

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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Evoke Pharma Inc

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**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 September 30, 2020

OR

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

Commission File Number 001-36075

EVOKE PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

20-8447886
(IRS Employer
Identification No.)

420 Stevens Avenue, Suite 370, Solana Beach, CA
(Address of principal executive offices)

92075
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 November 2, 2020, the registrant had 26,390,246 shares of common stock outstanding.



EVOKE PHARMA, INC.
FORM 10-Q
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Evoked Pharma, Inc. Condensed Balance Sheets

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,280,656	\$ 5,663,833
Prepaid expenses	336,432	581,706
Inventory	86,145	—
Other current assets	11,551	—
Total current assets	6,714,784	6,245,539
Operating lease right-of-use asset	36,115	138,538
Other assets	—	11,551
Total assets	<u>\$ 6,750,899</u>	<u>\$ 6,395,628</u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 765,603	\$ 1,033,383
Accrued compensation	715,423	843,162
Operating lease liability	36,115	138,538
Paycheck protection program loan	104,168	—
Milestone payable	5,000,000	—
Total current liabilities	6,621,309	2,015,083
Long-term Liabilities:		
Note payable	2,000,000	—
Accrued interest payable	53,005	—
Total long-term liabilities	2,053,005	—
Total liabilities	8,674,314	2,015,083
Stockholders' equity:		
Common stock, \$0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 26,332,122 and 24,431,914 at September 30, 2020 and December 31, 2019, respectively	2,633	2,443
Additional paid-in capital	94,691,151	90,108,492
Accumulated deficit	(96,617,199)	(85,730,390)
Total stockholders' (deficit) equity	(1,923,415)	4,380,545
Total liabilities and stockholders' (deficit) equity	<u>\$ 6,750,899</u>	<u>\$ 6,395,628</u>

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 205,032	\$ 822,444	\$ 6,450,979	\$ 2,774,924
General and administrative	1,874,578	814,218	4,387,284	2,955,371
Total operating expenses	2,079,610	1,636,662	10,838,263	5,730,295
Loss from operations	(2,079,610)	(1,636,662)	(10,838,263)	(5,730,295)
Other income (expense):				
Interest income	1,033	8,597	4,896	22,868
Interest expense	(50,528)	—	(53,442)	—
Total other income (expense)	(49,495)	8,597	(48,546)	22,868
Net loss	\$ (2,129,105)	\$ (1,628,065)	\$ (10,886,809)	\$ (5,707,427)
Net loss per share of common stock, basic and diluted	\$ (0.08)	\$ (0.07)	\$ (0.43)	\$ (0.26)
Weighted-average shares used to compute basic and diluted net loss per share	26,146,220	24,128,060	25,191,359	21,623,648

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.
Condensed Statements of Stockholders' (Deficit) Equity
(Unaudited)

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u> <u>Capital</u>	<u>Deficit</u>	<u>Stockholders'</u> <u>(Deficit) Equity</u>
Balance at January 1, 2020	24,431,914	\$ 2,443	\$ 90,108,492	\$ (85,730,390)	\$ 4,380,545
Stock-based compensation expense	—	—	310,162	—	310,162
Issuance of common stock from employee stock purchase plan	25,000	3	21,247	—	21,250
Net loss	—	—	—	(1,790,309)	(1,790,309)
Balance at March 31, 2020	24,456,914	2,446	90,439,901	(87,520,699)	2,921,648
Stock-based compensation expense	—	—	362,955	—	362,955
Issuance of common stock from At-The-Market offering, net	1,395,855	140	3,308,976	—	3,309,116
Issuance of common stock from warrant exercises	158,494	15	(15)	—	—
Net loss	—	—	—	(6,967,395)	(6,967,395)
Balance at June 30, 2020	26,011,263	2,601	94,111,817	(94,488,094)	(373,676)
Stock-based compensation expense	—	—	478,574	—	478,574
Issuance of common stock from employee stock purchase plan	93,491	9	98,156	—	98,165
Issuance of common stock from warrant exercises	223,131	22	(22)	—	—
Issuance of common stock from stock option exercise	4,237	1	2,626	—	2,627
Net loss	—	—	—	(2,129,105)	(2,129,105)
Balance at September 30, 2020	<u>26,332,122</u>	<u>\$ 2,633</u>	<u>\$ 94,691,151</u>	<u>\$ (96,617,199)</u>	<u>\$ (1,923,415)</u>

