Article 8 or breach of confidentiality obligations under Article 5 in no event, other than as set forth herein, shall Corium's liability to Agile in connection with this agreement for all causes of action and under all theories of liability exceed [***].

9.2 Scope of Limitations.The Parties have agreed that these limitations will survive and apply even if any limited remedy specified in this agreement is found to have failed of its essential purpose.

ARTICLE 10: COMPLIANCE WITH LAW

10.1 Compliance with Law. Each Party agrees to comply with all material laws and regulations applicable to it and to use its commercially reasonable efforts to perform its responsibilities and duties as described in this Agreement.

10.2 Debarment/Exclusion. Each Party represents that neither it nor any of its employees has been debarred or is subject to debarment proceedings by the FDA, or has been excluded or is subject to exclusion proceedings by the US HHS Office of Inspector General. If any such debarment or exclusion proceedings are commenced against a Party hereto (or any of its employees) during the Term, such Party shall notify the other Party in writing within five business days of the commencement of such proceedings, and shall keep the other Party informed, on a regular basis, of the status of such proceedings. Neither Corium nor Agile shall employ any persons or entities that have been debarred or excluded, or that are subject to

debarment or exclusion proceedings, for any aspect of the development, manufacturing, testing, or commercialization of the Product.

ARTICLE 11: TERM AND TERMINATION: MODIFICATION OF RIGHTS

11.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date, and shall continue for a period of ten (10) years unless terminated earlier pursuant to Section 11.2.

11.2 Termination Events. This Agreement shall only be terminated in the following manner, upon the occurrence of any of the events set forth in this Section 11.2.

(a) The Parties may terminate this Agreement at any time by written mutual agreement. The Parties agree to confer in good faith regarding possible mutual termination upon written request by either Party, if such Party determines that further commercialization of the Product is economically infeasible.

(b) Either Party may terminate this Agreement upon a material breach by the other Party; provided that the terminating Party shall provide the breaching Party with a written notice reasonably detailing such breach and such breach or default is not cured within sixty (60) days after receipt such notice.

(c) Either Party may terminate this Agreement in the event that the other Party hereto shall undergo a Bankruptcy Event.

(d) Either Party may terminate this Agreement in the event the other Party suffers a Force Majeure Event which is not resolved within one hundred eighty (180) days.

11.3 Rights and Duties Upon Termination.

(a) Except in cases of the termination of this Agreement for a Force Majeure Event or as otherwise expressly set forth in this Agreement, the termination or expiration of this Agreement shall not affect Purchase Orders placed by Agile and accepted by Corium at the time notice of termination is given and until the time any such termination becomes effective. Other than in the event of termination by Agile due to Corium's material breach or Bankruptcy Event (in which case any such purchase shall be at Agile's option), upon termination or expiration of this Agreement, Agile shall purchase from Corium (at [***]) all saleable raw materials and components purchased by Corium based on Purchase Orders or Agile's Firm Forecast.

(b) Payments of amounts owing to either Party under this Agreement as of its expiration or termination shall be due and payable within the later of: (i) [***] or (ii) [***].

(c) Within thirty (30) days following the of expiration or termination of this Agreement, each Party shall (subject to Section 2.4(d) and 11.3(e)) destroy or return to the other Party all tangible items bearing, containing or contained in any of the Confidential Information of the other Party, and shall provide the other Party written certification of such destruction or return.

(d) Following the expiration or termination of this Agreement, Corium shall make available to Agile or a Third-Party designated by Agile all Agile-owned equipment, tooling and related documentation as set forth on Exhibit D hereto for removal at Agile's expense.

(e) Upon the expiration or termination of this Agreement, except for early termination by Corium for cause or termination resulting from Agile's bankruptcy, Corium will provide Agile with access to its personnel and reasonable technical and regulatory support and assistance at Agile's expense with the transfer of Manufacture of the Product to a Third-Party designated by Agile. Such support and assistance shall not require Corium to divulge any proprietary Know-How or trade secrets unless pursuant to specific licensing, confidentiality, and other terms and conditions reasonably agreed to by Corium in advance. The licenses granted pursuant to Section 6.3 hereof shall survive any termination or expiration of this Agreement other than due to a material breach by Agile.

