UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

Commission File Number 001-36075

EVOKE PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-8447886**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**
420 Stevens Avenue, Suite 370, Solana Beach, CA	**92075**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 345-1494

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	EVOK	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 ☒

As of April 30, 2019, the registrant had 23,261,650 shares of common stock outstanding.

EVOKE PHARMA, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Evoke Pharma, Inc.

Condensed Balance Sheets

	March 31, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,028,550	$ 5,319,004
Prepaid expenses	219,479	329,218
Other current assets	11,551	—
Total current assets	4,259,580	5,648,222
Operating lease right-of-use asset	103,252	—
Other assets	—	11,551
Total assets	$ 4,362,832	$ 5,659,773
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 491,831	$ 476,202
Accrued compensation	692,304	1,158,251
Operating lease liability	103,252	—
Total current liabilities	1,287,387	1,634,453
Stockholders' equity:		
Common stock, $0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 17,877,533 and 17,427,533 at March 31, 2019 and December 31, 2018, respectively	1,788	1,743
Additional paid-in capital	83,643,658	82,628,312
Accumulated deficit	(80,570,001)	(78,604,735)
Total stockholders' equity	3,075,445	4,025,320
Total liabilities and stockholders' equity	$ 4,362,832	$ 5,659,773

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 746,882	$ 1,385,366
General and administrative	1,223,013	1,032,245
Total operating expenses	1,969,895	2,417,611
Loss from operations	(1,969,895)	(2,417,611)
Other income:		
Interest income	4,629	1,433
Gain from change in fair value of warrant liability	—	433,392
Total other income	4,629	434,825
Net loss	$ (1,965,266)	$ (1,982,786)
Net loss per share of common stock, basic and diluted	$ (0.11)	$ (0.13)
Weighted-average shares used to compute basic and diluted net loss per share	17,484,318	15,427,037

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Stockholders' Equity

(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2019	17,427,533	$ 1,743	$ 82,628,312	$ (78,604,735)	$ 4,025,320
Stock-based compensation expense	—	—	378,959	—	378,959
Issuance of common stock, net	450,000	45	636,387	—	636,432
Net loss	—	—	—	(1,965,266)	(1,965,266)
Balance at March 31, 2019	17,877,533	$ 1,788	$ 83,643,658	$ (80,570,001)	$ 3,075,445

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2018	15,413,610	$ 1,541	$ 73,202,863	$ (71,038,655)	$ 2,165,749
Stock-based compensation expense	—	—	393,775	—	393,775
Issuance of common stock, net	268,870	27	544,616	—	544,643
Reclassification of warrant liability due to warrant amendment	—	—	3,267,885	—	3,267,885
Net loss	—	—	—	(1,982,786)	(1,982,786)
Balance at March 31, 2018	15,682,480	$ 1,568	$ 77,409,139	$ (73,021,441)	$ 4,389,266

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Operating activities		
Net loss	$ (1,965,266)	$ (1,982,786)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	378,959	393,775
Change in fair value of warrant liability	—	(433,392)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	142,299	83,682
Accounts payable and other current liabilities	(482,878)	(879,245)
Net cash used in operating activities	(1,926,886)	(2,817,966)
Financing activities		
Proceeds from issuance of common stock, net	636,432	544,643
Net cash provided by financing activities	636,432	544,643
Net decrease in cash and cash equivalents	(1,290,454)	(2,273,323)
Cash and cash equivalents at beginning of period	5,319,004	7,679,267
Cash and cash equivalents at end of period	$ 4,028,550	$ 5,405,944
Non-cash financing activities		
Reclassification of warrant liability to equity due to amendment of warrants	—	$ 3,267,885

See accompanying notes to these unaudited condensed financial statements.

1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the "Company") was incorporated in the state of Delaware in January 2007. The Company is a specialty pharmaceutical company focused primarily on the development of drugs to treat gastroenterological disorders and disease.

Since its inception, the Company has devoted substantially all of its efforts to developing its sole product candidate, Gimoti™, and has not realized revenues from its planned principal operations. The Company filed a 505(b)(2) New Drug Application ("NDA") for Gimoti with the U.S. Food and Drug Administration ("FDA") on June 1, 2018, and on April 1, 2019, the Company received a Complete Response Letter ("CRL") from FDA for the NDA. The CRL stated that FDA has determined it cannot approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

The Company does not anticipate realizing revenues until FDA approves the NDA and the Company begins commercializing Gimoti, which events may never occur. The Company's activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has substantial expenditures for research and development, including funding its operations.

Going Concern

The Company has incurred recurring losses and negative cash flows from operations since inception and expects to continue to incur net losses for the foreseeable future until such time, if ever, that it can generate significant revenues from the sale of Gimoti. Although the Company ended the first quarter of 2019 with approximately $4.0 million in cash and cash equivalents, the Company anticipates that it will continue to incur losses from operations due to pre-approval and pre-commercialization activities, including interactions with FDA on the Company's NDA submission for Gimoti, responding to approvability issues raised in the CRL received from FDA, manufacturing of registration batches of Gimoti, and general and administrative costs to support operations. As a result, the Company believes that there is substantial doubt about its ability to continue as a going concern for one year after the date these financial statements are issued.

The determination as to whether the Company can continue as a going concern contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In its report on the Company's financial statements for the year ended December 31, 2018, the Company's independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern.

The Company's net losses may fluctuate significantly from quarter to quarter and year to year. The Company believes, based on its current operating plan, that its existing cash and cash equivalents, including net proceeds from the sale of common stock in April 2019, as disclosed in Note 5, will be sufficient to fund its operations into the first quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the Novos Growth, LLC ("NGP") Working Capital Loan and the NGP Credit Agreement, as disclosed in Note 6, that may extend the Company's cash runway into the second half of 2020, without accounting for any future Gimoti product revenue, although there can be no assurance in that regard. Under either situation, the Company may be required to raise additional funds through debt, equity or other forms of financing, such as potential collaboration arrangements, to fund future operations and continue as a going concern.

There can be no assurance that additional financing will be available when needed or on acceptable terms. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, financial condition and future prospects. There can be no assurance that the Company will be able to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because the Company's business is entirely dependent on the success of Gimoti, if the Company is unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, the Company will be required to curtail all of its activities and may be required to liquidate, dissolve or otherwise wind down its operations.

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2018, which has been derived from audited financial statements, and the unaudited interim condensed financial statements, have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and follow the requirements of the U.S. Securities and Exchange Commission ("SEC") for interim reporting. As

permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In management's opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position and its results of operations and its cash flows for the periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with the Company's financial statements and accompanying notes for the year ended December 31, 2018, which are contained in the Company's Annual Report on Form 10-K filed with the SEC on March 6, 2019. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates.

Contract Research Organizations and Consultants

The Company relies on contract research organizations ("CROs") and consultants to assist with ongoing regulatory discussions and submissions supporting the NDA. If these CROs and consultants are unable to continue their support, this could adversely affect FDA's review of the NDA.

In addition, the Company relies on third-party manufacturers for the production of Gimoti. If the third-party manufacturers are unable to continue manufacturing Gimoti, or if the Company loses one of its sole source suppliers used in its manufacturing processes, the Company may not be able to meet any development needs or commercial supply demand for Gimoti, if approved by FDA, and the development and/or commercialization of Gimoti could be materially and adversely affected.

The Company also relies on third-party sales and marketing organizations for the management of the pre-commercial launch preparation for Gimoti, as well as for a dedicated sales team to sell Gimoti, if approved by FDA. If such third-party organizations are unable to continue managing the launch preparation, or serving as a dedicated sales team, the commercialization of Gimoti could be materially and adversely affected.

Warrant Accounting

In March 2018, the Company entered into warrant amendments (the "Warrant Amendments") with each of the holders of the Company's outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016 (the "Warrants"). As a result of the Warrant Amendments, the Warrants are no longer classified as a liability on the Company's balance sheet, were adjusted to fair value as of the date of the Warrant Amendments, and were reclassified to additional paid-in capital, a component of stockholders' equity.

Prior to the Warrant Amendments, the Warrants were classified as warrant liability and recorded at fair value. These Warrants contained a feature that could have required the transfer of cash in the event a change of control occurred without the authorization of our board of directors, and therefore, were classified as a liability in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification 480, *Distinguishing Liabilities from Equity*.

This warrant liability was subject to remeasurement at each reporting date and the Company recognized any change in the fair value of the warrant liability in the statement of operations. The Company continued to adjust the carrying value of the warrants for changes in the estimated fair value until the date of the Warrant Amendments.

Stock-Based Compensation

Stock-based compensation expense for stock option grants and employee stock purchases under the Company's Employee Stock Purchase Plan (the "ESPP") is recorded at the estimated fair value of the award as of the grant date and is recognized as expense on a straight-line basis over the employee's requisite service period. The estimation of stock option and ESPP fair value requires management to make estimates and judgments about, among other things, employee exercise behavior, forfeiture rates and volatility of the Company's common stock. The judgments directly affect the amount of compensation expense that will be recognized.

The Company grants stock options to purchase common stock to employees and members of the board of directors with exercise prices equal to the Company's closing market price on the date the stock options are granted. The risk-free interest rate assumption was based on the yield of an applicable rate for U.S. Treasury instruments with maturities similar to those of the expected term of the award being valued. The weighted-average expected term of options and employee stock purchases was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to

the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the Company's historical volatility and, if necessary, supplemented with historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time. The assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense and costs paid to third-party contractors to perform research, conduct clinical trials and develop drug materials and delivery devices. The Company expenses costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred until FDA approval is received.

The Company does not own or operate manufacturing facilities for the production of Gimoti, nor does it plan to develop its own manufacturing operations in the foreseeable future. The Company currently depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its pre-commercial product development. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., who acquired Patheon UK Limited, for product development and manufacturing of Gimoti. The Company currently utilizes third-party consultants, which it engages on an as-needed, hourly basis, to manage product development and manufacturing contractors.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common stock outstanding that are subject to repurchase. The Company excluded 45,000 shares of common stock subject to repurchase from the weighted-average number of common stock outstanding for the three months ended March 31, 2018. Since the Company's repurchase right lapsed upon the filing of the NDA in June 2018, the Company no longer has any common stock subject to repurchase. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of common stock subject to repurchase, warrants to purchase common stock, options to purchase common stock under the Company's equity incentive plans and potential shares to be purchased under the ESPP. For the 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 because their inclusion would be anti-dilutive:

	Three Months Ended March 31,	
	2019	**2018**
Common stock subject to repurchase	—	45,000
Warrants to purchase common stock	2,713,561	2,797,561
Common stock options	3,672,624	2,811,624
Employee stock purchase plan	6,126	6,902
Total excluded securities	6,392,311	5,661,087

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842). 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. The Company adopted this standard effective January 1, 2019, as required. The Company determines if an arrangement is a finance lease, operating lease or short-term lease at inception. The Company elected the "package of practical expedients," which permits the Company not to reassess prior conclusions about lease identifications, lease classification and initial direct costs. The Company also elected not to separate lease and non-lease components when certain conditions are met. As discussed in Note 3, the Company's only significant lease is its facility lease, which expires on December 31, 2019, and is classified as an operating lease.

3. Commitments

Facility Lease

In December 2016, the Company entered into an operating lease for office space in Solana Beach, California. The lease commenced on January 1, 2017, was extended in September 2018, and has an expiration date of December 31, 2019. According to ASU No. 2016-02, the Company recognized an operating lease ROU asset and liability based on the present value of the future minimum lease payments over the lease term at the commencement date, using the Company's assumed incremental borrowing rate, and then amortizes the ROU assets and liabilities over the lease term. The Company applies a discount rate to the minimum lease payments within the lease agreement to determine the value of right-of-use assets and lease liabilities. Unless the rate implicit in the lease is determinable, ASU No. 2016-02 requires the use of the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term for a similar amount to the lease payments in a similar economic environment. The Company noted that the implicit rate in the lease was not determinable and calculated its incremental borrowing rate primarily based on the Company's assumed borrowing rate of 12%. On January 1, 2019, the Company recorded an operating lease ROU asset and liability of approximately $136,000 based on the present value of the remaining minimum lease payments. During the three months ended March 31, 2019, operating lease ROU asset and liability were included in prepaid expenses and other assets and accounts payable and other current liabilities, respectively, on the statement of cash flows.

Rent expense for the three months ended March 31, 2019 and 2018 was approximately $38,000 and $35,000, respectively. The Company also pays pass through costs and utility costs, which are expensed as incurred.

4. Technology Acquisition Agreement

In June 2007, the Company acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc. ("Questcor") pursuant to an Asset Purchase Agreement. The Company paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in the Company's Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc ("Mallinckrodt") acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the Asset Purchase Agreement with the Company to Mallinckrodt. In addition to the payments previously made to Questcor, the Company may also be required to make additional milestone payments totaling up to $52 million. In March 2018, the Company and Mallinckrodt amended the Asset Purchase Agreement to defer development and approval milestone payments, such that, rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, the Company would be required to make a single $5 million payment one year after the Company receives FDA approval to market Gimoti.

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, the Company will be required to pay Mallinckrodt a low single digit royalty on net sales of Gimoti. The Company's obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032.

5. Stockholders' Equity

At the Market Equity Offering Program

In November 2017, the Company filed a shelf registration with the SEC on Form S-3. The shelf registration statement includes a prospectus for the at-the-market offering to sell up to an aggregate of $16.0 million of shares of the Company's common stock through B. Riley FBR, Inc. ("FBR") as a sales agent (the "FBR Sales Agreement"). During the three months ended March 31, 2018, the Company sold 268,870 shares of common stock at a weighted-average price per share of $2.10 pursuant to the FBR Sales Agreement and received proceeds of approximately $545,000, net of commissions and fees. During the three months ended March 31, 2019, the Company sold 450,000 shares of common stock at a weighted-average price per share of $1.44 pursuant to the FBR Sales Agreement and received proceeds of approximately $636,000, net of commissions and fees. In April 2019, the Company sold 5,384,117 shares of common stock at a weighted-average price per share of $0.86 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.5 million, net of commissions and fees.

Future sales will depend on a variety of factors including, but not limited to, market conditions, the trading price of the Company's common stock and the Company's capital needs. There can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that the Company deems appropriate.

In addition, the Company will not be able to make future sales of common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on the Company's assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of

operations. The Company has no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement.

Warrants

In March 2018, the Company entered into the Warrant Amendments with each of the holders of the Company's outstanding Warrants acquired as a part of the Company's financings which closed in July and August 2016. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of the Company's common stock are no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting in a net gain of approximately $433,000 in the statement of operations, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital.

In September 2018, warrants to purchase 84,000 shares of the Company's common stock, issued to representatives of the underwriters in connection with the Company's initial public offering in September 2013, expired and were cancelled.

Stock-Based Compensation

Stock-based compensation expense includes charges related to employee stock purchases under the ESPP and stock option grants. The Company measures stock-based compensation expense based on the grant date fair value of any awards granted to its employees. Such expense is recognized over the period of time that employees provide service and earn rights to the awards.