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u> <u>Capital</u>	<u>Deficit</u>	<u>Stockholders'</u> <u>Equity</u>
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
Stock-based compensation expense	—	—	344,841	—	344,841
Issuance of common stock, net	6,236,423	623	5,039,333	—	5,039,956
Net loss	—	—	—	(2,114,096)	(2,114,096)
Balance at June 30, 2019	24,113,956	2,411	89,027,832	(82,684,097)	6,346,146
Stock-based compensation expense	—	—	331,303	—	331,303
Issuance of common stock, net	117,958	12	123,801	—	123,813
Net loss	—	—	—	(1,628,065)	(1,628,065)
Balance at September 30, 2019	<u>24,231,914</u>	<u>\$ 2,423</u>	<u>\$ 89,482,936</u>	<u>\$ (84,312,162)</u>	<u>\$ 5,173,197</u>

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.
Condensed Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating activities		
Net loss	\$ (10,886,809)	\$ (5,707,427)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,151,691	1,055,103
Milestone expense	5,000,000	—
Accrued interest	53,442	—
Change in operating assets and liabilities:		
Prepaid expenses and other assets	261,552	(345,975)
Accounts payable and other current liabilities	(498,379)	383,896
Net cash used in operating activities	(4,918,503)	(4,614,403)
Financing activities		
Proceeds from issuance of common stock, net	3,309,116	5,800,201
Proceeds from issuance of common stock from employee stock purchase plan	119,415	—
Proceeds from issuance of common stock from stock option exercised	2,627	—
Proceeds from paycheck protection program	104,168	—
Proceeds from Eversana line of credit	2,000,000	—
Net cash provided by financing activities	5,535,326	5,800,201
Net increase in cash and cash equivalents	616,823	1,185,798
Cash and cash equivalents at beginning of period	5,663,833	5,319,004
Cash and cash equivalents at end of period	\$ 6,280,656	\$ 6,504,802

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Notes to Condensed Financial Statements (Unaudited)

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 and commercialization of drugs to treat gastroenterological disorders and disease.

Since its inception, the Company has devoted its efforts to developing its sole product, Gimoti™ (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. On June 19, 2020, the Company received approval from the U.S. Food and Drug Administration (“FDA”) for its 505(b)(2) New Drug Application (“NDA”) for Gimoti. The Company launched U.S. commercial sales of Gimoti in October 2020 through its commercial partner Eversana Life Science Services, LLC (“Eversana”).

The Company’s activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has launched its first commercial product, including market acceptance of the product and the potential need to obtain additional funding for 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 had approximately \$6.3 million in cash and cash equivalents at September 30, 2020, the Company anticipates that it will continue to incur losses from operations due to commercialization activities, including manufacturing commercial batches of Gimoti, and general and administrative costs to support operations. 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. 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 financial statements do not include any adjustments that may result from the outcome of this uncertainty.

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 will be sufficient to fund its operations into the second quarter of 2021, excluding any potential additional borrowings from the revolving credit facility with Eversana (the “Eversana Credit Facility”), as discussed in Note 5, and future Gimoti product revenue. This period could be shortened if there are any unanticipated increases in planned spending. Even with the remaining amount available under the Eversana Credit Facility and future Gimoti product revenue, 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 commercialization activities. 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 successfully commercialize Gimoti. Because the Company’s business is entirely dependent on the success of Gimoti, if the Company is unable to secure additional financing, successfully commercialize Gimoti or identify and execute on strategic alternatives for Gimoti or the 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.

Contract Research Organizations and Consultants

The Company relies on contract research organizations (“CROs”) and consultants to assist with ongoing regulatory discussions and submissions to FDA. If these CROs and consultants are unable to continue their support, this could adversely affect the operations of the Company.

In addition, the Company relies on third-party suppliers and manufacturer 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 commercial supply demand for Gimoti and the commercialization of Gimoti could be materially and adversely affected.

The Company also relies on Eversana for the management of the commercialization of Gimoti, distribution services and a dedicated sales team to sell Gimoti. If Eversana is unable to continue serving as a dedicated sales team or distributing Gimoti, the commercialization of Gimoti could be materially and adversely affected.