11.4 Termination of this Agreement for any reason shall be without prejudice to (i) either Party's rights under this Agreement with respect to claims arising out of events occurring prior to such termination; (ii) Corium's right to receive all payments owed or accrued under this Agreement for periods prior to the date of termination; and (iii) any other remedies which either Party may otherwise have.

11.5 Survival. Articles 1, 5, 6, 7, 8, 9,11, and 12 shall survive the termination for any reason of this Agreement. Any payments due under this Agreement with respect to any period prior to its termination shall be made notwithstanding the termination of this Agreement.

ARTICLE 12: MISCELLANEOUS

12.1 Waiver and Amendment. Any waiver by any Party hereto of a breach of any provisions of this Agreement shall not be implied and shall not be valid unless such waiver is recited in writing and signed by such Party. Failure of any Party to require, in one or more instances, performance by the other Party in strict accordance with the terms and conditions of this Agreement shall not be deemed a waiver or relinquishment of the future performance of any such terms or conditions or of any other terms and conditions of this Agreement. A waiver by either Party of any term or condition of this Agreement shall not be deemed or construed to be a waiver of such term or condition for any other term. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement of either Party. This Agreement may not be amended except in writing, signed by both Parties.

12.2 Relationship of the Parties. For all purposes of this Agreement, Corium and Agile shall be deemed to be independent entities and anything in this Agreement to the contrary notwithstanding, nothing herein shall be deemed to constitute Corium and Agile as partners, joint ventures, co-owners, an association or any entity separate and apart from each Party itself, nor shall this Agreement constitute any Party hereto an employee or agent, legal or otherwise, of the other Party for any purposes whatsoever. Neither Party hereto is authorized to make any statements or representations on behalf of the other Party or in any way obligate the other Party, except as expressly authorized in writing by the other Party. Anything in this

Agreement to the contrary notwithstanding, no Party hereto shall assume nor shall be liable for any liabilities or obligations of the other Party, whether past, present or future.

12.3 Headings. The headings set forth at the beginning of the various Articles of this Agreement are for reference and convenience and shall not affect the meanings of the provisions of this Agreement.

12.4 Notices. Notices required under this Agreement shall be in writing and sent by registered or certified mail, postage prepaid, and confirmed by registered or certified mail and addressed as follows:

If to Agile: Agile Therapeutics, Inc.
101 Poor Farm Road
Princeton, NJ 08540
Attention: General Counsel

With a copy to: _____

If to Corium: Corium, Inc.
235 Constitution Drive
Menlo Park, CA 94025
Attention: Head of Corporate Development/Legal Department

All notices shall be deemed to be effective five days after the date of mailing (but only if followed by certified or registered confirmation). Either Party may change the address at which notice is to be received by written notice pursuant to this Section 12.4.

12.5 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, it shall be stricken and the remaining provisions shall remain in full force and effect; provided, however, that if a provision is stricken so as to significantly alter the economic arrangements of this Agreement, the Parties agree to negotiate in good faith modifications to this Agreement to effectuate the initial intent of this Agreement.

12.6 Assignment. This Agreement shall not be assigned by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed, or conditioned, except that either Party may assign this Agreement, in whole or in part, to any successor (including the surviving company in any consolidation, reorganization or merger) or assignee of all or substantially all of its business, or to a wholly owned subsidiary or Affiliate. Any attempted assignment in violation of the foregoing shall be null and void and without effect. This Agreement will be binding upon any permitted assignee of either Party. No assignment shall have the effect of relieving any Party to this Agreement of any of its obligations hereunder.