The estimated fair value of each stock option award granted was determined on the date of grant using the Black Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	**2018**
Common Stock Options		
Risk free interest rate	2.55%	2.66%
Expected option term	6.0 years	6.0 years
Expected volatility of common stock	90.34%	90.15%
Expected dividend yield	0.0%	0.0%

The estimated fair value of the shares to be acquired under the ESPP was determined on the initiation date of each six-month purchase period using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for ESPP shares to be purchased during the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	**2018**
Employee Stock Purchase Plan		
Risk free interest rate	2.52%	1.85%
Expected term	0.5 years	0.5 years
Expected volatility of common stock	130.36%	58.76%
Expected dividend yield	0.0%	0.0%

The Company recognized non-cash stock-based compensation expense to employees and directors in its research and development and its general and administrative functions as follows:

	Three Months Ended March 31,	
	2019	**2018**
Research and development	$ 152,174	$ 188,777
General and administrative	226,785	204,998
Total stock-based compensation expense	$ 378,959	$ 393,775

As of March 31, 2019, there were approximately $2.9 million of unrecognized compensation costs related to outstanding employee and board of director options, which are expected to be recognized over a weighted-average period of 1.52 years.

6. Commercial Services Agreement

On January 5, 2019, the Company entered into a commercial services agreement with NGP (the "NGP Agreement") for the commercialization of Gimoti. Pursuant to the NGP Agreement, NGP will manage the commercial operations for a dedicated sales team to market Gimoti, if approved by FDA, to gastroenterologists and other targeted health care providers.

Under the terms of the NGP Agreement, the Company maintains ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. The Company will also retain a contract sales organization, which would be managed by NGP. The Company will record sales for Gimoti and retain more than 80% of product profits. NGP will receive a percentage of product profits in the mid-to-high teens as a service fee (such product profit amount, the "Contribution Profits").

Pursuant to the NGP Agreement, NGP has agreed to finance the Company's working capital requirements for specified commercialization costs in an amount by which Contribution Profits are expected to fall (or do actually fall) below zero (as projected by sales forecasts and a commercialization budget) to be drawn by the Company on a monthly basis, as needed ("NGP Working Capital Loan"), pursuant to a credit agreement between the Company and NGP ("NGP Credit Agreement"). The NGP Working Capital Loan will be repaid by the Company, if at all, only out of positive Contribution Profits, unless the NGP Agreement is terminated (a) by NGP due to a material breach by the Company, or (b) by the Company other than due to the gross negligence or intentional misconduct of NGP. Termination of the NGP Agreement by NGP for any other reason (including, without limitation, minimum net sales thresholds and negative Contribution Profits, as described below) will cause the NGP Working Capital Loan to be forgiven in full. The interest rate and other terms of the NGP Working Capital Loan will be set forth in the NGP Credit Agreement.

In addition, under the NGP Agreement, NGP has agreed to provide a line of credit of up to $5.0 million to the Company following NDA approval of Gimoti, if any, and for a period of up to nine months thereafter. The line of credit will be extended pursuant to a credit agreement between the parties. NGP will receive a low single digit percentage on net sales of Gimoti in lieu of any interest on the line of credit (the "NGP Credit Fee"); provided that in no event shall the cumulative NGP Credit Fee exceed twice the amount of the principal borrowed by the Company. The line of credit will mature on the earlier of 30 days following the date the NGP Credit Fee is twice the amount of the borrowed principal and the two-year anniversary of the date the principal is borrowed by the Company. In the event the Company secures financing from a third-party wholesale distributor for the purchase of Gimoti for launch in excess of $2.5 million dollars, NGP will no longer be required to offer the line of credit.

The term of the NGP Agreement is five years from the date of commercial launch of Gimoti, if any, after which the Company will recapture 100% of product sales and assume all corresponding responsibilities. Within 30 days after each one-year anniversary of the NGP Agreement, either party may terminate the NGP Agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the NGP Agreement for the material breach of the other party, subject to a 60-day cure period, or in the event an insolvency petition of the other party is pending for more than 60 days. Either party may also terminate the NGP Agreement upon
30-days written notice to the other party if Gimoti is subject to a safety recall, the parties are unable to agree to a commercialization plan and budget by a specified date, or if the Contribution Profit is negative for any calendar quarter beginning with the first full calendar quarter nine months following commercial launch. In addition, NGP may terminate the NGP Agreement if the Company withdraws Gimoti from the market for more than 180 days or if the Company is unable to provide product samples for use by the salesforce in a timely manner. NGP may also terminate the NGP Agreement since Gimoti was not approved by FDA by April 30, 2019, but, as of May 7, 2019, has not elected to do so. The Company may terminate the NGP Agreement upon a change of control of the Company, subject to a one-time payment equal to between four times and one times annualized service fees paid by the Company under the NGP Agreement, with such amount based on which year (between one and five years) after commercial launch the change of control occurs, provided if the change of control occurs within one year of commercial launch, such amount will be the greater of the specified annualized service fee amount and $5 million.

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 6, 2019. Past operating results are not necessarily indicative of results that may occur in future periods.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, such as the New Drug Application, or NDA, for Gimoti and our plans and expectations to address the issues raised in the Complete Response Letter, or CRL, received from U.S. Food and Drug Administration, or FDA, regulatory developments, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. For all 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.

We use our registered trademark, EVOKE PHARMA, and our trademarked product name, GIMOTI, in this Quarterly Report on Form 10-Q. Solely for convenience, trademarks and tradenames referred to in this Quarterly Report on Form 10-Q 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 that the applicable owner will not assert its rights, to these trademarks and tradenames.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Evoke," "we," "us" and "our" refer to Evoke Pharma, Inc.

Overview

We are a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. We are developing Gimoti, an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a GI disorder afflicting millions of individuals worldwide and is characterized by slow or delayed gastric emptying and evidence of gastric retention in the absence of mechanical obstruction and can cause various serious digestive system symptoms and other complications. Metoclopramide tablets and injection are the only products currently approved in the United States to treat the symptoms associated with acute and recurrent diabetic gastroparesis. Gimoti is a novel nasal spray formulation of metoclopramide designed to provide systemic delivery of the molecule through the nasal mucosa. We submitted an NDA for Gimoti to FDA on June 1, 2018 and received a Day-74 FDA filing communication letter in August 2018. The letter stated that the NDA was sufficiently complete to permit a substantive review and set a target goal date under the Prescription Drug User Fee Act, or PDUFA, of April 1, 2019.

On March 1, 2019, we received a multi-disciplinary review letter, or DRL, from FDA, which provided preliminary notice of certain deficiencies identified during FDA's initial review of the Gimoti NDA. Specifically, the DRL described concerns with the information provided in the NDA that insufficient evidence had been offered regarding product quality control and reproducibility for the commercially available sprayer device used with Gimoti, that there is a lack of adequate information to support sex-based efficacy claims and that the pharmacology data provided may not demonstrate bioavailability to the Listed Drug, Reglan Tablets10 mg. On March 14, 2019, we submitted a response to the DRL to FDA. In addition, on March 21, 2019, we had a meeting with FDA to obtain feedback on our responses.

On April 1, 2019, we received a CRL from FDA for our NDA. The CRL, which cited fewer issues than the DRL, stated that FDA has determined it cannot approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low maximum observed plasma concentration, or C_{max}, in subjects representing less than 5% of the total administered Gimoti doses in the pivotal pharmacokinetic, or PK, study. FDA stated the overall lower mean C_{max} was driven by the data from these few doses. Without the aberrant doses, our analysis shows the data met the bioequivalence criteria for both men and women, although there is no assurance that FDA will agree with our conclusion. FDA recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address the issue. Additionally, FDA requested data from three registration batches of commercial product to be manufactured at the proposed commercial manufacturing site, by the proposed commercial process and tested using validated analytical methods. These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution and other essential performance characteristrics for the commercial product specifications.

We believe that the issues raised by the CRL, which were related to the concerns over reproducible dose delivery, can be addressed, and expect to meet and work with FDA to gain a fuller understanding of FDA's requirements for approval. However, there is no guarantee that we will be able to adequately address the issues raised to FDA's satisfaction.

On January 5, 2019, we entered into a commercial services agreement, or NGP Agreement, with Novos Growth, LLC, or NGP, for the commercialization of Gimoti. Pursuant to the NGP Agreement, NGP will manage the commercial operations for a dedicated sales team to market Gimoti, if approved by FDA, to gastroenterologists and other targeted health care providers.

Under the terms of the NGP Agreement, we maintain ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. We will also retain a contract sales organization, which would be managed by NGP. We will record sales for Gimoti and retain more than 80% of product profits. NGP will receive a percentage of product profits, or Contribution Profits, in the mid-to-high teens as a service fee. During the term of the NGP Agreement, NGP agrees to not commercialize a competing product in the United States other than pursuant to the NGP Agreement.

Pursuant to the NGP Agreement, NGP has agreed to finance our working capital requirements for specified commercialization costs in an amount by which Contribution Profits are expected to fall (or do actually fall) below zero (as projected by sales forecasts and a commercialization budget) to be drawn by us on a monthly basis, as needed, or NGP Working Capital Loan, pursuant to a credit agreement between us and NGP, or NGP Credit Agreement. The NGP Working Capital Loan will be repaid by us, if at all, only out of positive Contribution Profits, unless the NGP Agreement is terminated (a) by NGP due to a material breach by us, or (b) by us other than due to the gross negligence or intentional misconduct of NGP. Termination of the NGP Agreement by NGP for any other reason (including, without limitation, minimum net sales thresholds and negative Contribution Profits, as described below) will cause the NGP Working Capital Loan to be forgiven in full. The interest rate and other terms of the NGP Working Capital Loan will be set forth in the NGP Credit Agreement.

In addition, under the NGP Agreement, NGP has agreed to provide a line of credit of up to $5.0 million to us following NDA approval of Gimoti, if any, and for a period of up to nine months thereafter. The line of credit will be extended pursuant to a credit agreement to be negotiated in good faith by the parties. NGP will receive a low single digit percentage on net sales of Gimoti, or NGP Credit Fee, in lieu of any interest on the line of credit; provided that in no event shall the cumulative NGP Credit Fee exceed twice the amount of the principal borrowed by us. The line of credit will mature on the earlier of 30 days following the date the NGP Credit Fee is twice the amount of the borrowed principal and the two-year anniversary of the date the principal is borrowed by us. In the event we secure financing from a third-party wholesale distributor for the purchase of Gimoti for launch in excess of $2.5 million dollars, NGP will no longer be required to offer the line of credit.

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock prior to our initial public offering in September 2013, borrowings under our bank loans and the sale of shares of our common stock on the Nasdaq Capital Market. We have incurred losses in each year since our inception. Substantially all of our operating losses resulted from expenses incurred in connection with advancing Gimoti through development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for at least the next several years. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

As of March 31, 2019, we had cash and cash equivalents of approximately $4.0 million. Current cash on hand, including the approximately $4.5 million of net proceeds received in April 2019 from the sale of common stock through the FBR Sales Agreement, is intended to fund interactions with FDA on the NDA submission for Gimoti, respond to approvability issues raised in the CRL received

from FDA, and manufacture registration batches of Gimoti. In addition, cash will be needed to fund pre-commercialization and pre-approval activities for Gimoti, including hiring a sales force, preparing for marketing and commercial manufacturing of Gimoti, and general and administrative costs to support operations. Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents, including net proceeds from our sale of common stock in April 2019, will be sufficient to fund our operations into the first quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement that may extend our cash runway into the second half of 2020, without accounting for any future Gimoti product revenue, although there can be no assurance in that regard. Under either situation, we may be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

Technology Acquisition Agreement

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc., or Questcor, pursuant to an asset purchase agreement. We paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in our Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the asset purchase agreement with us to Mallinckrodt. In addition to the payments previously made to Questcor, we may be required to make additional milestone payments totaling up to $52 million. In March 2018, we amended the asset purchase agreement with Mallinckrodt to defer development and approval milestone payments, such that rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, we would be required to make a single $5 million payment one year after we receive FDA approval to market Gimoti.

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay Mallinckrodt a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032.

Financial Operations Overview

Research and Development Expenses

We expense all research and development expenses as they are incurred. Research and development expenses primarily include:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our clinical trials;
- manufacturing and stability testing costs and related supplies and materials; and
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense.

All of our research and development expenses to date have been incurred in connection with the development of Gimoti. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. While we submitted the NDA for Gimoti in June 2018, the successful development and commercialization of Gimoti is still highly uncertain, in part due to our receipt of the CRL from FDA. We are unable to estimate with any certainty the costs we will incur in the continued development and regulatory review of Gimoti, though such costs may be significant. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;

- the number of doses that subjects receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of subjects;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not yet know when Gimoti may be commercially available, if at all.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Other general and administrative expenses include professional fees for accounting, tax, patent costs, legal services, insurance, facility costs and costs associated with being a publicly-traded company, including fees associated with investor relations and directors and officers liability insurance premiums. We expect that general and administrative expenses will increase in the future as we expand our operating activities, prepare for the growth needs associated with potential commercialization of Gimoti and continue to incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and SEC requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations.

Other Income

Other income consists primarily of changes in the fair value of the warrant liability, which represents the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period. The warrant liability was revalued each reporting period until March 2018, when we entered into warrant amendments, or the Warrant Amendments, with each of the holders of our outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016, or the Warrants. We previously used the Black Scholes valuation model to value the related warrant liability at each reporting date. As a result of the Warrant Amendments, the Warrants are no longer required to be accounted for as a liability and are no longer required to be revalued at each reporting period.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

The critical accounting policies and estimates underlying the accompanying unaudited financial statements are those set forth in Part II, Item 7 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 6, 2019.

Other Information

None.

Results of Operations

Comparison of Three Months Ended March 31, 2019 and 2018

The following table summarizes the results of our operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Increase/ (Decrease)
	2019	2018	
Research and development expenses	$ 746,882	$ 1,385,366	$ (638,484)
General and administrative expenses	$ 1,223,013	$ 1,032,245	$ 190,768
Other (income)	$ (4,629)	$ (434,825)	$ (430,196)

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2019 compared to the three months ended March 31, 2018, decreased by approximately $638,000. During 2019, we incurred expenses responding to requests for additional information from FDA, and preparing for future manufacturing and potential commercial launch of Gimoti, while in 2018 we incurred expenses preparing the Gimoti NDA. Costs incurred in 2019 included approximately $572,000 for wages, taxes and employee insurance, including approximately $152,000 of stock-based compensation expense, approximately $103,000 related to manufacturing, and approximately $68,000 related to responding to FDA questions on the NDA and the DRL. Costs incurred in 2018 included approximately $726,000 for wages, taxes and employee insurance, including approximately $189,000 of stock-based compensation expense, approximately $440,000 related to the preparation of the NDA, and approximately $211,000 related to manufacturing costs.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2019 compared to the three months ended March 31, 2018, increased by approximately $191,000. Costs incurred in 2019 primarily included approximately $617,000 for wages, taxes and employee insurance, including approximately $227,000 of stock-based compensation expense, approximately $491,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, and approximately $35,000 for pre-commercialization costs. Costs incurred in 2018 primarily included approximately $459,000 for wages, taxes and employee insurance, including approximately $205,000 of stock-based compensation expense, and approximately $481,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other Income. Other income for the three months ended March 31, 2019 compared to the three months ended March 31, 2018, decreased by approximately $430,000 due primarily to no longer being required to revalue the Warrants. Since the date of the Warrant Amendments in March 2018, the Warrants are no longer classified as a liability on our balance sheet, were adjusted to fair value and were reclassified to additional paid-in capital, a component of stockholders' equity. Prior to the amendment, the Warrants were accounted for as a liability and were required to be revalued at each reporting period.