Impact of COVID-19

To date, the Company has not experienced material disruptions to its financial condition or operations from the novel coronavirus disease (“COVID-19”) pandemic. The Company has begun its commercial activities, including commercial manufacturing, and with Eversana, the commercial sales of Gimoti. However, there can be no assurance that the Company or Eversana will not be impacted by the COVID-19 pandemic. For example, Eversana’s commercialization efforts may be adversely affected by operational restrictions imposed on its sales force from quarantines, travel restrictions and bans and other governmental restrictions related to COVID-19. As a result of these restrictions, their sales force may not be able to conduct in-person interactions with physicians and customers and may be restricted to conducting educational and promotional activities for Gimoti virtually, which may impact Eversana’s ability to market Gimoti. In addition, the COVID-19 pandemic may disrupt the operations of the Company’s third-party suppliers and manufacturers and delay the Company’s manufacturing timelines of Gimoti, which may negatively impact the Company’s ability to successfully commercialize Gimoti and generate product sales. Further, the COVID-19 pandemic and mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on the Company’s business and financial condition, including impairing its ability to raise capital when needed. In April 2020, the Company applied for and was approved for a Small Business Administration (“SBA”) loan under the Paycheck Protection Program (“PPP”), established by the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act. On May 1, 2020, the Company received the loan proceeds of approximately \$104,000. Processes are being developed for companies to submit for loan forgiveness and the Company plans to submit for loan forgiveness when such processes are finalized.

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2019, 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, 2019, which are contained in the Company’s Annual Report on Form 10-K filed with the SEC on March 12, 2020. 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.

Inventory

Subsequent to FDA approval of Gimoti in June 2020, the Company began a manufacturing process for the production of Gimoti for sale and began capitalizing inventory. As the manufacturing process was not completed until October 2020, the inventory was classified as work-in-process at September 30, 2020. Following the completion and release of the product by the Company’s manufacturer in October 2020, inventory is being stated at the lower of cost or net realizable value and recognized on a first-in, first-out method. Prior to FDA approval, expenses associated with the manufacturing of Gimoti were recorded as research and development expense.

The Company will analyze its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments will be recognized through cost of sales in the period in which they are incurred.

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, except awards with a performance condition. Awards with performance conditions commence vesting when the satisfaction of the performance condition is probable. 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, supplemented, as necessary, 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. The Company accounts for forfeitures as the forfeitures occur.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense, costs paid to third-party contractors for product development activities and drug product materials and technology acquisition milestones. The Company has expensed costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred prior to FDA approval received June 19, 2020.

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 depended on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its pre-commercial product development, and will continue to depend on such third-party manufacturers for its commercial manufacturing. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., through its subsidiary Patheon UK Limited, for the 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. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of 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 to do so would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Warrants to purchase common stock	1,841,879	2,713,561	1,841,879	2,713,561
Common stock options	4,273,065	3,114,371	4,273,065	3,114,371
Employee stock purchase plan	4,716	7,294	4,716	7,294
Total excluded securities	6,119,660	5,835,226	6,119,660	5,835,226

3. 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 on the one-year anniversary after the Company receives FDA approval to market Gimoti. At the time of the Gimoti NDA approval by FDA, the Company recorded the \$5 million payable owed to Mallinckrodt with a due date of June 19, 2021, along with a \$5 million research and development expense.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success. 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, subject to possible extension should any additional, later expiring, patents be granted.

4. 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 nine months ended September 30, 2019, the Company sold 6,804,381 shares of common stock at a weighted-average price per share of \$0.87 pursuant to the FBR Sales Agreement and received proceeds of approximately \$5.8 million, net of commissions and fees. During the nine months ended September 30, 2020, the Company sold 1,395,855 shares of common stock at a weighted-average price per share of \$2.42 pursuant to the FBR Sales Agreement and received proceeds of approximately \$3.3 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.

Warrant Exercises

During the nine months ended September 30, 2020, certain holders of warrants exercised their warrants to purchase 871,682 shares of the Company's common stock by a "cashless" exercise and received 381,625 shares of the Company's common stock. The warrants had exercise prices ranging from \$2.41 to \$3.12 per share. The shares were issued, and the warrants were originally sold, in reliance upon the registration exemption set forth in Section 4(a)(2) of the Securities Act of 1933.

Stock Option Exercises

During the nine months ended September 30, 2020, certain holders of stock options exercised their stock options to purchase 4,237 shares of the Company's common stock. The stock options had exercise prices of \$0.62 per share.

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.

During the nine months ended September 30, 2020, the Company granted stock options to purchase 1,172,000 shares of the Company's common stock. Of such options, 437,500 did not begin vesting until the date that FDA approved the Gimoti NDA. 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 nine months ended September 30, 2020 and 2019:

	Nine Months Ended	
	September 30,	
	2020	2019
Common Stock Options		
Risk free interest rate	0.39% - 0.96%	1.80% - 2.55%
Expected option term	5.5 - 6.0 years	4.27 - 6.0 years
Expected volatility of common stock	99.73% - 103.99%	90.34% - 112.58%
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 and nine months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Employee Stock Purchase Plan				
Risk free interest rate	0.13%	1.89%	0.13% - 1.11%	1.89% - 2.52%
Expected term	0.5 years	0.5 years	0.5 years	0.5 years
Expected volatility of common stock	111.98%	170.68%	69.72% - 111.98%	130.36% - 170.68%
Expected dividend yield	0.0%	0.0%	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 during the three and nine months ended September 30, 2020 and 2019 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 31,186	\$ 179,227	\$ 286,148	\$ 533,518
General and administrative	447,388	152,076	865,543	521,585
Total stock-based compensation expense	<u>\$ 478,574</u>	<u>\$ 331,303</u>	<u>\$ 1,151,691</u>	<u>\$ 1,055,103</u>

As of September 30, 2020, there was approximately \$2.5 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 1.13 years.

5. Commercial Services and Loan Agreements with Eversana

On January 21, 2020, the Company entered into a commercial services agreement (the “Eversana Agreement”) with Eversana for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States. Eversana will manage the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti within the United States.

Under the terms of the Eversana Agreement, the Company maintains ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. Eversana will utilize its internal sales organization, along with other commercial functions, for market access, marketing, distribution and other related patient support services. The Company will record sales for Gimoti and retain more than 80% of net product profits once the parties’ costs are reimbursed. Eversana will receive reimbursement of its commercialization costs pursuant to an agreed upon budget and a percentage of product profits in the mid-to-high teens. Net product profits are the net sales (as defined in the Eversana Agreement) of Gimoti, less (i) reimbursed commercialization costs, (ii) manufacturing and administrative costs set at a fixed percentage of net sales, and (iii) third party royalties. During the term of the Eversana Agreement, Eversana agreed to not market, promote, or sell a competing product in the United States.

The Eversana Agreement terminates on June 19, 2025, unless terminated earlier pursuant to its terms. Upon expiration or termination of the agreement, the Company will retain all profits from product sales and assume all corresponding commercialization responsibilities. Within 30 days after each of the first three annual anniversaries of commercial launch, either party may terminate the agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the agreement: for the material breach of the other party, subject to a 60-day cure period; in the event an insolvency, petition of the other party is pending for more than 60 days; upon 30 days written notice to the other party if Gimoti is subject to a safety recall; if the other party is in breach of certain regulatory compliance representations under the agreement; if the Company discontinues the development or production of Gimoti; if the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch; or if there is a change in applicable laws that makes operation of the services as contemplated under the agreement illegal or commercially impractical. Either party may also terminate the Eversana Agreement upon a change of control of the Company’s ownership, subject, in the event that the Company initiates such termination, to a one-time payment equal to between two times and one times annualized service fees paid by the Company under the Eversana Agreement, with such amount based on which year after commercial launch the change of control occurs. Such payment amount would be reduced by the amount of previously reimbursed commercialization costs and profit split paid for the related prior twelve-month period and any revenue which occurred prior to the termination yet to be collected. In addition, Eversana may terminate the Eversana Agreement if the Company withdraws Gimoti from the market for more than 90 days.

In connection with the Eversana Agreement, the Company and Eversana also entered into the Eversana Credit Facility, pursuant to which Eversana agreed to provide a revolving Credit Facility of up to \$5 million to the Company upon FDA approval of the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility terminates on June 19, 2025, unless terminated

earlier pursuant to its terms. The Eversana Credit Facility is secured by all of the Company's personal property other than its intellectual property. Under the terms of the Eversana Credit Facility, the Company cannot grant an interest in its intellectual property to any other person. Each loan under the Eversana Credit Facility will bear interest at an annual rate equal to 10.0%, with such interest due at the end of the loan term. In June 2020, the Company borrowed \$2 million from the Eversana Credit Facility.

The Company may prepay any amounts borrowed under the Eversana Credit Facility at any time without penalty or premium. The maturity date of all amounts, including interest, borrowed under the Eversana Credit Facility will be 90 days after the expiration or earlier termination of the Eversana Agreement. The Eversana Credit Facility also includes events of default, the occurrence and continuation of which provide Eversana with the right to exercise remedies against the Company and the collateral securing the loans under the Eversana Credit Facility, including the Company's cash. These events of default include, among other things, the Company's failure to pay any amounts due under the Eversana Credit Facility, an uncured material breach of the representations, warranties and other obligations under the Eversana Credit Facility, the occurrence of insolvency events and the occurrence of a change in control.