12.7 Event of Force Majeure. Except for the payment of money, neither Party shall be responsible or liable to the other hereunder for the failure or delay in the performance of this Agreement due to any civil unrest, war, fire, earthquake, hurricane, accident or other casualty, or any labor disturbance or act of God or the public enemy, or any other contingency beyond

the Party's reasonable control (a "Force Majeure Event"). In the event of the applicability of this Section 12.7 the Party failing or delaying performance shall use commercially reasonable efforts to eliminate, cure and overcome any of such causes and resume the performance of its obligations. Upon the occurrence of a Force Majeure Event, the Party failing or delaying performance shall promptly notify the other Party, in writing, setting forth the nature of the occurrence, its expected duration and how such Party's performance is affected. The failing or delaying Party shall resume performance of its obligations hereunder as soon as practicable after the force majeure event ceases.

12.8 Public Disclosure. Neither Party shall disclose to third Parties, nor originate any publicity, news release or public announcement, written or oral, whether to the public, the press, stockholders or otherwise, referring to the existence or terms of this Agreement the subject matter to which it relates, the performance under it or any of its specific terms and conditions, except as required by law, without the prior written consent of the other Party. If a Party decides to make an announcement, it will give the other Party such notice as is reasonably practicable and an opportunity to comment upon the announcement.

12.9 No Conflict. Each Party represents that neither this Agreement nor any of its obligations hereunder will conflict or result in a breach of any arrangement or agreement between such Party and any Third Party.

12.10 Entire Agreement; Conflict of Terms. This Agreement, including the exhibits hereto, and as supplemented by the Quality Agreement, sets forth the entire understanding between the Parties hereto as to the subject matter hereof. To the extent that the terms of this Agreement conflict with the terms of the Development, License and Commercialization Agreement, entered into as of October 18, 2006, as amended (including the Commercial Proposal, effective as of March 30, 2012) (collectively the "DLCA"), the terms of this Agreement shall prevail with respect to the subject matter of this Agreement. In particular, Articles 5 and 6 shall no longer apply as of the Effective Date, and Article 3 shall no longer apply as of October 31, 2020.

12.11 Limitation of Grant. Nothing in this Agreement shall be construed as granting by implication, estoppel, or otherwise, any license or rights than otherwise set forth herein.

12.12 Governing Law. This Agreement shall be governed by, and construed, and enforced in accordance with the substantive laws of the State of New York, without giving effect to its rules concerning conflicts of laws.

12.13 Dispute Resolution. The Parties recognize that a bona fide dispute as to certain matters may arise from time to time during the term of this Agreement that may relate to the Parties' rights and obligations hereunder. The Parties agree that they shall use reasonable efforts to resolve any dispute that may arise in an amicable matter. If the Parties are unable to resolve such a dispute within thirty (30) days, then before either Party shall be entitled to file a lawsuit in connection with such dispute, either Party within fifteen (15) days, may by written notice to the other Party, require the Parties to submit any such disputed matter to the Chief Executive Officers of the Parties, who shall meet and use good faith efforts to negotiate a resolution within thirty (30) days of receipt of such notice. In the event that the Chief

Executive Officers are unable to resolve such dispute within such 30-day period, either Party shall be entitled to seek all legal recourse available to it in connection therewith. The Chief Executive Officers shall issue their resolution in writing.

12.14 This Agreement may be executed in multiple counterparts, each of which shall be deemed an original agreement and both of which shall constitute one and the same agreement. The counterparts of this Agreement may be executed and delivered by facsimile or other electronic signature (including portable document format) by either of the Parties and the receiving Party may rely on the receipt of such document so executed and delivered electronically or by facsimile as if the original had been received.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the date first written above by their duly authorized representatives.

CORIUM, INC.

By: _____
Name:
Title:
Date:

By: _____
Name:
Title:
Date:

AGILE THERAPEUTICS, INC.

By: _____
Name:
Title:
Date:

Exhibit A
Guaranteed Minimum

The amount of Product ordered by Agile [***].

Exhibit B
Commercial Terms

[***]

Exhibit C
Agile Owned 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: August 11, 2020

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

Exhibit 31.2

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

I, Dennis P. Reilly, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2020

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

Exhibit 32.1

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

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2020 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: August 11, 2020

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

Exhibit 32.2

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

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Dennis P. Reilly, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: August 11, 2020

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