Liquidity and Capital Resources

In November 2017, we filed a shelf registration with the SEC on Form S-3. The shelf registration statement includes a prospectus for the at-the-market offering to sell up to an aggregate of $16.0 million of shares of our common stock through B. Riley FBR, Inc., or FBR, as a sales agent, or FBR Sales Agreement. During the year ended December 31, 2018, we sold 1,985,054 shares of common stock at a weighted-average price per share of $2.38 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.6 million, net of commissions and fees. During the three months ended March 31, 2019, we sold 450,000 shares of common stock at a weighted-average price per share of $1.44 pursuant to the FBR Sales Agreement and received proceeds of approximately $636,000, net of commissions and fees. In April 2019, we sold 5,384,117 shares of common stock at a weighted-average price per share of $0.86 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.5 million, net of commissions and fees.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K ("Form 10-K"), and our public float is less than $75 million, and for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the baby shelf rules. As of April 30, 2019, our public float was approximately $34.3 million, based on 20,183,420 shares of outstanding common stock held by non-affiliates at a price of $1.70 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on April 1, 2019. As a result of our public float being below $75 million, we will be limited by the baby shelf rules until such time as our public float exceeds $75 million, which means we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. As of April 30, 2019, we had the capacity to issue up to approximately $2.1 million of additional shares of common stock pursuant to the FBR Sales Agreement.

Future sales under the FBR Sales Agreement will depend on a variety of factors including, but not limited to, market conditions, the trading price of our common stock and our capital needs. There can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

In addition, we will not be able to make future sales of common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations. We have no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement.

In March 2018, we entered into the Warrant Amendments with each of the holders of our outstanding Warrants acquired as part of our financings which closed in July and August 2016. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of our common stock are no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting in a gain of approximately $433,000 in the statement of operations, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital, a component of stockholders' equity.

Management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm also included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2018 with respect to our ability to continue as a going concern. This doubt about our ability to continue as a going concern for at least twelve months from the date of the financial statements could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing Gimoti, but it cannot be marketed until regulatory approvals have been obtained. We believe, based on our current operating plan, that our existing cash and cash equivalents, including net proceeds from the sale of common stock in April 2019, will be sufficient to fund our operations into the first quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement that may extend our cash runway into the second half of 2020, without accounting for any future Gimoti product revenue, although there can be no assurance in that regard. Under either situation, we may be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

These estimates of cash runway could be shortened if there are any significant increases in planned spending on responding to the issues raised by FDA in the CRL, pre-commercialization and pre-approval activities, including hiring a sales force, preparing for marketing and manufacturing of Gimoti, and our general and administrative costs to support operations. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We expect to continue to incur expenses and increase operating losses for at least the next several years. In the near-term, we anticipate incurring costs as we:

- respond to the issues raised in the CRL, conduct additional development activities, if required, and prepare an NDA resubmission;
- continue the pre-approval and pre-commercialization activities for Gimoti;
- continue the preparation of the commercial manufacturing process;
- maintain, expand and protect our intellectual property portfolio; and
- continue to fund the additional accounting, legal, insurance and other costs associated with being a public company.

The following table summarizes our cash flows for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	$ (1,926,886)	$ (2,817,966)
Net cash provided by financing activities	$ 636,432	$ 544,643
Net increase (decrease) in cash and cash equivalents	$ (1,290,454)	$ (2,273,323)

Operating Activities. The primary use of our cash has been to fund our clinical research and other general operations. The cash used in operating activities during the three months ended March 31, 2019 was primarily related to ongoing communication with FDA related to the NDA and the DRL, and pre-approval and pre-commercialization activities. The cash used in operating activities during the three months ended March 31, 2018 was primarily related to the preparation of the NDA. We expect that cash used in operating activities will increase in 2019 due to responding to the CRL and pre-approval and pre-commercialization activities, as well as commercialization activities should FDA approve the NDA for Gimoti.

Financing Activities. During the three months ended March 31, 2019, we received net proceeds of approximately $636,000 from the sale of 450,000 shares of common stock pursuant to the FBR Sales Agreement. During the three months ended March 31, 2018, we received net proceeds of approximately $545,000 from the sale of 268,870 shares of common stock pursuant to the FBR Sales Agreement.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- we may not have sufficient financial and other resources to complete clinical development for Gimoti, including to address the issues raised by FDA in the CRL and to resubmit the NDA;
- we may not be able to provide acceptable evidence of safety and efficacy for Gimoti;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we receive approval of the NDA if and when it is resubmitted;
- FDA may disagree with the design of our future clinical trials, if any are necessary;
- variability in subjects, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- FDA may not agree with the analysis of our clinical trial results;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval;
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Gimoti, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue;
- if approved, Gimoti will compete with well-established products already approved for marketing by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and
- we may not be able to establish commercial-scale manufacturing capabilities.

Off-Balance Sheet Arrangements

Through March 31, 2019, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Contractual Obligations and Commitments

There were no material changes outside the ordinary course of our business during the three months ended March 31, 2019 to the information regarding our contractual obligations that was disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 6, 2019.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of March 31, 2019, there have been no material changes in our market risk from that described in "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Quantitative and Qualitative Disclosures about Market Risk" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 6, 2019.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Business Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Business Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Business Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2019.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are currently not a party to any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors included in "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 6, 2019, other than as set forth below:

Risks Related to our Business, including the Development, Regulatory Approval and Potential Commercialization of our Product Candidate, Gimoti

Our business is entirely dependent on the success of Gimoti, which failed to achieve the primary endpoint of symptom improvement in a Phase 3 clinical trial in female patients with symptoms associated with diabetic gastroparesis. While we are continuing to pursue regulatory approval based on the results of our completed comparative exposure PK trial, we received a CRL from FDA for our Gimoti NDA and we cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Gimoti.

To date, we have devoted all of our research, development and clinical efforts and financial resources toward the development of Gimoti, our patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. Gimoti is our only product candidate. In July 2016, we announced topline results from our Phase 3 clinical trial that evaluated the efficacy and safety of Gimoti in women with symptoms associated with diabetic gastroparesis. In this study, Gimoti did not achieve its primary endpoint of symptom improvement in the Intent-to-Treat (ITT) group at Week 4.

In December 2016, we announced the completion of a pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. Data from the comparative exposure PK trial will serve as a portion of the 505(b)(2) data package to include prior efficacy and safety data developed by us and FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets 10 mg. In October 2017, we announced positive topline results from the comparative exposure PK trial. In addition, based on feedback received from FDA at an additional pre-NDA meeting, we proposed a risk mitigation strategy and post-approval safety trial as part of the NDA we submitted for Gimoti to FDA on June 1, 2018. We received a Day-74 filing communication letter in August 2018 that stated that the NDA was sufficiently complete to permit a substantive review and set a target goal date under PDUFA of April 1, 2019. On March 1, 2019, we received a DRL from FDA, which provided preliminary notice of certain deficiencies identified during FDA's initial review of the Gimoti NDA. Specifically, the DRL described concerns with the information provided in the NDA, including concerns that insufficient evidence had been offered regarding product quality control and reproducibility specific to the commercially available sprayer device used with Gimoti, that there is a lack of adequate information to support sex-based efficacy claims and that the pharmacology data provided may not demonstrate bioavailability to the Listed Drug, Reglan Tablets 10 mg.

On April 1, 2019, we received a CRL from FDA for our NDA. The CRL stated that FDA determined it could not approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low C_{max} in subjects representing less than 5% of the total administered Gimoti doses in the pivotal PK study. FDA stated the overall lower mean C_{max} was driven by the data from these few doses. Without the aberrant doses, our analysis shows the data met the bioequivalence criteria for both men and women, although there is no assurance that FDA will agree with our conclusion. FDA recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address the issue. Additionally, FDA requested data from three registration batches of commercial product to be manufactured at the proposed commercial manufacturing site, by the proposed commercial process and tested using validated analytical methods These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution and other essential performance characteristics for the commercial product specifications. We believe that the issues raised by the CRL, which were related to the concerns over reproducible dose delivery, can be addressed, and expect to meet and work with FDA to gain a fuller understanding of FDA's requirements for approval. However, there is no guarantee that we will be able to adequately address the issues raised to FDA's satisfaction.

Because our business is entirely dependent on the success of Gimoti, if we are unable to successfully complete development of and receive regulatory approval of this product candidate, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in the complete loss of an investment in our securities.

In addition to the above factors, the future regulatory and commercial success of Gimoti is subject to a number of additional risks, including the following:

- we may not be able to provide acceptable evidence of safety and efficacy for Gimoti, including as a result of the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced Listed Drug, Reglan Tablets 10 mg.;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval, including C_{max} falling below the equivalence range in the comparative exposure PK trial;
- FDA may not agree with the analysis of our clinical trial results, including our analysis of results of the PK trial;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we receive approval of the NDA if and when it is resubmitted;
- we may not have sufficient financial and other resources to complete clinical development for Gimoti;
- if approved, Gimoti will compete with well-established products already approved for marketing by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- our reliance on NGP and any third-party sales organization to commercialize Gimoti, if approved;
- we may not be able to maintain commercial manufacturing arrangements with third-party manufacturers or establish and maintain commercial-scale manufacturing capabilities;
- FDA may disagree with the design of any future clinical trials, if any are necessary;
- variability in subjects, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Gimoti, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue; and
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights.

Of the large number of drugs in development in this industry, only a small percentage result in the submission of an NDA to FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market Gimoti, any such approval may be subject to limitations on the indicated uses for which we may market the product.

We may require substantial additional funding and may be unable to raise capital when needed, which would force us to liquidate, dissolve or otherwise wind down our operations.

Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations into the first quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement that may extend our cash runway into the second half of 2020, without accounting for any future Gimoti product revenue, although there can be no assurance in that regard. Under either situation, we may be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to raise additional funds to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

Our estimates of the amount of cash necessary to fund our activities may prove to be wrong and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti that may be required by FDA, including any pre-approval or post-approval trials FDA or other regulatory agencies may require evaluating the efficacy or safety of Gimoti;
- the costs involved for additional data collection and analysis to respond to FDA questions related to the NDA and to respond to the CRL and resubmit the NDA;

- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for Gimoti;
- the costs required to commercialize Gimoti, including expenses incurred under our commercialization agreement with NGP, and the costs of establishing or outsourcing additional sales, marketing and distribution capabilities;
- the commercial success of Gimoti, if approved;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Gimoti;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- costs associated with any other product candidates that we may develop, in-license or acquire.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. Furthermore, the issuance of additional shares or other securities by us, or the possibility of such issuance, may cause the market price of our shares to decline and dilute the holdings of our existing stockholders. If we raise additional funds by incurring debt, the terms of the debt may involve significant cash payment obligations, as well as covenants and specific financial ratios that may restrict our ability to operate our business. We cannot provide any assurance that our existing capital resources will be sufficient to enable us to identify or execute a viable plan for continued clinical development of Gimoti, resubmit the NDA or to otherwise survive as a going concern.

Final marketing approval for Gimoti by FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

We submitted an NDA for Gimoti in June 2018. Under PDUFA, FDA is subject to a two-tiered system of review times - Standard Review and Priority Review. For drugs subject to standard review, such as Gimoti, FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. In its Day-74 filing communication letter, FDA assigned a target goal date under PDUFA of April 1, 2019 for the Gimoti NDA. On April 1, 2019, we received a CRL from FDA for our NDA. The CRL stated that FDA could not approve the NDA in its present form and provided recommendations to address the remaining approvability issues in an NDA resubmission. We believe that the issues raised by the CRL, can be addressed, and we expect to meet and work with FDA to gain a fuller understanding of FDA's requirements for approval. However, there is no guarantee that we will be able to adequately address the issues raised to FDA's satisfaction.

Moreover, the duration of FDA's review of any resubmitted NDA may depend on the number and type of other NDAs that are submitted with FDA around the same time period. In addition, FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

We cannot provide any assurance as to whether or when we will obtain regulatory approval to commercialize Gimoti. We cannot, therefore, predict the timing of any future revenue. Because Gimoti is our only product candidate this risk is particularly significant for us. We cannot commercialize Gimoti until the appropriate regulatory authorities have reviewed and approved marketing applications for this product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for Gimoti. In addition, we may experience delays or the application may be rejected based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. For example, in 2009 following an FDA review of metoclopramide spontaneous safety reports, FDA required a boxed warning be added to the metoclopramide product label concerning the chance of tardive dyskinesia, or TD, for patients taking these products. FDA requires a boxed warning (sometimes referred to as a "Black Box" Warning) for products that have shown a significant risk of severe or life-threatening adverse events. Recently, the European Medicines Agency's Committee on Medicinal Products for Human Use, or CHMP, has reviewed and has proposed labeling changes for marketed metoclopramide products in the European Union based on age, dosing guidelines or indications. Based on their assessment of the limited efficacy and safety data currently available to the CHMP, the CHMP recommended to the European Medicines Agency that indications with limited or inconclusive efficacy data, including GERD, dyspepsia and gastroparesis, be removed from the approved product label in the European Union. There can be no assurance as to whether FDA will re-review approved metoclopramide product labels as a result of any such regulatory actions in the European Union or otherwise. If marketing approval for Gimoti is delayed, limited or denied, our ability to market the product candidate, and our ability to generate product sales, would be adversely affected.

In addition, in a written communication, FDA responded to our request for proprietary name review by conditionally accepting our proposed proprietary brand name, Gimoti. However, FDA issued the CRL even though it had previously approved this proprietary name. FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with the

names of other products, which could lead to identification of the wrong medication or other prescribing, ordering, dispensing, administration, or monitoring errors. FDA may also object to a product name if it believes the name functions to overstate the efficacy, minimize the risk, broaden the proposed indication, make unsubstantiated superiority claims, or is otherwise false or misleading. If FDA objects to the product name Gimoti as part of any NDA resubmission review process, we may be required to adopt an alternative name for our product candidate. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for Gimoti and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidate.

Risks Related to Our Financial Position and Need for Capital

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm also included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2018 with respect to this uncertainty. This doubt about our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing Gimoti, but it cannot be marketed until regulatory approvals have been obtained.

Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents, including net proceeds from the sale of common stock in April 2019, will be sufficient to fund our operations into the first quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement that may extend our cash runway into the second half of 2020, without accounting for any future Gimoti product revenue, although there can be no assurance in that regard. This period could be shortened if there are any significant increases in planned spending on our Gimoti development program than anticipated. Under either situation, we may be required to raise additional funds in order to continue as a going concern. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize Gimoti.

We will require substantial additional future capital in order to finance any additional development activities for Gimoti, including any requirements requested by FDA, including our response to the approvability issues raised by FDA in the CRL, as well as for pre-commercial activities, including marketing and manufacturing of Gimoti. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti required by FDA, including any additional trials FDA or other regulatory agencies may require evaluating the safety of Gimoti;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing Gimoti for clinical trials and other studies and, if approved, for commercial sale;
- our need and ability to hire additional management, development and scientific personnel;
- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the timing and costs associated with establishing sales and marketing capabilities;
- market acceptance of Gimoti;

- the extent to which we are required to pay milestone or other payments under our Mallinckrodt asset purchase agreement and the timing of such payments;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Some of these factors are outside of our control. We cannot provide any assurance that our existing capital will be sufficient to enable us to fund any additional clinical development required for Gimoti, and, in any event, we will need to raise additional capital to complete such clinical development, as well as to prepare to commercialize Gimoti should we receive product approval. We may need to raise additional funds in the near future for commercialization for Gimoti.