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 audited financial statements and accompanying notes thereto for the fiscal year ended December 31, 2019 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 12, 2020. 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, commercial activities to be conducted by Eversana Life Science Services, LLC, or Eversana, the pricing and reimbursement for Gimoti, future regulatory developments, research and development costs, the timing and likelihood of success, plans and objectives of management for future operations, future results of current and anticipated products and the expected impact of the novel coronavirus, or COVID-19 pandemic, on us or on third parties on whom we rely, 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. This Quarterly Report on Form 10-Q also includes trademarks, tradenames and service marks that are the property of other organizations. 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 and commercialization of drugs to treat gastrointestinal, or GI, disorders and diseases. Since our inception, we have devoted our efforts to developing our sole product, Gimoti (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. On June 19, 2020, we received approval from the U.S. Food and Drug Administration, or FDA for our 505(b)(2) New Drug Application, or NDA, for Gimoti. We launched U.S. commercial sales of Gimoti in October 2020 through our commercial partner Eversana.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious GI symptoms as well as other system complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Gimoti is the only nasally-administered drug currently approved in the United States to treat the symptoms in adults with acute and recurrent diabetic gastroparesis.

On January 21, 2020, we entered into an agreement with Eversana for the commercialization of Gimoti, or the Eversana Agreement. Pursuant to the Eversana Agreement, Eversana commercializes and distributes Gimoti in the United States. Eversana also manages the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti within the United States.

Eversana also provided a \$5 million revolving credit facility, or Eversana Credit Facility, which became available upon FDA approval of Gimoti. In June 2020, we borrowed \$2 million under the Eversana Credit Facility.

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. These 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 operating losses until revenues from sales of Gimoti, which we launched in October 2020, exceed our expenses, if ever. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

As of September 30, 2020, we had cash and cash equivalents of approximately \$6.3 million. Current cash on hand is intended to fund commercialization activities for Gimoti, including manufacturing commercial batches 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 will be sufficient to fund our operations into the second quarter of 2021, excluding any potential additional borrowings from the Eversana Credit Facility and future Gimoti product revenue. This period could be shortened if there are any unanticipated increases in planned spending, including as a result of the COVID-19 pandemic. Even with the remaining amount available under the Eversana Credit Facility, and Gimoti product revenue, we may be required to raise additional funds in order to continue as a going concern. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing, successfully commercialize Gimoti or identify and execute other 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.

Impact of COVID-19

To date, we have not experienced material disruptions to our financial condition or operations from the novel coronavirus disease, or COVID-19 pandemic. We have begun our commercial activities, including commercial manufacturing, and with Eversana commercial sales of Gimoti. However, there can be no assurance that we or Eversana will not be impacted by the COVID-19 pandemic. For example, Eversana's commercialization efforts may be adversely affected by operational restrictions imposed on its sales force from quarantines, travel restrictions and bans and other governmental restrictions related to COVID-19. As a result of these restrictions, their sales force may not be able to conduct in-person interactions with physicians and customers and may be restricted to conducting educational and promotional activities for Gimoti virtually, which may impact Eversana's ability to market Gimoti. In addition, the COVID-19 pandemic may disrupt the operations of our third-party suppliers and manufacturers and delay our manufacturing timelines of Gimoti, which may negatively impact our ability to successfully commercialize Gimoti and generate product sales. Further, the COVID-19 pandemic and mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. In April 2020, we applied for and were approved for a Small Business Administration, or SBA, loan under the Paycheck Protection Program, or PPP, established by the Coronavirus Aid, Relief, And Economic Security, or CARES Act. On May 1, 2020, we received loan proceeds of approximately \$104,000. Based on the SBA guidelines, we believe that the balance of the loan and accrued interest will be forgiven in accordance with the terms of the PPP loan. Processes are being developed for companies to submit for loan forgiveness and we plan to submit for loan forgiveness when such processes are finalized.

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 FDA approval to market Gimoti. At the time of the Gimoti NDA approval by FDA, we recorded the \$5 million payable owed to Mallinckrodt with a due date of June 19, 2021, along with a \$5 million research and development expense.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success. 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, subject to possible extension should any additional, later expiring, patents be granted.

Financial Operations Overview

Revenue

Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Gimoti, which we launched in October 2020 through our commercial partner Eversana. If we or Eversana fail to successfully launch Gimoti and grow and maintain sales, we may never generate significant revenues and our results of operations and financial position will be adversely affected.

Research and Development Expenses

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

- clinical and regulatory-related costs;
- expenses incurred under agreements with contract research organizations, or CROs;
- manufacturing 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. With the FDA approval of Gimoti, we expect research and development costs to decrease and shift to commercialization and selling costs. However, we expect to begin planning for an FDA post-marketing commitment pharmacokinetics trial of Gimoti. This trial, which we expect to begin in 2021, will characterize dose proportionality of a lower dosage strength of Gimoti to accommodate patients that may require further dosage adjustments. We are unable to estimate with any certainty the costs we will incur related to this trial, or the regulatory review of such lower dosage of Gimoti, though such costs may be significant. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

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

- per subject trial costs;
- the number of sites included in the trials;
- 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; and
- the duration of subject follow-up.

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 continue to progress with the commercialization of Gimoti and we reimburse Eversana from the net profits attained from sales of Gimoti.

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 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, 2019, which was filed with the SEC on March 12, 2020.

Other Information

None.

Results of Operations

Comparison of Three Months Ended September 30, 2020 and 2019

The following table summarizes the results of our operations for the three months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Increase/ (Decrease)
	2020	2019	
Research and development expenses	\$ 205,032	\$ 822,444	\$ (617,412)
General and administrative expenses	\$ 1,874,578	\$ 814,218	\$ 1,060,360

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 decreased by approximately \$617,000. The decrease during the three months ended September 30, 2020 is primarily due to a decrease in research and development activity following the Gimoti NDA approval by FDA in June 2020. During the three months ended September 30, 2020, we incurred costs of approximately \$158,000 related primarily to continued stability testing of batches of Gimoti manufactured prior to FDA approval and approximately \$36,000 for wages, taxes and employee insurance, including approximately \$31,000 of stock-based compensation expense. Following FDA approval of Gimoti, and until we begin our post-marketing commitment pharmacokinetics trial, which is expected to begin in 2021, we expect future research and development expenses to remain consistent with the current quarter as we have shifted our focus to commercialization and selling activities, but we will continue to test the stability of Gimoti manufactured prior to approval.

In 2019, we incurred expenses primarily related to responding to requests for additional information from FDA for the Gimoti NDA and manufacturing registration batches of Gimoti as required by FDA. Costs incurred in 2019 included approximately \$493,000 for wages, taxes and employee insurance, including approximately \$179,000 of stock-based compensation expense, approximately \$248,000 related to manufacturing, and approximately \$75,000 related to responding to FDA information requests on the NDA and preparing for the NDA resubmission.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 increased by approximately \$1.1 million as we have shifted our focus to selling activities. Costs incurred in 2020 primarily included approximately \$1.1 million for wages, taxes and employee insurance, including approximately \$447,000 of stock-based compensation expense, and approximately \$654,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Of the general and administrative expenses incurred during the three months ended September 30, 2020, approximately \$745,000 related to commercialization activities. Costs incurred in 2019 primarily included approximately \$423,000 for wages, taxes and employee insurance, including approximately \$152,000 of stock-based compensation expense, and approximately \$326,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. General and administration costs are expected to increase in future periods as we continue to progress with the commercialization of Gimoti.

Comparison of Nine Months Ended September 30, 2020 and 2019

The following table summarizes the results of our operations for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2020	2019	
Research and development expenses	\$ 6,450,979	\$ 2,774,924	\$ 3,676,055
General and administrative expenses	\$ 4,387,284	\$ 2,955,371	\$ 1,431,913
Other (income) expense, net	\$ 48,546	\$ (22,868)	\$ (71,414)

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 increased by approximately \$3.7 million. The increase during the nine months ended September 30, 2020 is primarily due to recording a \$5 million expense in June 2020 upon achieving a technology acquisition milestone related to FDA's approval of Gimoti. Although the expense was recorded when incurred, the payment is not due to Mallinckrodt until June 19, 2021. During the nine months ended September 30, 2020, we also incurred expenses responding to requests for additional information from FDA related to the NDA and preparing for future manufacturing and the commercial launch of Gimoti. Excluding the Mallinckrodt milestone expense, research and development expenses decreased during 2020 as we have shifted our focus to commercialization and selling activities. Costs incurred in 2020 included approximately \$784,000 for wages, taxes and employee insurance, including approximately \$286,000 of stock-based compensation expense, and approximately \$581,000 related to acquiring

raw material prior to obtaining FDA approval of Gimoti and to continued testing of Gimoti batches that were manufactured prior to FDA approval.

In 2019, we incurred expenses primarily related to responding to requests for additional information from FDA and manufacturing registration batches of Gimoti as required by FDA. Costs incurred in 2019 included approximately \$1.8 million for wages, taxes and employee insurance, including approximately \$534,000 of stock-based compensation expense, approximately \$787,000 related to manufacturing, and approximately \$150,000 related to responding to FDA information requests regarding the NDA and preparing for the NDA resubmission.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 increased by approximately \$1.4 million. Costs incurred in 2020 primarily included approximately \$2.3 million for wages, taxes and employee insurance, including approximately \$866,000 of stock-based compensation expense, and approximately \$1.8 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Of the general and administrative expenses incurred during the nine months ended September 30, 2020, approximately \$1.2 million related to pre-commercialization and commercialization activities. Costs incurred in 2019 primarily included approximately \$1.4 million for wages, taxes and employee insurance, including approximately \$522,000 of stock-based compensation expense, approximately \$1.2 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, approximately \$116,000 for outside consultants and approximately \$68,000 for pre-commercialization costs.