We may seek additional funding through collaboration agreements, public or private equity financings, debt financings or receivables financings. For example, we currently may sell from time to time, at our option, up to an aggregate of $16.0 million of shares of our common stock through FBR, as sales agent pursuant to the FBR Sales Agreement. Sales pursuant to the FBR Sales Agreement are registered pursuant to a shelf registration statement on Form S-3 which was declared effective by the SEC on December 28, 2017. As of April 30, 2019, we had sold approximately $10.0 million of shares of our common stock pursuant to the FBR Sales Agreement. However, there can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

Under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the FBR Sales Agreement, is limited to an aggregate of one-third of our public float. As of April 30, 2019, our public float was approximately $34.3 million which means we may only sell approximately $2.1 million of securities using our shelf registration statements. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. In addition, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline and dilute the holdings of our existing stockholders. If we raise additional funds by incurring debt, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

If we are unable to obtain funding on a timely basis, if required, we will be unable to complete additional clinical development of Gimoti and may be required to significantly curtail all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidate or some of our technologies or otherwise agree to terms unfavorable to us.

If we fail to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on the Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum closing bid price per share of $1.00 and continued business operations so that we are not characterized as a "public shell company." As of the date hereof, the closing bid price of our common stock is below $1.00 per share. If we were to fail to meet the minimum closing bid price requirement of $1.00 for 30 consecutive business days, we could become subject to delisting. Although Nasdaq may provide us with a compliance period in which to regain compliance with the minimum closing bid price requirement, we cannot assure you that we would be able to regain compliance within the period provided by Nasdaq. In order to regain compliance with such requirement, the closing bid price of our common stock would need to meet or exceed $1.00 per share for at least 10 consecutive business days during the compliance period. If we were not able to regain compliance within the allotted compliance period for this requirement or any other applicable listing standard, including any extensions that may be granted by Nasdaq, our shares of common stock would be subject to delisting. In the event that our common stock is delisted from the Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Index to Exhibits

Exhibit Number	Description of Exhibit
3.1 (1)	Amended and Restated Certificate of Incorporation of the Company
3.2 (1)	Amended and Restated Bylaws of the Company
4.1 (2)	Form of the Company's Common Stock Certificate
4.2 (3)	Investor Rights Agreement dated as of June 1, 2007
4.3 (3)	Warrant dated June 1, 2012 issued by the Company to Silicon Valley Bank
4.4 (4)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 25, 2016
4.5 (5)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated August 3, 2016
4.6 (6)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.7 (7)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.8 (8)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
10.1	Commercial Services Agreement, dated as of January 5, 2019, between the Company and Novos Growth, LLC. (certain portions of this exhibit have been omitted and are subject to confidential treatment)
10.2	First Amendment to the Commercial Services Agreement, dated as of February 28, 2019, between the Company and Novos Growth, LLC
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on September 30, 2013.
(2) Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 filed with the SEC on August 16, 2013.
(3) Incorporated by reference to the Company's Registration Statement on Form S-1 filed with the SEC on May 24, 2013.
(4) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on July 20, 2016.
(5) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2016.
(6) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2016
(7) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on March 23, 2018
(8) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 4, 2018

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

Evoke Pharma, Inc.

Date: May 8, 2019

By: /s/ David A. Gonyer
David A. Gonyer
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2019

By: /s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
Executive Vice President, Chief Business Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN INFORMATION (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED

COMMERCIAL SERVICES AGREEMENT

This Commercial Services Agreement (the "**Agreement**") is made on January 5, 2019 (the "**Effective Date**") by and between:

Evoke Pharma, Inc., with a place of business at 420 Stevens Avenue, Suite 370, Solana Beach, CA ("**Evoke**"); and

Novos Growth, LLC, with a place of business at 150 N Riverside Plaza, Suite 3400, Chicago, IL 60606 ("**Novos**").

Evoke and Novos are hereinafter referred to individually as a "**Part**y" and collectively as the "**Parties**".

BACKGROUND

Whereas, Evoke is a pharmaceutical company that owns Commercialization (as defined below) rights of the Product (as defined below) in the Territory (as defined below);

Whereas, Novos is a pharmaceutical consulting services company that has experience supervising and managing the day-to-day marketing and distribution of pharmaceutical products; and

Whereas, Evoke wishes to engage Novos to supervise and manage the day-to-day Commercialization of the Product in the Territory (as defined below) under the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, and other consideration received by the Parties, the Parties hereby agree as follows:

1. DEFINITIONS

For the purposes of this Agreement, the following words and expressions shall have the stated definitions:

1.1. "**Act**" means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), as amended from time to time, together with any rules, regulations, guidances, guidelines and requirements of the FDA as may be in effect from time to time.

1.2. "**Adverse Event**" means the development of an undesirable or unexpected medical condition or the deterioration of a pre-existing medical condition following or during exposure to the Product, whether or not considered causally related to the Product, the exacerbation of any pre-existing condition(s) occurring following or during the use of the Product or any other adverse event, adverse experience or adverse drug experience described in the FDA's Investigational New Drug safety reporting and post-marketing reporting regulations, 21 C.F.R. § 312.32, § 314.80 and § 600.80, respectively, as they may be amended from time to time. For purposes of this Agreement,

without limiting the forgoing, “undesirable medical condition” includes symptoms (e.g., nausea, chest pain), signs (e.g., tachycardia, enlarged liver) or the abnormal results of an investigation (e.g., laboratory findings, electrocardiogram), including unfavorable side effects, toxicity, injury, overdose, sensitivity reactions or failure of the Product to exhibit its expected pharmacologic/biologic effect.

1.3. "**Affiliate**" means any entity that is, directly or indirectly, controlled by, under common control with, or in control of a party, where "control" means power to elect or appoint a majority of directors or to direct the management of an entity.

1.4. “**Anti-Corruption Laws**” means the Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010, the Anti-Kickback Statute, the False Claims Act, the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, released April 2003, the Antifraud and Abuse Amendment to the Social Security Act, and any other applicable law, rule, regulation or industry code governing anti-bribery and anti-corruption laws and laws for the prevention of kickbacks, fraud, abuse, racketeering, money laundering or terrorism.

1.5. “**Applicable Law**” means (a) all applicable laws, rules and regulations, including any applicable rules, regulations, guidelines or other requirements of Governmental Authorities that may be in effect in the Territory from time to time during the Term, including (i) the Act, (ii) the PDMA, (iii) Anti-Corruption Laws, (iv) all federal, state or local statutes, laws, ordinances, regulations or guidelines relating to employment, safety and health of employees and the withholding and payment of required taxes with respect to employees, (v) all federal, state or local statutes, laws, ordinances, regulations or guidelines relating to data protection and privacy, including the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act and (b) the PhRMA Code on Interactions with Healthcare Professionals.

1.6. "**Business Day**" means a day on which companies in the United States are generally open for business.

1.7. “**Change of Control**” means (x) the acquisition of Evoke by another entity by means of any transaction or series of related transactions (including, without limitation, any merger, consolidation in which the majority of the outstanding shares of Evoke are exchanged for securities or other consideration issued, or caused to be issued, by the acquiring entity or its subsidiary, but excluding any transaction effected primarily for the purpose of changing Evoke’s jurisdiction of incorporation), unless Evoke’s shareholders of record as constituted immediately prior to such transaction or series of related transactions will, immediately after such transaction or series of related transactions hold at least a majority of the voting power of the surviving or acquiring entity or (y) a sale of all or substantially all of the assets of Evoke to which this Agreement pertains.

1.8. "**Commercialization**", "**Commercialize**" and "**Commercializing**" mean all of the normal and customary activities undertaken by a pharmaceutical company to accomplish the commercialization of a pharmaceutical product, including without limitation the storage, distribution, sales, promotion and marketing of the Product and managing returns of the Product, Patient Access Programs, and reimbursements but expressly excludes activities related to development or testing of the Product or Manufacturing.

1.9. "**Commercial Launch**" the first dispensation of the Product by a pharmacy in the Territory after NDA Approval of the Product. For clarity, "Commercial Launch" does not include the provision of Product to Third Parties solely as samples or donations, or for clinical trials or other research and development activities.

1.10. "**Competing Product**" means a product with an indication approved by FDA for the treatment of gastroparesis or gastric stasis, which for purposes of this Agreement, shall not be deemed to be the treatment of constipation.

1.11. "**Compliance Provisions**" means those representations, warranties and covenants of Novos set forth in Section 6.2, Section 6.3, and Section 8.1.

1.12. "**Confidential Information**" means all business, operational, marketing, financial, technical, manufacturing, scientific, or other information that is confidential or proprietary to a Party, an Affiliate of a Party, and is not generally known to the public, and shall include Manufacturing Data and this Agreement (and the terms hereof).

1.13. "**Contribution Profit**" means Net Sales, less the following: [***]. In the event of any dispute arising between the Parties on the determination or calculation of Contribution Profit or any component or accounting thereof that the Parties are unable to resolve despite negotiating in good faith, either Party may submit the dispute to a neutral and mutually agreeable nationally recognized public accounting firm, for a determination thereof, whose decision shall be binding upon the Parties.

1.14. "**Corporate Trademarks**" means the trade names, corporate names and corporate logos of Evoke or Evoke's Affiliates used in the Prescribing Information, Promotional Materials, training materials or other material provided hereunder or otherwise authorized or approved by Evoke.

1.15. "**Data Fees**" means fees paid to third parties, such as [***], for physician prescribing data.

1.16. "**Designated Samples**" means Product that is designated for use as patient samples by Evoke.

1.17. "**Detail**" means a face-to-face visit during which a Sales Force representative makes a presentation with respect to the Product to an Eligible Prescriber, such that (i) the relevant characteristics of the Product are described by the Sales Force representative in a fair and balanced manner consistent with the requirements of this Agreement and Applicable Law and (ii) such Eligible Prescriber is given an opportunity to place an order for Product in accordance with this Agreement. When used as a verb, "Detail" means to perform a Detail.

1.18. "**Eligible Prescriber**" means a health care provider that (a) has the authority to prescribe the Product under Applicable Law and (b) is allowed to receive all forms of promotion.

1.19. "**Evoke Commercialization Costs**" means all direct out-of-pocket costs incurred by Evoke (including any cost for which Evoke reimburses Novos for the Novos Commercialization Costs) for the Commercialization of the Product (including, without limitation, the costs of the Sales Force) that are: (i) prior to Commercial Launch, identified in the Commercialization Plan and incurred within the budgeted amounts set forth in the Commercialization Budget; and (ii) following Commercial Launch, identified in the Commercialization Plan and incurred within plus or minus [***] of the budgeted amounts set forth in the Commercialization Budget.

1.20. “**Executive Officers**” means, with respect to Evoke, its Chief Executive Officer, and with respect to Novos, its Chief Executive Officer.

1.21. “**FDA**” means the Unites States Food and Drug Administration.

1.22. “**Field Alert**” means a field alert report, as required under 21 C.F.R. § 314.81(b)(1), as such regulation may be amended from time to time.

1.23. “**Governmental Authority**” means any supranational, international, federal, state or local court, administrative agency or commission or other governmental authority or instrumentality, domestic or foreign, including FDA.

1.24. "**Intellectual Property Rights**" means all intellectual property rights anywhere in the world, whether or not registered, including patents, utility models, rights in inventions, trademarks, service marks, rights in trade dress (including product configuration and packaging), rights in business and trade names, rights in domain names, designs, copyrights, trade secrets, rights in know-how and confidential information, and, in each case, rights of a similar or corresponding character.

1.25. "**Know-How**" means all proprietary information related to Product, including all patentable and non-patentable inventions, discoveries, technologies, knowledge, trade secrets, experience, skill, techniques, methods, processes (including manufacturing processes), procedures, formulas, compounds, compositions of matter, assays, tests (including diagnostic tests), materials, specifications, descriptions, results and data (including Manufacturing Data), business or financial information or information of any type whatsoever, in any tangible or intangible form, marketing reports, business plans, standard operating procedures, and procedures.

1.26. "**Commercialization Know-How**" means the Know-How in the possession of Evoke as of the Effective Date of this Agreement or that becomes controlled by Evoke at any time during the Term, and is reasonably required for the Commercialization of the Product in the Territory.

1.27. "**Manufacture**" and "**Manufacturing**" mean all activities related to the manufacture of a pharmaceutical product for the Territory, including without limitation manufacturing for clinical use or commercial sale, as well as compliance with Applicable Laws relating to the foregoing activities, but expressly excludes activities related to Commercialization.

1.28. "**Manufacturing Data**" means all data, information, material, and documentation developed or generated with respect to the Manufacturing of a pharmaceutical product, including manufacturing and control data and other data and documentation requested by or submitted to a Regulatory Authority.

1.29. “**NDA**” means a New Drug Application filed with the FDA requesting permission to place a drug on the market in accordance with 21 CFR Part 314, and all amendments or supplements filed pursuant to the requirements of the FDA.

1.30. “**NDA Approval**” means the approval of a NDA by FDA for Commercialization of the Product.

1.31. "**Net Sales**" with respect to the Product means the gross amount actually invoiced by Evoke and its Affiliates for sales by Evoke and its Affiliates of the Product to Third Parties in a bona-fide, arms-length transaction, as determined by Evoke’s usual and customary accounting methods,

which are in accordance with Evoke's accounting standards as consistently applied, less the following deductions from such gross amounts which are actually incurred, allowed, accrued or specifically allocated in accordance with Evoke's standard business practices:

[***]

For the avoidance of doubt, sales or other transfers of Product between or among Evoke and/or its Affiliates shall not be counted for purposes of determining Net Sales, but resale of such Product by Evoke or any Affiliate to Third Parties shall be counted for purposes of determining Net Sales. Furthermore, Net Sales shall not include use of or distribution by Evoke or its Affiliates of Product for non-clinical or clinical studies, patient-assistance programs, charitable donations or compassionate use.

1.32. "**Other Reportable Information**" means any communication or other information that is otherwise required to be reported by Novos to Evoke in accordance with the training to be provided under this Agreement, other than Adverse Events.

1.33. "**Patient Access Programs**" means programs to assist patients with filling their prescriptions, including, without limitation, through help desks, triage procedures, bailment programs, and reduced cost or no cost prescription fulfillment.

1.34. "**PDMA**" means the Prescription Drug Marketing Act of 1987, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder and in effect from time to time.

1.35. "**Person**" means any individual, partnership, limited partnership, limited liability company, joint venture, syndicate, sole proprietorship, corporation, unincorporated association, trust, trustee, executor, administrator or other legal personal representative, or any other legal entity, including a Governmental Authority.

1.36. "**Prescribing Information**" means the FDA-approved labeling for the Product.

1.37. "**Product**" means Gimoti™, the nasally delivered formulation of metoclopramide that is the subject of New Drug Application No. [***] and any other formulation of metoclopramide that may be subsequently commercialized by Evoke or any Affiliate thereof, and any additional product that Evoke may acquire and the Parties agree to add to this Agreement.

1.38. "**Product Copyrights**" means all copyrightable subject matter related to the Product included in the Prescribing Information, the Promotional Materials, training materials or other material provided hereunder or otherwise authorized or approved by Evoke under this Agreement for use by Novos in performing the Services.

1.39. "**Product Know-How**" means all Know-How exclusively relating to the Product arising out of or in connection with either Party's or their respective Affiliates' activities under or in connection with this Agreement. Product Know-How excludes any Commercialization Know-How and any Confidential Information exclusively related to the Product.

1.40. "**Product Quality Complaint**" means any and all manufacturing or packaging-related complaints related to the Product, including (a) any complaint involving the possible failure of the Product to meet any of the specifications for the Product and (b) any dissatisfaction with the design,

package or labeling of the Product.

1.41. "**Product Trademarks**" means the product trademarks held by Evoke during the Term in the Territory with respect to the Commercialization of the Product, including any product trademarks used in the Prescribing Information, Promotional Materials, training materials or other material provided hereunder or otherwise authorized or approved by Evoke, excluding the Corporate Trademarks.

1.42. "**Regulatory Authority**" means any national, federal, state, or local governmental or regulatory authority, agency, department, bureau, commission, council or other government entity, including FDA, Centers for Medicare and Medicaid Services (CMS), and the Office of Inspector General of the U.S. Department of Health and Human Services, regulating or otherwise (a) exercising authority with respect to the development, manufacture, approval, registrations, licensing, or commercialization of the Product in such regulatory jurisdiction in the Territory, or (b) having legal authority with respect to the exploitation of the Product in the Territory.

1.43. "**Regulatory Documentation**" means all applications, registrations, licenses, authorizations and approvals, all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to the Product, and all data contained in any of the foregoing, including all Regulatory Authority approvals, regulatory drug lists, advertising and promotion documents and related FDA submissions and correspondence, adverse event files and complaint files and related FDA submissions.

1.44. "**Sales & Promotion Policies**" means Evoke's compliance policies and other policies generally applicable to the Commercialization of pharmaceutical products in the Territory, in each case approved by Evoke, as the same may be amended, modified or supplemented from time to time upon notice by Evoke to Novos.

1.45. "**Services**" means the day-to-day supervision and management by Novos of the Commercialization of the Product in the Territory, including the pre-commercial services set forth in Exhibit A, the launch and commercial services set forth in Exhibit B, and the functional services set forth in Exhibit C.

1.46. "**Territory**" means the United States and all of its territories and possessions.

1.47. "**Third Party**" means any Person other than Evoke, Novos and their respective Affiliates.

2. APPOINTMENT [***]

2.1. **Appointment**. Subject to the terms and conditions of this Agreement, on and from the Effective Date and for the duration of the Term, Evoke hereby appoints Novos to perform the Services, and Novos hereby agrees to perform the Services in accordance with Applicable Law. In performing the Services, Novos shall maintain a reasonably adequate number of qualified and trained staff to execute the Services in a commercially reasonable and workman like manner in accordance with industry standards.

2.2. [***]

2.3. **Retained Rights**. Evoke reserves the right to discontinue developing or producing the Product at

its discretion at any time and for any reason acting in good faith and without the intent to affect the rights or remedies of either party hereunder, including due to legal or regulatory requirements, administrative or court orders, or safety risks; provided, however, that Evoke shall notify Novos as soon as practicable after any such discontinuance. Notwithstanding Section 2.1 or any other provision of this Agreement, Evoke will retain the exclusive right to Manufacture or have Manufactured and supply the Product in or outside the Territory. In addition, Evoke shall retain the right to develop the Product in the Territory and outside the Territory and the right to Commercialize the Product inside and outside the Territory.

2.4. **Other Rights**. Novos acknowledges and agrees that, as between the Parties, Evoke owns all rights, title and interest in and to the Intellectual Property Rights and regulatory rights in the Product. Without limiting the foregoing, Evoke shall own all right, title and interest in and to (a) the Product, (b) the Product Trademarks, the Corporate Trademarks, and the Product Copyrights, and (c) any and all Product Know-How developed by either Party in the course of performing its obligations under this Agreement. Novos shall and does hereby assign all right, title and interest it may have in and to any Product Know-How, without additional compensation, and shall take such other actions as Evoke may request to fully effect Evoke's ownership of such Product Know-How.

2.5. **Use of Affiliates**. Evoke shall have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, and Novos shall have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates; provided, however, that (a) any such Affiliate shall be bound by the obligations of such Party under this Agreement, (b) any actions, omissions or conduct by such Affiliate shall be deemed to be actions, omissions or conduct of such Party, and (c) such Party shall remain responsible for the performance of its obligations under this Agreement. Novos shall not use any Third Parties to perform the Services or otherwise satisfy Novos' obligations hereunder for any period, without the prior written consent of Evoke, in Evoke's sole discretion.

2.6. **Initial Delivery of Commercialization Know-How**. Evoke shall promptly deliver to Novos copies or embodiments of the Commercialization Know-How and any other information or material that is held or subsequently acquired by Evoke during the Term that Evoke reasonably believes is necessary for Novos to perform the Services. Evoke shall provide such information and material to Novos in electronic format to the extent reasonably possible.

2.7. **Provision of Technical Assistance and Support**. During the Term, Evoke shall promptly provide to Novos or its Affiliates at Novos' request reasonable and currently available technical assistance and support necessary for Novos to perform the Services in the Territory, to the extent Evoke is reasonably able to provide such technical assistance and support.

2.8. **Safety Concerns, Changes and Updates.** Each Party shall inform the other Party within forty eight (48) hours with regard to any safety concerns with respect to the Product, or recalls by FDA, in each case that come to the attention of such Party.

3. COMMERCIALIZATION

3.1. **Alliance Managers**. Each Party shall designate a single person (each, an "**Alliance Manager**") to oversee contact between the Parties for all matters related to Commercialization of the Product. Except as otherwise specified herein, the Alliance Managers shall: (a) function as a single point

of contact in all substantive communications with the other Party relative to the performance of by Novos of its Commercialization obligations; and (b) perform any other functions agreed by the Parties. Each Party may replace its Alliance Manager at any time by written notice to the other Party. The initial Alliance Managers are set forth on Exhibit E.

3.2. **Commercialization Plan and Commercialization Budget**

a. **Content**. The Commercialization of the Product shall be governed by a Commercialization plan (the "**Commercialization Plan**"), and the costs and expenses relating to the Commercialization of the Product shall be governed by a Commercialization budget (the "**Commercialization Budget**"). An initial Commercialization Plan and an initial Commercialization Budget shall be completed by the Parties and attached hereto as Exhibit F and Exhibit G, respectively, in each case prior to February 28, 2019, that shall govern the period of time from the Effective Date until the date that is 12 months following the Commercial Launch of the Product. The initial Commercialization Budget will include a detailed budget and will define which costs will be incurred prior to approval, between approval and launch, and after launch, in each case with a goal of efficiently using working capital until the Product has demonstrated its ability to achieve revenue suitable for the Product and the associated costs. The Commercialization Budget will include the cost incurred and cash flow and working capital financing requirements. Each Commercialization Plan shall include without limitation the topics set forth in Schedule 3.2a.

b. **Updates**. Novos shall, from time to time and in any event no less than on an annual basis, update each Commercialization Plan and Commercialization Budget for the following year. Novos shall submit such updated Commercialization Plans and Commercialization Budgets to the JGC for review and approval at least two (2) weeks before the date of the fourth quarter meeting of the JGC, but in no event later than October 31 of each calendar year for the following calendar year. Within thirty (30) days following such submission, the JGC shall either approve the Commercialization Plan and Commercialization Budget prepared by Novos or approve a modified Commercialization Plan and Commercialization Budget. Any material changes to the Commercialization Plan and Commercialization Budget shall be mutually agreed to in writing by Novos and Evoke.

c. **Activities and Expenses**. Novos shall be responsible for all activities under the Commercialization Plan and those activities set forth in Exhibits A – C, and Evoke shall be responsible for those corporate functions set forth in Exhibit D. Each Party shall be responsible for their own internal costs under this Agreement, but Evoke shall be responsible for all third party costs (including the fees of Affiliates of Novos, which shall be at fair market value) and out-of-pocket expenses of both Parties. All direct out-of-pocket costs incurred by Novos for the Commercialization of the Product that are: (i) prior to Commercial Launch, identified in the Commercialization Plan and incurred within the budgeted amounts set forth in the Commercialization Budget; and (ii) following Commercial Launch, identified in the Commercialization Plan and incurred within plus or minus [***] of the budgeted amounts set forth in the Commercialization Budget ("Novos Commercialization Costs") shall be reimbursed by Evoke pursuant to Section 5. Any such Novos Commercialization Costs shall be invoiced by Novos to Evoke. For the avoidance of doubt, such Novos Commercialization Costs shall not include and Evoke shall have no responsibility for any overhead costs of Novos or the salaries or benefit costs of any

Novos personnel.

d. **Commercialization Responsibilities**. Without limiting the foregoing, Novos' responsibilities shall include the pre-commercial services set forth in Exhibit A, the launch and commercial services set forth in Exhibit B, and the functional services set forth in Exhibit C. Novos shall perform the Services solely for the Product and not for any other products of Evoke. Evoke shall be responsible for the corporate functions set forth in Exhibit D, the development, Manufacture, labelling, packaging, storage, logistics, distribution, marketing, and sale of the Products and obtaining and maintaining NDA Approval for the Product. Notwithstanding the foregoing, Novos shall manage and supervise the logistics, distribution, marketing, and sale of the Products and coordinate activities with a third party logistics vendor for such logistics and distribution of the Products and with a third party commercial sales organization for such marketing and sale of the Products, as each is contracted by Evoke.

e. **Sales Force**. Evoke will be responsible for engaging sales representatives as set forth in the Commercialization Plan (the "**Sales Force**") to market the Product under the supervision and management of Novos. The Parties acknowledge and agree that the intent and purpose of this Agreement is to maximize the sales volume of Products and profitability and that a sales force expansion is contemplated in the Commercialization Plan for this purpose. Upon the reasonable request from a Party, the Parties shall discuss in good faith whether to increase the full time equivalent number of Sales Force representatives. Any increase or decrease in the full time equivalent number of Sales Force representatives from the full time equivalent numbers set forth in the Commercialization Plan shall require the mutual written agreement of the Parties.

f. **Training**. Novos shall be responsible for conducting the Product sales and policy training program specified in Section 3.4 according to the policies and procedures of Evoke.

g. **Cross-Border Transactions**. Novos shall inform Evoke of any cross-border transactions with respect to the Product that come to the attention of Novos and shall not engage in any activities to facilitate or support such cross-border transactions.

h. **Performance Concerns**. At the request of Evoke, the Alliance Managers shall discuss in good faith any concerns that Evoke may have regarding the performance of the Sales Force hereunder.

3.3. **Field Observations and Sales Meetings**.

a. Upon Evoke's request, Novos shall conduct a reasonable number of field observations (which field observations Evoke may also attend in its sole discretion) with the Sales Force representatives during normal business hours to evaluate overall quality assurance of the Detailing of the Product by the Sales Force. If any such observations indicate that the compliant message is not being delivered or received with respect to the Product, Novos shall report such observations to Evoke, and the Alliance Managers shall discuss what, if any, corrective plan of action is required to address any failure by the Sales Force representatives; provided that Evoke shall have the sole authority to determine whether to change the content of the Promotional Materials or messages being delivered with respect to the Product during Details.

b. At any sales meetings during which the Product is discussed, Novos shall have a reasonable number of Novos personnel with responsibilities for the Product attend such sales meetings (which meetings Evoke may also attend in its sole discretion) and, if necessary, communicate critical Product-related information at such meetings.

3.4. **Training Program and Materials**. Novos shall train the members of the Sales Force, prior to such member performing any Commercialization activities, with respect to: (i) disease entity; (ii) Product knowledge; (iii) competitive product knowledge; (iv) compliance with Applicable Law in accordance with the Sales & Promotion Policies and the Compliance Provisions; (v) reporting of Adverse Events, Field Alerts, Product Quality Complaints, Manufacturing Information Requests, and Other Reportable Information in accordance with the terms hereof; (vi) use of Promotional Materials; and (vii) such other information the JGC deems necessary or appropriate (collectively, the "**Sales Force Training Matters**"). Once approved by the JGC, Novos shall not change any initial Sales Force Training Matters in any way and Novos shall not use any training materials in connection with the Product other than the initial Sales Force Training Matters.

3.5. **Minimum Requirements**. Novos shall verify that each Sales Force Representative has satisfactorily completing the initial training specified in Section 3.4, has completed a series of role-playing scenarios of a Detail of the Product to the reasonable satisfaction of Novos, and shall verify on an annual basis that each Sales Force Representative maintains any applicable licenses.

3.6. **Promotional Materials**. Novos shall be responsible managing and supervising the Sales Forces' promotion of the Product in the Territory in accordance with the Commercialization Plan, including without limitation, designing and producing promotional, marketing and educational materials (in any form or medium), such as printed brochures, videos, and other materials for use by Sales Force representatives, distributors or medical providers or in advertisements or web sites ("**Promotional Materials**"). Notwithstanding the foregoing, Evoke shall retain final approval rights over the Promotional Materials, which approval rights shall not be unreasonably withheld, and final responsibility for the compliance of, and for monitoring for compliance of, all Commercialization activities and the Sales Force with Applicable Law. Novos shall provide Evoke with copies of all Promotional Materials in a timely manner to pursue regulatory review where appropriate. No Promotional Materials will be distributed without prior written consent by Evoke.

3.7. **Sales Reports**. Within fifteen days after the end of each calendar month, Novos shall deliver to Evoke a report setting forth the total prescriptions during such calendar month broken out by Sales Force representative and territory. Novos shall provide such report to Evoke in an Excel spreadsheet to the extent reasonably possible.

3.8. **Trademarks and Copyrights.**

a. Evoke hereby grants to Novos a non-exclusive, royalty free and limited license (without the right to grant sublicenses) to use the Product Trademarks, Corporate Trademarks and Product Copyrights as contained in the applicable Promotional Materials or other material provided hereunder or otherwise authorized or approved by Evoke solely as contained in such Promotional Materials or other material and solely for purposes of Novos performing the Services, which license shall terminate immediately upon the expiration or earlier termination of this Agreement for any reason. Novos acknowledges and agrees that, as between the Parties, Evoke owns all rights, title and interest in and to the Product Trademarks, Corporate Trademarks and the Product

Copyrights, including any form or embodiment thereof and the goodwill now and hereafter associated therewith and that all use of the Product Trademarks, Corporate Trademarks and the Product Copyrights by or on behalf of Novos shall inure to the benefit of Evoke and its Affiliates. Novos shall not make any use of the Product Trademarks, Corporate Trademarks or the Product Copyrights, separate and apart from the Promotional Materials or other materials provided to Novos by Evoke under this Agreement.

b. Novos shall not use, seek to register or register, nor permit any of its Affiliates to use, seek to register or register, any trademark, service mark, name or logo, including as part of any domain name, social media handle or other identifiers, which is confusingly similar to, or a colorable imitation of, the Product Trademarks, Corporate Trademarks or Product Copyrights in any jurisdiction worldwide. Novos shall not challenge, nor permit any of its Affiliates to challenge, Evoke's or its Affiliates' rights in, or the validity, enforceability, scope, or registrability of, any of the Product Trademarks, Corporate Trademarks or Product Copyrights or any registration or application therefor.