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 nine months ended September 30, 2019, we sold 6,804,381 shares of common stock at a weighted-average price per share of \$0.87 pursuant to the FBR Sales Agreement and received proceeds of approximately \$5.8 million, net of commissions and fees. During the nine months ended September 30, 2020, we sold 1,395,855 shares of common stock at a weighted-average price per share of \$2.42 pursuant to the FBR Sales Agreement and received proceeds of approximately \$3.3 million, net of commissions and fees.

As of October 31, 2020, we had the capacity to issue up to approximately \$1.7 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.

Under current SEC regulations, if at the time we file our Annual Report on 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. During June 2020, our public float exceeded \$75 million, thereby allowing us to conduct primary offerings without being constrained by the baby shelf rules. We will remain unconstrained by the baby shelf rules under our Form S-3 shelf registration statement until the date we file a new registration statement or our Form 10-K for the fiscal year ending December 31, 2020, at which time if our public float is less than \$75 million, the amount of securities we may sell under a Form S-3 registration statement will again be limited by the baby shelf rules.

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 connection with the Eversana Agreement, we entered into the Eversana Credit Facility, pursuant to which Eversana agreed to provide a revolving Credit Facility of up to \$5 million to us upon FDA approval of the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility terminates on June 19, 2025, unless terminated earlier pursuant to its terms. The Eversana Credit Facility is secured by all of the Company's personal property other than its intellectual property. Under the terms of the Eversana Credit Facility, we cannot grant an interest in our intellectual property to any other person. Each loan under the Eversana Credit Facility will bear interest at an annual rate equal to 10.0%, with such interest due at the end of the loan term. In June 2020, we borrowed \$2 million from the Eversana Credit Facility.

Management concluded that there is substantial doubt about 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. As of September 30, 2020, we had cash and cash equivalents of approximately \$6.3 million. We believe, based on our current operating plan, that our

existing cash and cash equivalents will be sufficient to fund our operations into the second quarter of 2021, excluding any potential additional borrowings from the Eversana Credit Facility and future Gimoti product revenue. This period could be shortened if there are unanticipated increases in planned spending, including as a result of the COVID-19 pandemic. Even with the Eversana Credit Facility and Gimoti product revenue, we 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. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing, successfully commercialize Gimoti, or identify and execute other 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 commercialization activities, including 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 as we:

- continue the commercialization activities for Gimoti;
- manufacture the commercial batches of Gimoti;
- conduct the post-marketing commitment pharmacokinetics trial of Gimoti and any additional development activities should we seek additional indications;
- maintain, expand and protect our intellectual property portfolio; and
- continue to fund the accounting, legal, insurance and other costs associated with being a public company.

The following table summarizes our cash flows for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended		Increase/ (Decrease)
	September 30,		
	2020	2019	
Net cash used in operating activities	\$ (4,918,503)	\$ (4,614,403)	\$ 304,100
Net cash provided by financing activities	\$ 5,535,326	\$ 5,800,201	\$ (264,875)
Net increase (decrease) in cash and cash equivalents	\$ 616,823	\$ 1,185,798	\$ (568,975)

Operating Activities. The primary use of our cash has been to fund our clinical research, prepare our NDA, manufacture Gimoti, and other general operations. The cash used in operating activities during the nine months ended September 30, 2020 was primarily related to ongoing communication with FDA related to the resubmitted NDA, pre-approval and commercialization activities and other ongoing costs of operating the business. The cash used in operating activities during the nine months ended September 30, 2019 was primarily related to ongoing communication with FDA related to the NDA and to manufacturing registration batches of Gimoti. We expect that cash used in operating activities will increase due to commercialization activities, including manufacturing of Gimoti.