4. MANAGEMENT OF THE COLLABORATION

4.1. **Joint Governance Committee**. The Parties shall establish a committee (the "**Joint Governance Committee**" or "**JGC**") as more fully described in this Section 4. The JGC shall have review, oversight, and decision-making responsibilities for all Commercialization activities performed under this Agreement. Each Party agrees to keep the JGC informed of its progress and activities under this Agreement.

4.2. **Membership**. The JGC shall be comprised of three (3) representatives (or such other number of representatives as the Parties may agree) from each of Evoke and Novos. Each Party shall provide the other with a list of its initial members of the JGC no later than thirty (30) days prior to the first scheduled meeting of the JGC, which shall be no later than sixty (60) days after the Effective Date. Each Party may replace any or all of its representatives on the JGC at any time upon written notice to the other Party in accordance with Section 15. Each representative of a Party shall have relevant expertise in pharmaceutical drug product Commercialization, and be suitable in seniority and experience and have been delegated the authority to make decisions on behalf of the applicable Party with respect to matters within the scope of the JGC's responsibilities. Any member of the JGC may designate a substitute to attend and perform the functions of that member at any meeting of the JGC. Each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend meetings of the JGC as non-voting participants, subject to the confidentiality obligations of Section 11. Evoke shall designate a chairperson to oversee the operation of the JGC.

4.3. **Responsibilities**. The JGC shall perform the following functions, subject to the final decision-making authority of the respective Parties as set forth in Section 4.4:

a. review and approve the following: (i) the Commercialization Plan, the Commercialization Budget or recommend amendments or revisions thereto, (ii) pricing and reimbursement, (iii) payer contracting, and (iv) Sales Forces expansion or reduction;

b. review and approve the Sales Force Training Matters;

c. review and monitor Novos' training activities with respect to the Sales Force;

d. review and approve the compensation for the Sales Force;

e. review and monitor Novos' performance of the Services under the Agreement;

f. serve as an information transfer vehicle, from time to time, to facilitate discussions regarding the Commercialization of the Product;

g. review, and provide a forum for the Parties to discuss and approve or not approve, any subcontractors through which Novos intends to conduct any Services hereunder;

h. resolve disputes between the Parties with respect to Commercialization of the Product;

i. such other responsibilities as may be assigned to the JGC pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

4.4. **Decisions**. Except as otherwise provided herein, with respect to Commercialization of the Product, all decisions of the JGC shall be made by consensus, with each Party having one vote. If the JGC cannot agree on a matter within its authority hereunder within thirty (30) days after it has met and attempted to reach such decision, then, either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution. The Parties' respective Executive Officers shall meet within fifteen (15) days after such matter is referred to them, and shall negotiate in good faith to resolve the matter. If the Executive Officers are unable to resolve the matter within thirty (30) days after the matter is referred to them, then the issue shall be finally resolved by Evoke. Notwithstanding the foregoing or any other provision of this Agreement, Novos is not advising Evoke on legal and regulatory matters and Evoke shall make its own independent evaluation of such matters and proceed at its own risk with respect to the legal and regulatory compliance of the Commercialization of the Product.

5. Fees and Payments

5.1. **Service Fee.** In consideration of the performance of the Services by Novos, Evoke shall pay Novos a commercial services fee ("**Service Fee**") of [***] of the Contribution Profit.

5.2. **Manner of Payment**. The Service Fee and Novos Commercialization Costs payments shall be paid by wire transfer to a bank account designated by Novos on a [***] basis, with such payment being made for the prior [***] no later than [***] after the end of such prior [***] in which such Net Sales payments or Novos Commercialization Costs invoice were actually received by Evoke. The Parties shall true up the amount of the Service Fees within [***] from the end of each [***] based on any adjustments to the Contribution Profit subject to any Service Fees previously paid by Evoke, which shall result in a payment to Novos at the time thereof or a credit being issued to Evoke.

5.3. **Taxes**. The amounts payable by a Party to the other Party pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 5.3, the receiving Party shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The paying

Party shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if the receiving Party is entitled under any applicable tax treaty to a rate reduction of, or the elimination of, applicable withholding tax, it may deliver to the paying Party or the appropriate Governmental Authority (with the assistance of the paying Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the paying Party of its obligation to withhold such tax and the paying Party shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that the paying Party has received evidence, in a form satisfactory to the paying Party, of the receiving Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the Payments are due. If, in accordance with the foregoing, the paying Party withholds any amount, it shall pay to the receiving Party the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to the receiving Party proof of such payment within ten (10) days following such payment.

5.4. **Line of Credit.** Following NDA Approval of the Product and up to nine months thereafter, upon three (3) months prior written notice by Evoke, in the event that Evoke is unable to secure Channel Management Financing from any vendor or strategic partner pursuant to reasonably standard terms, Novos shall either finance or obtain third party financing sufficient to make available to Evoke up to Five Million U.S. Dollars ($5,000,000) in cash in Two Million Five Hundred Thousand U.S. Dollars ($2,500,000) increments (the total amount borrowed, the "**Principal**") pursuant to a credit agreement to be negotiated in good faith by the Parties (the "**Credit Agreement**"). "**Channel Management Financing**" shall mean funds advanced to Evoke for the purchase of quantities of Products for potential sale into distribution channels by a vendor or strategic partner in excess of [***]. The Credit Agreement shall include terms such that for each Two Million Five Hundred Thousand U.S. Dollars ($2,500,000) increment that Evoke elects to borrow, in lieu of interest for the borrowing thereof Novos shall be entitled to receive an additional [***] of Net Sales included in the Service Fee (the "**Credit Fee**"). The Credit Fee shall be a financing fee and shall not reduce the Principal. Evoke must repay the amount of the Principal to Novos on the earlier of: (i) thirty (30) days following the date that the cumulative Credit Fee reaches twice the amount of the Principal, but shall not be paid before the date thereof except as otherwise expressly permitted herein; and (ii) the two (2) year anniversary of the date the Principal is borrowed by Evoke. In no event shall the cumulative Credit Fee paid by Evoke exceed twice the amount of the Principal.

5.5. **Working Capital**. In order to provide Evoke with month-by-month working capital, Novos shall finance or obtain third party financing sufficient to finance the amount by which the projected monthly Contribution Profit is expected to fall (or does actually fall) below zero (as projected by Product sales forecasts and the Commercialization Budget for that month), such amount (the "**Working Capital Loan**") pursuant to a credit agreement to be negotiated in good faith by the Parties (the "**Working Capital Agreement**"). The Working Capital Loan shall be drawn down by Evoke on a monthly basis as needed to cover the amount by which the Contribution Profit falls below zero. Evoke shall pay interest on the Working Capital Loan in an amount mutually agreed to by the Parties. The Working Capital Loan will be repaid to Novos, if at all, only out of the positive Contribution Profit. If Novos elects to terminate this Agreement for any reason other than for a material breach of this Agreement by Evoke pursuant to Section 14.2.b, any amounts of Working Capital Loan and any interest due thereon then due under the Working Capital Agreement shall be and hereby are forgiven in full. If Evoke elects to terminates this Agreement

due to the gross negligence or intentional misconduct of Novos, any such amounts then due under the Working Capital Agreement shall be and hereby are forgiven in full. If Novos terminates this Agreement for the material breach of this Agreement by Evoke or if Evoke terminates this Agreement other than due to the gross negligence or intentional misconduct of Novos, any amounts then due under the Working Capital Agreement shall remain due and payable by Evoke pursuant to the Working Capital Agreement.

6. REGULATORY MATTERS

6.1. **Ownership of Regulatory Documentation and Approvals**. As between the Parties, Evoke shall own all right, title and interest in and to (a) all Regulatory Documentation concerning the Product and all information contained therein and (b) all regulatory approvals made or granted with respect to the Product, including any NDA Approval.

6.2. **Responsibility for Regulatory Approvals and Regulatory Communications**.

a. As between the Parties, Evoke shall have the sole right and responsibility for any regulatory approvals and regulatory compliance with respect to the Product.

b. As between the Parties, Evoke shall have the sole right (i) to make any communications, reports, submissions and responses to FDA concerning the Product, including by reporting Adverse Events, Other Reportable Information and Field Alerts and (ii) to take any action (including any investigations) and conduct all communications with all Third Parties that relate to all Product Quality Complaints or complaints related to tampering or contamination with respect to the Product, Adverse Events, Other Reportable Information and Field Alerts with respect to the Product; provided, however, that Novos shall be responsible for any communications, reports, submissions or responses to Regulatory Authorities that it may be required to make under Applicable Law in connection with performing its activities hereunder; and provided, further that Novos shall, to the extent permitted by Applicable Law and as requested by Evoke, provide Evoke with either (x) reasonable advance written notice of, and an opportunity to discuss in good faith, any proposed communication with FDA in advance thereof with respect to the Product or any activities of Evoke hereunder or (y) otherwise provide written notice to Evoke of any communication with FDA concerning the Product or any activities of Evoke hereunder promptly following such communication and attach copies of such communication (whether by FDA or Novos) to such notice.

c. Novos shall cooperate with all of Evoke's reasonable requests and assist Evoke in connection with Evoke: (i) preparing any and all reports to FDA concerning the Product; (ii) preparing and disseminating all communications to Third Parties concerning the Product; and (iii) investigating and responding to any Product Quality Complaint, Adverse Event, Other Reportable Information, Field Alert, or other compliance inquiry or investigation related to the Product.

d. Except to the extent required by Applicable Law, Novos shall not (i) make any statements, whether written or oral, to a Third Party regarding a Product Quality Complaint, Adverse Event, Other Reportable Information, Field Alert, or other compliance inquiry or investigation with respect to the Product other than to inform the Third Party that information in respect thereof has been or will be conveyed by Novos to Evoke or (ii) take any action concerning any Regulatory Authority approval under which the Product is sold.

6.3. **Adverse Events, Other Reports and Threatened Governmental Authority Action**.

a. Novos shall report to Evoke and the JGC within twenty-four (24) hours from the time it becomes aware of:

i. an Adverse Event or Other Reportable Information associated with the use of the Product or information in or coming into its possession or control concerning such Adverse Event or Other Reportable Information;

ii. information that might necessitate the filing by Evoke of a Field Alert; or

iii. any Product Quality Complaint associated with the use of the Product.

b. Without limitation of Section 6.3a, with respect to Adverse Events, Other Reportable Information, Field Alerts and Product Quality Complaints, in each case with respect to the Product, Novos shall (i) train and inform members of the Sales Force in accordance with Evoke's policies and procedures, and require any Novos employee who has performed or is performing any Commercialization activity, to comply with Applicable Law in connection with collection of information regarding the foregoing, and the reporting of such information; and (ii) except for the monitoring of the Sales Force (via ride alongs and other commercially reasonable programs) for compliance with Applicable Law, which shall be the sole responsibility of Evoke, establish and actively supervise and manage procedures and protocols reasonably designed to ensure that all relevant information relating to the foregoing that comes to the attention of Novos, with respect to any member of the Sales Force or any Novos employee who has performed or is performing any Commercialization activity, is promptly conveyed to Novos so that Novos can comply with its reporting obligations hereunder. For the avoidance of doubt, Novos shall only be responsible for training, informing, managing, and supervising members of the Sales Force in accordance with the policies and procedures of Evoke, and Novos shall not be responsible for any member of the Sales Force's failure to comply with the policies and procedures of Evoke or Applicable Law but Novos shall notify Evoke of any such failure that comes to the attention of Novos, the risk of which shall be allocated under Evoke's agreement with a third party commercial sales organization.

c. Evoke may, at its option, establish procedures for members of the Sales Force to provide such information referenced in Section 6.3a or Section 6.3b directly to Evoke or its designee, which may be established or modified by Evoke from time to time by written notice to Novos.

d. Novos shall promptly notify Evoke if it receives information regarding any threatened or pending action regarding the Product by any Governmental Authority in the Territory.

7. PRODUCT MATTERS

7.1. **Orders for Product; Terms of Sale; Returns**. Evoke shall have the sole responsibility and right to take, accept, reject or cancel orders, fill orders and establish and modify the terms and conditions of the sale of the Product (including with regard to any patient assistance programs and returns). All sales will be recorded in Evoke's name.

7.2. **Returned Product**. Evoke shall have the sole responsibility and right to accept returned Product. Novos shall not solicit the return of any Product, but if for any reason Novos should

receive any returned Product, Novos shall promptly notify Evoke. Novos shall return to Evoke any Product returned to Novos and fully complete and deliver to Evoke the applicable returned goods form provided by Evoke. At Evoke's request, Novos will cooperate with Evoke regarding Evoke's handling of any returned Product; provided, however, that Novos shall have no obligation to test, evaluate, process, repair, or replace any returned Product.

7.3. **Recalled Product**. Each Party shall promptly notify the other Party in writing of any facts relating to the advisability of the recall, destruction or withholding from the market of the Product in the Territory. Evoke shall have the sole responsibility and right to determine if any recall, withdrawal or other form of market action is necessary with respect to the Product and shall be solely responsible for taking all actions to effect such recall, withdrawal or market action. At Evoke's request, Novos will cooperate with Evoke regarding Evoke's handling of any recalls, withdrawals or market actions; provided, however, that Novos shall have no obligation to evaluate, determine, or conduct any such recalls, withdrawals, or market actions.

8. COMPLIANCE MATTERS

8.1. **Compliance with Laws and Policies**.

a. Novos shall be legally responsible and liable for the actions, omissions and conduct of its employees performing the Services, including any breach of any Anti-Corruption Laws. Novos shall train the Sales Force's compliance with Applicable Law in accordance with Evoke's policies and procedures and the Sales & Promotion Policies and promptly inform Evoke of any noncompliance by such Sale Force that comes to the attention of Novos provided that Novos shall have no responsibility to monitor for or ensure any such compliance by the Sales Force, which shall be handled directly by Evoke. Novos shall notify Evoke in writing promptly if any Third Party (including any Governmental Authority) notifies Novos in writing that either Party's Commercialization activities with respect to the Product are not in compliance with Applicable Law.

b. Without limiting Section 8.1a, Evoke shall create and maintain a Sales Force compliance program that includes: (i) Evoke compliance monitoring focused on specific risk areas (including off-label promotion, fraud and abuse and false claims) to assess whether Evoke's policies and procedures are being followed by the Sales Force; and (ii) a mechanism for the Sales Force to report, anonymously if they choose, any concerns including matters such as potential illegal activity with respect to the Sales Forces' Commercialization activities. Novos shall report to Evoke promptly, but in no event later than three (3) Business Days after becoming aware of any allegation or investigation (and before reporting any such activity to any Regulatory Authority) with respect to the alleged failure by a member of the Sales Force to comply with the requirements set forth in Section 8.1a or any reports provided pursuant to clause (ii) above and what action, if any, was taken by Novos as a result. Without limitation of the foregoing, Evoke shall investigate any reports provided pursuant to clause (ii) above and promptly report the results of such investigation to Novos.

c. Novos acknowledges and agrees that any direct or indirect payment or transfer of value, as defined in the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h(e)(10)) and its implementing regulations (42 C.F.R. § 403.900 et seq.), including any compensation, reimbursement for expenses, meals, travel, and medical journal reprints ("**Payments or Transfers of Value**") to any physician licensed to practice in the Territory or any teaching

hospital in the Territory (each, a "**Covered Recipient**") is subject to transparency reporting requirements, including disclosure on the federal Open Payments website. Novos shall implement Evoke's policies and procedures requiring the Sales Force not to contract with or make any Payment or Transfer of Value to a Covered Recipient on behalf of Evoke without Evoke's prior written approval, in Evoke's sole discretion. Novos shall comply with all reporting required by Applicable Law with respect to any Payments or Transfers of Value provided by the Sales Force to Covered Recipients in connection with this Agreement that come to the attention of Novos. Novos shall also provide Evoke with any and all information about Payments or Transfers of Value the Sales Force provides to Covered Recipients that come to the attention of Novos in connection with this Agreement to the extent required to enable Evoke to comply with its transparency obligations under Applicable Law. All Payments or Transfers of Value made by the Sales Force to Covered Recipients in connection with this Agreement shall be made according to a centrally managed, pre-set rate structure based on a fair market value analysis. Novos shall provide to Evoke detailed expenditure information in a manner that conforms to industry standards, and Novos shall maintain such documentation for a minimum of five (5) years.

8.2. **Obligation to Notify**. Novos shall promptly notify Evoke upon becoming aware of any breach or violation by the Sales Force of the Anti-Corruption Laws and shall take such steps as the Parties may reasonably agree to avoid a potential violation of the Anti-Corruption Laws.

9. INDEPENDENT CONTRACTOR

9.1. **Independent Contractor Status**. The status of each Party under this Agreement shall be that of an independent contractor. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any Person that it has any such right or authority.

10. STATEMENTS, RECORD-KEEPING AND AUDITS

10.1. **Evoke Statement of Fees.** All payments made to Novos under this Agreement shall be accompanied by a written statement detailing the Service Fees paid, including the calculation thereof based on Net Sales.

10.2. **Evoke Records of Sales**. Evoke shall keep accurate and sufficient records, in accordance with generally-accepted accounting procedures (GAAP) in the relevant jurisdiction, of Net Sales and other financial information to determine any payment of any Service Fees to be made to Novos under this Agreement.

10.3. **Audits of Evoke**. At the request of Novos, Evoke shall, and shall cause its Affiliates to, permit an independent auditor designated by Novos, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 10.2 to ensure the accuracy of all reports and payments made hereunder, no more than once during any twelve (12)-consecutive month period during the Term and a period of twenty four (24) months thereafter and no more than once with respect to any period so examined; provided that if any such audit reveals that Evoke is or was not in material compliance with Applicable Law or this Agreement, Novos shall have the right to conduct such additional audits as may be reasonably required by Novos to determine whether Evoke has appropriately remedied such non-compliance. The cost of any such audit shall be borne by Novos, unless the audit uncovers an underpayment by Evoke that

exceeds the greater of [***] and [***] of the total owed for the period in question, Novos shall reimburse Evoke for any third party costs reasonably incurred in connection with the audit. If any such audit concludes that additional payments were owed or that excess payments were received during such period, the owing Party shall pay the additional payments or the receiving Party shall reimburse such excess payments within sixty (60) days after the date on which such audit is completed.

10.4. **Novos Records**.

a. Novos shall keep, or shall cause to be kept, complete and accurate books and records (financial and otherwise) pertaining to the performance of the Commercialization activates, including monthly sales data by Sales Force representative and territory, records of Detail performance, training test results and copies of training tests as specified in Section 3.4, in sufficient detail to verify compliance with its obligations hereunder and to calculate and verify all amounts payable hereunder. Novos shall keep such books and records, or shall cause such books and records to be kept, for a period of three (3) years after the expiration or termination hereof or such longer period as required by Applicable Law. All financial books and records kept by Novos hereunder shall be maintained in accordance with generally accepted accounting principles of the United States, consistently applied.

b. Without limitation of the foregoing, Novos shall keep, or cause to be kept, complete and accurate books and records relating to its obligations under this Agreement, including Novos's compliance with Applicable Law, the Sales & Promotion Policies and the Compliance Provisions, including with respect to: (i) Evoke's policies and procedures concerning compliance with Applicable Law, the Sales & Promotion Policies and the other compliance obligations set forth herein; (ii) records of any investigations and remedial and disciplinary actions taken to address violations of any of the foregoing; and (iii) records of any payments made in connection with this Agreement (collectively, the "**Compliance Records**"). Such books and records shall be kept for a period of ten (10) years after the expiration or termination hereof or such longer period as required by Applicable Law.

10.5. **Audits of Novos**. At the request of Evoke, Novos shall, and shall cause its Affiliates to, permit an independent auditor designated by Evoke, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 10.4 to ensure Novos' compliance with this Agreement, including the accuracy of all reports and payments and Marketing Expenses made hereunder, no more than once during any twelve (12)-consecutive month period during the Term and a period of twenty four (24) months thereafter and no more than once with respect to any period so examined; provided that if any such audit reveals that Novos is or was not in material compliance with Applicable Law, the Sales & Promotion Policies or the Compliance Provisions with respect to its obligations under this Agreement, Evoke shall have the right to conduct such additional audits as may be reasonably required by Evoke to determine whether Novos has appropriately remedied such non-compliance. The cost of any such audit shall be borne by Evoke, unless (a) with respect to an audit of payments made hereunder, the audit reveals that Evoke has overpaid by more than [***] or (b) with respect to an audit of the Compliance Records, such audit reveals noncompliance by Novos with Applicable Law, the Sales & Promotion Policies or the Compliance Provisions with respect to its obligations under this Agreement, in which case ((a) or (b)), Novos shall reimburse Evoke for any third party costs reasonably incurred in connection with the audit. If any such audit concludes that additional payments were owed or that excess payments were received during

such period, the owing Party shall pay the additional payments or the receiving Party shall reimburse such excess payments within sixty (60) days after the date on which such audit is completed.

11. CONFIDENTIALITY

11.1. **Maintaining Confidentiality.** Confidential Information disclosed under this Agreement shall remain the property of the disclosing Party. At all times during the Term and for five (5) years following the expiration or termination of this Agreement, the receiving Party shall use the Confidential Information solely for the purposes set forth in this Agreement and shall not disclose such Confidential Information to any Third Party except as permitted under this Agreement or with the disclosing Party's prior written consent. The receiving Party shall use at least the same care for maintaining confidentiality of the Confidential Information as it uses to maintain the confidentiality of its own Confidential Information of similar value, but in no event less than commercially reasonable measures within the pharmaceutical industry.

11.2. **Exceptions to Confidentiality**. The receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party:

a. that the receiving Party can demonstrate by reasonable evidence was in the receiving Party's possession and at its free disposal prior to disclosure by the disclosing Party;

b. that was in the public domain at the time of disclosure by the disclosing Party;

c. that subsequently comes into the public domain through no fault, action or omission of the receiving Party;

d. that becomes available to receiving Party without any obligation of confidentiality from a Third Party that is not known to have a confidentiality obligation to the disclosing Party; or

e. that the receiving Party can demonstrate by reasonable evidence was developed independently by the receiving Party without use of or reliance on any Confidential Information of the other Party.

11.3. **Authorized Disclosure**. Each Party may disclose Confidential Information to the extent that such disclosure is:

a. to its directors, officers, employees, advisers, consultants, attorneys, auditors, agents, contractors, or representatives that reasonably need to know the information for the purposes set out in this Agreement, and who are subject to confidentiality substantially as protective as those set forth in this Agreement;

b. to its Affiliates, including their directors, officers, employees, advisors, consultants, agents, contractors or representatives, to the extent they reasonably need to know the information for the purposes set out in this Agreement, and who are subject to confidentiality obligations substantially as protective as those set forth in this Agreement;

c. to its legal counsels or auditors to conduct internal check, assessment or auditing who need to know the Confidential Information for the purpose of a Party's internal check, assessment or auditing; or

d. as required by laws, rules of public stock exchanges or court orders, provided that the receiving Party may disclose only such information as is legally required, and provided further that the receiving Party shall provide the disclosing Party with as much advance written notice of such requirement as is reasonably possible and a reasonable opportunity to object to or limit such disclosure. Notwithstanding the foregoing, if either Party determines a disclosure of the terms of this Agreement and/or their ancillary documents is required by law or court order, it shall notify the other Party in writing at least ten (10) Business Days before the time of the proposed disclosure, to the extent reasonably possible.

11.4. **Return or Destruction of Confidential Information**. Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information (i) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (ii) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 11.1.

11.5. **Use of Name and Disclosure of Terms**. Except as necessary to perform a Party's obligations under this Agreement, each Party (a) shall keep the existence, terms, and the subject matter (including the applicable transactions) covered by this Agreement confidential and shall not disclose such information to any other Person through a press release or otherwise and (b) shall not mention or otherwise use the name or any trademark of the other Party or its Affiliates in connection with this Agreement, in each case ((a) and (b)), without the prior written consent of the other Party in each instance (which shall not be unreasonably withheld, conditioned or delayed). The restrictions imposed by this Section 11.5 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law or the requirements of a national securities exchange or another similar regulatory body, provided that any such disclosure shall be governed by Section 11.3. Nor shall the restrictions imposed by this Section 11.5 prohibit either Party from announcing this Agreement to the public promptly following the Effective Date, including such key terms and other items appropriate for such a public release, in each case subject to the written consent of the other Party, which shall not be unreasonably withheld. Further, the restrictions imposed on each Party under this Section 11.5 are not intended, and shall not be construed, to prohibit a Party from (x) identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Article 11 or (y) disclosing (i) information for which consent has previously been obtained and (ii) information of a similar nature to that which has been previously disclosed publicly with respect to this Agreement, each of which ((i) and (ii)) shall not require advance approval, but copies of which shall be provided to the other Party as soon as practicable after the release or communication thereof.

12. REPRESENTATIONS AND WARRANTIES

12.1. **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that as of the Effective Date:

a. it is an independent legal entity duly organized, validly existing in good standing under the laws of the place of its establishment or incorporation;

b. it has full authority to enter into this Agreement and to perform its obligations under this Agreement;

c. it has authorized its representative to sign this Agreement, and the provisions of this Agreement are legally binding upon it from the Effective Date;

d. its execution of this Agreement and performance of its obligations under it will not violate (i) any provision of its business license, articles of incorporation, articles of association or similar organizational documents; (ii) any Applicable Laws or any governmental authorization or approval; and (iii) any contract to which it is a party or to which it is subject, or result in a default under any such contract;

e. no lawsuit, arbitration or other legal or governmental proceeding is pending or, to its knowledge, threatened against it that would affect its ability to perform its obligations under this Agreement; and

f. it has disclosed to the other Party all documents issued by any Governmental Authority that may have a material adverse effect on its ability to fully perform its obligations under this Agreement, and none of the documents it has previously provided to the other Party contain any misstatements or omissions of material facts.

12.2. **Evoke's Representations and Warranties**. Evoke represents and warrants that as of the Effective Date and within the Term of this Agreement:

a. Evoke has the right to enter into this Agreement; and

b. as at the Effective Date, Evoke is not aware of any claim alleging that the manufacture, packaging, distribution, sale or use of the Product in the Territory, or that the use of any registered trademark or registered copyright within the Product Trademarks, Corporate Trademarks or Product Copyrights infringes or misappropriates the Intellectual Property Rights or other rights of any Third Party, and to the knowledge of Evoke, the manufacture, packaging, distribution, sale or use of the Product in the Territory and the use of any registered Trademark or registered Copyright within the Product Trademarks, Corporate Trademarks or Product Copyrights in the Territory does not infringe or misappropriate the Intellectual Property Rights or other rights of any Third Party.

12.3. **Representations, Warranties and Covenants of Novos**.

a. Novos represents, warrants and covenants to Evoke that it has not been debarred and is not subject to debarment and that it shall not knowingly use in any capacity, in connection with the Services, any Person who has been debarred pursuant to Section 306 of the Act or who is the subject of a conviction described in such section.

b. Novos represents and warrants to Evoke that (i) it and its Affiliates are in compliance with (A) the PhRMA Code on Interactions with Healthcare Professionals and (B) all state codes or requirements that limit or regulate interactions with healthcare practitioners and (ii) Novos has not been excluded from any federal health care program, including Medicare, Medicaid and the Civilian Health and Medical Program of the Uniformed Services. If Novos or any employee of Novos involved in performing the Services is excluded during the Term or Novos reasonably believes exclusion is contemplated, Novos shall immediately notify Evoke in writing upon Novos becoming aware of such exclusion. If Novos is so excluded, or in the case of any employee who is excluded, if Novos permits such employee to continue to perform any Services, then Evoke shall have the right to terminate this Agreement upon written notice to Novos. Any termination of this Agreement pursuant to this Section 12.3b shall be treated as a termination pursuant to Section 14.2.b as if Novos had committed a material breach, except that in such event no cure period shall apply and Evoke shall have the right to effect such termination immediately upon written notice to Novos, in its sole discretion.

c. Novos represents and warrants to Evoke that (i) it has adequate cash flow and otherwise has the financial resources, capacity and capabilities to timely and adequately perform its obligations hereunder, (ii) it has not initiated a voluntary proceeding under any applicable bankruptcy code, and (iii) there is no involuntary proceeding under any applicable bankruptcy code pending against Novos. In addition, Novos represents and warrants that it will continue to be able to run its business as a going concern over the nine (9) month period beginning on the Effective Date. If on any date hereafter Novos has reason to believe that it will not continue to be able to run its business as a going concern over any nine (9) month period during the Term, then Novos shall notify Evoke in writing within two (2) days thereafter.

12.4. **DISCLAIMER OF WARRANTIES**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

13. INDEMNIFICATION, LIMITATION OF LIABILITY AND INSURANCE

13.1. **Evoke Indemnity**. Subject to the procedures set forth in Section 13.3, in addition to any other remedy available to Novos, Evoke shall indemnify, hold harmless and defend Novos, its Affiliates, and their respective directors, officers, employees, representatives and agents (the "**Novos Indemnitees**") from and against any and all losses, damages, liabilities, judgments, fines, and amounts paid in settlement, including any associated costs and expenses (including reasonable attorneys' fees) ("**Losses**"), which result directly or indirectly from any claim, demand, suit, action or proceeding brought or initiated by a Third Party against them ("**Claims**") to the extent that such Claims arise out of (i) the manufacture, packaging, sale or use of the Product, including any death or personal injury arising out of the defective manufacture of the Product by or on behalf of Evoke; (ii) any infringement of the Intellectual Property Rights of a Third Party by the Product; or (iii) the gross negligence, fraud or willful misconduct of any of the Evoke Indemnities in performing any obligations under this Agreement; provided, however, that Evoke shall not be required to indemnify, hold harmless or defend any Novos Indemnitee against any claim to the extent that Novos has an obligation to indemnify an Evoke Indemnitee under Section 13.2.

13.2. **Novos Indemnity**. Subject to the procedures set forth in Section 13.3, in addition to any other remedy available to Evoke, Novos shall indemnify, hold harmless and defend the Evoke, its Affiliates, and their respective directors, officers, employees, representatives and agents (the "**Evoke Indemnitees**") from and against any Losses, which result directly or indirectly from any Claims to the extent that such Claims arise out of the gross negligence, fraud or willful misconduct by Novos in connection with this Agreement; provided, however, that Novos shall not be required to indemnify, hold harmless or defend any Evoke Indemnitee against any claim to the extent that Evoke has an obligation to indemnify a Novos Indemnitee under Section 13.1.

13.3. **Procedures**. Any indemnified party submitting an indemnity claim under this Section 13, as applicable ("**Indemnified Party**"), shall: (a) promptly notify the indemnifying Party ("**Indemnifying Party**"), of such claim in writing and furnish the Indemnifying Party with a copy of the applicable communication, notice or other action relating to the event for which indemnity is sought; provided that, no failure to provide such notice pursuant to this clause (a) shall relieve the Indemnifying Party of its indemnification obligations, except to the extent such failure materially prejudices the Indemnifying Party's ability to defend or settle the claim; (b) give the Indemnifying Party the authority, information and assistance necessary to defend or settle such suit or proceeding in such a manner as the Indemnifying Party shall determine; and (c) give the Indemnifying Party sole control of the defense (including the right to select counsel, at the Indemnifying Party's expense) and the sole right to compromise and settle such suit or proceeding; provided, however, that in the case of the foregoing clauses (b) and (c), the Indemnifying Party shall not, without the written consent of the Indemnified Party, compromise or settle any suit or proceeding unless such compromise or settlement (i) is solely for monetary damages (for which the Indemnifying Party shall be responsible), (ii) does not impose injunctive or other equitable relief against the Indemnified Party and (iii) includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding. The Indemnified Party (in its capacity as such) may participate in the defense at its own expense.

13.4. **Limitation of Liability**. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND EXCEPT AS A RESULT OF NEGLIGENCE, COMMON LAW FRAUD OR WILLFUL MISCONDUCT, A BREACH OF ARTICLE 11 OR SECTION 2.2 OR IN CONNECTION WITH A PARTY'S INDEMNIFICATION OBLIGATIONS, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER OR THEIR AFFILIATES, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, AND OTHER THAN EVOKE'S PAYMENT OBLIGATIONS HEREUNDER: (i) FOR LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (IN EACH CASE, WHETHER OR NOT FORESEEABLE AT THE EFFECTIVE DATE), OR (ii) FOR ANY DAMAGES CALCULATED BY REFERENCE TO A MULTIPLIER OF REVENUE, PROFITS, OR SIMILAR METHODOLOGY, CONNECTED WITH OR RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION WITH, OR RELATED HERETO, INCLUDING ANY SUCH DAMAGES WHICH ARE BASED UPON BREACH OF CONTRACT, TORT, BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY.

13.5. **Insurance.** Each Party shall at all times maintain insurance policies or self-insurance in such amounts and with such scope of coverage as are normal and customary in the pharmaceutical industry for a Person of comparable size and engaged in activities comparable to the activities in which such Party engages hereunder. If requested by the other Party, the insured Party shall furnish a certificate of insurance or other reasonable proof of coverage (which may be a

certificate or other evidence issued by a Party under a program of self-insurance) evidencing the requisite coverage required under this Section 13.5 during the Term. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement for a period of five (5) years.

14. TERM AND TERMINATION

14.1. **Term.** The Agreement shall take into effect as of the date of execution of both Parties and shall remain in effect for a term of five years from the date of the Commercial Launch unless earlier terminated as provided hereunder (the "**Term**").

14.2. **Termination**. This Agreement may be terminated as follows:

a. **Termination for revenue shortfall**. After each anniversary date of the Commercial Launch, either Party shall be entitled to terminate the Agreement if cumulative Net Sales have not exceeded the amount set forth below in the twelve month period immediately preceding such anniversary date (the "**Minimum Net Revenue**" or "**MNR**") as long as such termination is exercised within thirty (30) days of such anniversary date:

[***]

b. **Termination upon material breach.** Either Party may terminate this Agreement if the other Party materially breaches this Agreement, and such breach, if curable, is not cured within sixty (60) days upon receipt from the other Party of written notice of the material breach.

c. **Termination for Insolvency**. Either Party may terminate this Agreement immediately on written notice if the other Party (or, if applicable, a parent of such other Party) shall file in any court or Governmental Authority, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the other Party or of its assets, or if the other Party (or, if applicable, a parent of such other Party) shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party (or, if applicable, a parent of such other Party) shall propose or be a party to any dissolution or liquidation, or if the other Party (or, if applicable, a parent of such other Party) shall make a general assignment for the benefit of its creditors.

d. **Termination by Evoke for Change of Control.** In the event of a Change of Control of Evoke, Evoke shall have the option to terminate the Agreement upon thirty (30) days' written notice and payment to Novos of a one-time payment determined by the date that such written notice is provided relative to the anniversary date of the Commercial Launch. More particularly, if such date is in:

i. Year 1 (within 12 months from the Commercial Launch): Evoke shall pay Novos the greater of:
   - [***] annualized Service Fees calculated based on the last three months of Service Fees, or

- $5M plus any Principal and any Working Capital Loan previously drawn and not paid down;

ii. Year 2: Evoke shall pay [***] annualized Service Fees calculated based on the last three months of Service Fees plus any Principal and any Working Capital Loan previously drawn and not paid down;

iii. Year 3: Evoke shall pay [***] annualized Service Fees calculated based on the last three months of Service Fees plus any Principal and Working Capital Loan previously drawn and not paid down; or

iv. Years 4 & 5: Evoke shall pay [***] annualized Service Fees calculated based on the last three months of Service Fees plus any Principal and Working Capital Loan previously drawn and not paid down.

e. Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party if: (i) the Product is subject to a recall based on material safety concerns for the Product, which shall not include any recall for packaging or labeling issues, manufacturing concerns, or the like; (iii) the Parties have been unable to agree on the initial Commercialization Plan and Commercialization Budget for the Product by February 28, 2019 despite negotiating in good faith; (iv) the product is not Commercially Launched within 9 months of FDA approval or (v) the overall Contribution Profit is negative for any calendar quarter (January through March, April through June, July through September, or October through December) beginning with the first full calendar quarter following 9 months after the Commercial Launch of the Product.

f. Novos can terminate this Agreement upon thirty (30) days written notice to Evoke if: (i) the Product is not approved for the treatment of gastroparesis (including diabetic gastroparesis) or gastric stasis by April 30th of 2019; (ii) Evoke withdraws the Product from the market in the Territory for a period of greater than one hundred eighty (180) days; or (iii) sample Products are not available for use by the Sales Force representatives on a timely basis following the finalization of the sample Product manufacturing methods and any regulatory approvals needed to manufacture sample Products and following the availability of sufficient manufacturing capacity to manufacture and validate the sample Products.

g. Evoke may terminate this agreement pursuant to Section 12.3(b).

14.3. **Effect of Termination**.

a. Upon the effective date of expiration or termination of this Agreement, Novos shall promptly cease all performance of the Services and promptly discontinue the use of any Commercialization Know-How, Product Trademarks, Product Copyrights, and Corporate Trademarks. At Evoke's election, Novos either shall (a) promptly return to Evoke or (b) destroy and certify to Evoke such destruction of, all Promotional Materials, training materials, and all other information related to the Product or the activities provided for by this Agreement.

b. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit any remedies that may otherwise be available in law or equity.

14.4. **Accrued Rights**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration, including, without limitation, Novos' rights to any amounts owed by Evoke hereunder or under the Credit Agreement. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

14.5. **Survival**. The rights and obligations of the Parties set forth in Section 1 (Definitions), Section 2.4 (Other Rights), Section 6.1 (Ownership of Regulatory Documentation and Approvals), Section 8.1.c (Novos Compliance with Laws and Policies), Section 10.3 (Audits of Evoke), Section 10.4 (Novos Records), Section 10.5 (Audits of Novos), Section 11 (Confidentiality), Section 13 (Indemnification, Limitation of Liability and Insurance), Section 14.5 (Survival), Section 15 (Notice), and Section 16 (General Provisions) shall survive the termination or expiration of this Agreement.

15. NOTICE

Any notice or written communication provided for in this Agreement by a Party to the other Party, including but not limited to any and all offers, writings, or notices to be given hereunder, shall be made by registered mail or by courier service delivered letter, promptly transmitted or addressed to the appropriate Party. The date of receipt of a notice or communication hereunder shall be the date of delivery confirmed by the USPS or the courier service in the case of a courier service delivered letter. All notices and communications shall be sent to the appropriate address set forth below, until the same is changed by notice given in writing to the other Party effective as above

Notice to Evoke: Dave Gonyer, CEO

Address: Evoke Pharma, Inc.
420 Stevens Ave, Ste 370
Solana Beach, CA 92075

Notice to Novos:

Address:

16. GENERAL PROVISIONS

16.1. **Force Majeure**. Except as otherwise set out in this Agreement, no Party to this Agreement shall have any liability whatsoever or (without prejudice to any payments of monies due) be deemed to be in default for any delays or failures in performance of any of its obligations under this Agreement to the extent such delay or failure is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority (including government shut down) or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical. The affected Party shall use all reasonable endeavors to remedy the event or limit the effects of the said event of force majeure upon the other Party in a timely manner. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the

terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution, including the extension of any Product approval date under Section 14.2(f). If any force majeure event continues for a period of at least ninety (90) days that would prevent the performance of any material obligation of or receipt of any material benefit (including, without limitation, payment) by a Party under this Agreement, the affected Party shall have the right to terminate this Agreement upon thirty (30) days written notice to the other Party.

16.2. **Governing Law**. This Agreement shall in all respects be governed by and interpreted according to the laws of New York and the United States without regard to or application of conflict-of-law rules or principles.

16.3. **Integrity.** This Agreement together with the Exhibits attached hereto constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all prior agreements, understandings and discussions, whether oral or written, of the Parties with respect to the subject matter hereof. Any modification of this Agreement shall be effective only when in writing and signed by the Parties.

16.4. **Assignability.** Neither Party may assign this Agreement without the consent of the other Party, except as otherwise provided in this Section 16.4. Either Party may assign this Agreement in whole or in part to any Affiliate of such Party without the consent of the other Party; provided that, such assigning Party provides the other Party with written notice of such assignment and the assignee agrees in writing to assume performance of all assigned obligations. Further, either Party may assign this Agreement, and all of its rights and obligations, without the consent of the other Party, to its successor in interest by way of merger, acquisition, or sale of all or substantially all of its business or assets; provided that, the assigning Party provides the other Party with written notice of such assignment within thirty (30) days after such assignment, merger, acquisition or sale and the assignee agrees in writing to assume performance of all assigned obligations.

16.5. **Severability**. If any provision contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, but this Agreement shall be construed by limiting such invalid, illegal or unenforceable provision, or if such is not possible, by deleting such invalid, illegal or unenforceable provision from this Agreement; provided that (i) such provision shall be deemed to be replaced by a provision which achieves the original intent of the Parties to the fullest extent possible; (ii) should this Agreement as a result of such deleting not any more reasonably correspond to the good faith intent of the Parties, either Party may propose amendments to the other provisions of this Agreement in order to have the Agreement correspond to such good faith intent and the Parties shall negotiate in good faith on such amendments.

16.6. **Waiver**. No course of dealing or failing of either Party to strictly enforce any term, right or condition of this Agreement in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. Such waiver or relinquishment (either generally or any given instance and either retroactively or prospectively) shall only be effective if made expressly in writing by the Party with reference to the specific term, right or condition.

16.7. **No Third Party Rights.** The provisions of this Agreement are for the sole benefit of the Parties, their successors and permitted assignees, and they shall not be construed as conferring any rights in any other Persons except as otherwise expressly provided in this Agreement.

16.8. **Headings**. The descriptive headings in this Agreement are for convenience only and shall not be interpreted so as to limit or affect in any way the meaning of the language in the pertaining article, section, paragraph or sub-paragraph.

16.9. **Costs and Expenses.** Each Party shall, unless specifically otherwise agreed hereunder, bear their own costs and expenses connected with such Party's activities and performance under this Agreement.

16.10. **Counterparts**. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[Intentionally left blank.]

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

Evoke: Evoke Pharma, Inc.

/s/ David A. Gonyer

Name: David A. Gonyer

Title: Chief Executive Officer

Novos: Novos Growth, LLC

/s/ Benjamin T. Bove

Name: Benjamin T. Bove

Title: Chief Executive Officer

[***]

Exhibit 10.2

First Amendment to the

Commercial Services Agreement

This First Amendment to the Commercial Services Agreement (the **"Amendment")** is made on February 28, 2019 (the **"Amendment Effective Date")** by and between Evoke Pharma, Inc., with a place of business at 420 Stevens Avenue, Suite 370, Solana Beach, CA **("Evoke"),** and Novos Growth, LLC, with a place of business at 150 N Riverside Plaza, Suite 3400, Chicago, IL 60606 **("Novos"),** and hereby amends the Commercial Services Agreement between Evoke and Novos with an effective date of January 5, 2019 (the **"Agreement").**

Any terms not defined herein shall have the meaning set forth in the Agreement.

1. Section 3.2(a) of the Agreement is hereby deleted in its entirety and replaced with the following:

a. **Content.** The Commercialization of the Product shall be governed by a Commercialization plan (the **"Commercialization Plan"),** and the costs and expenses relating to the Commercialization of the Product shall be governed by a Commercialization budget (the **"Commercialization Budget").** An initial Commercialization Plan and an initial Commercialization Budget shall be completed by the Parties and attached hereto as Exhibit F and Exhibit G, respectively, in each case prior to **March 8, 2019,** that shall govern the period of time from the Effective Date until the date that is 12 months following the Commercial Launch of the Product. The initial Commercialization Budget will include a detailed budget and will define which costs will be incurred prior to approval, between approval and launch, and after launch, in each case with a goal of efficiently using working capital until the Product has demonstrated its ability to achieve revenue suitable for the Product and the associated costs. The Commercialization Budget will include the cost incurred and cash flow and working capital financing requirements. Each Commercialization Plan shall include without limitation the topics set forth in Schedule 3.2a.

2. Section 14.2(e) of the Agreement is hereby deleted in its entirety and replaced with the following:

e. Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party if: (i) the Product is subject to a recall based on material safety concerns for the Product, which shall not include any recall for packaging or labeling issues, manufacturing concerns, or the like; the Parties have been unable to agree on the initial Commercialization Plan and Commercialization Budget for the Product by **March 8, 2019** despite negotiating in good faith; the product is not Commercially Launched within 9 months of FDA approval or (v) the overall Contribution Profit is negative for any calendar quarter (January through March, April through June, July through September, or October through December) beginning with the first full calendar quarter following 9 months after the Commercial Launch of the Product.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

Evoke Pharma, Inc.

By: /s/ David A. Gonyer
Name: David A. Gonyer
Title: Chief Executive Officer

Novos Growth, LC

By: /s/ Benjami T. Bove
Name: Benjamin T. Bove
Title: Chief Executive Officer

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David A. Gonyer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Evoke Pharma, 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(s) 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; and

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

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

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

Date: May 8, 2019

/s/ David A. Gonyer
David A. Gonyer
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew J. D'Onofrio, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Evoke Pharma, 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(s) 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; and

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

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

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

Date: May 8, 2019

/s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
Executive Vice President, Chief Business Officer,
Treasurer and Secretary
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION 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 Evoke Pharma, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Gonyer, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: May 8, 2019

/s/ David A. Gonyer
David A. Gonyer
President and Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION 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 Evoke Pharma, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew J. D'Onofrio, Executive Vice President, Chief Business Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: May 8, 2019

/s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
Executive Vice President, Chief Business Officer, Treasurer and Secretary

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.