Financing Activities. During the nine months ended September 30, 2020, we received net proceeds of approximately \$3.3 million from the sale of 1,395,855 shares of common stock pursuant to the FBR Sales Agreement, \$2 million from borrowings under the Eversana Credit Facility, approximately \$104,000 from the PPP loan, and approximately \$119,000 from the sale of 118,491 shares of common stock pursuant to our ESPP. During the nine months ended September 30, 2019, we received net proceeds of approximately \$5.8 million from the sale of 6,804,381 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:

- the costs of commercialization activities, including costs associated with commercial manufacturing;
- the commercial success of Gimoti, including competition with well-established products approved earlier by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- the impact of the COVID-19 pandemic on us or on third parties on whom we rely;

- our ability to manufacture sufficient quantities of Gimoti to meet demand, including whether our contract manufacturers, suppliers, and/or consultants are able to meet appropriate timelines;
- our ability to access the Eversana Credit Facility, which remains subject to certain customary conditions;

- the progress and costs of the post-marketing commitment to conduct a pharmacokinetics trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and the costs of any additional clinical trials we may pursue to expand the indication of Gimoti;
- our ability to obtain, maintain and enforce our patents and other intellectual property rights, and the costs incurred to do so;
- 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.

Off-Balance Sheet Arrangements

Through September 30, 2020, 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 nine months ended September 30, 2020 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, 2019, filed with the SEC on March 12, 2020, except for the \$2 million borrowing from Eversana as discussed in Note 5 in our Notes to Condensed Financial Statements. In addition, with the approval of the Gimoti NDA, we are now committed to pay Mallinckrodt \$5 million as discussed in Note 3 in our Notes to Condensed Financial Statements.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of September 30, 2020, 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, 2019, filed with the SEC on March 12, 2020.

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), as of September 30, 2020 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 September 30, 2020.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended September 30, 2020 that materially affect, 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, 2019, filed with the SEC on March 12, 2020, or the 2019 annual report, other than as set forth below:

Risks Related to our Business, including the Regulatory Compliance and Commercialization of our Product, Gimoti

Our business is entirely dependent on the success of Gimoti, which may never generate sufficient sales to become profitable.

To date, we have devoted all of our research, development and clinical efforts and financial resources toward the development of our only product, Gimoti.

Because our business is entirely dependent on the success of Gimoti, if we are unable to successfully commercialize this product, 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 other factors included in “Item 1A. Risk Factors” in our 2019 annual report, the future commercial success of Gimoti is subject to a number of additional risks, including the following:

- Gimoti will compete with well-established products, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- our reliance on Eversana to commercialize Gimoti;
- our ability, with Eversana, to hire, train and maintain a sales team for Gimoti;
- the impact of the COVID-19 pandemic on our ability to generate sales for Gimoti;
- we may not be able to develop market demand for, and later increase sales of, Gimoti through our sales and marketing efforts;
- our ability to obtain adequate levels of coverage and reimbursement for Gimoti from commercial health plans and government health programs;
- we may not be able to maintain commercial manufacturing arrangements with third-party manufacturers or establish and maintain commercial-scale manufacturing capabilities;
- contract manufacturers, suppliers and/or consultants may not meet appropriate timelines;
- our ability to successfully conduct a post-marketing approval pharmacokinetics trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, including the risk that FDA may disagree with the design of the clinical trial;
- patients taking Gimoti may suffer adverse effects for reasons that may or may not be related to Gimoti, which may adversely affect Gimoti’s commercial profile; and
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights.

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 second quarter of 2021, excluding the \$3.0 million remaining amount available under the Eversana Credit Facility and future Gimoti product revenue. This period could be shortened if there are any significant increases in planned spending other than anticipated. Even with the remaining amount available under the Eversana Credit Facility and Gimoti product revenue, we will likely 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 we will be able to raise additional funds on acceptable terms, or at all. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing, successfully commercialize Gimoti or identify and execute on other commercialization 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 costs of commercialization activities, including costs associated with commercial manufacturing;
- the commercial success of Gimoti, including competition with well-established products approved earlier by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- the impact of the COVID-19 pandemic on us or on third parties on whom we rely;
- our ability to manufacture sufficient quantities of Gimoti to meet demand, including whether our contract manufacturers, suppliers, and/or consultants are able to meet appropriate timelines;
- the progress and costs of the post-marketing commitment pharmacokinetics trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and the costs of any additional clinical trials we may pursue to expand the indication of Gimoti;
- our ability to obtain, maintain and enforce our patents and other intellectual property rights and the costs incurred in doing so;
- 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 or to otherwise survive as a going concern.

Any termination or suspension of, or delays in the completion of, the post-marketing pharmacokinetics trial of Gimoti or any other future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

In connection with FDA's approval of Gimoti, we committed to conduct a pharmacokinetics trial to characterize dose proportionality of a lower dose strength compared to the current 15 mg dose strength. We expect to initiate this trial in 2021. We do not know whether any trials will produce data on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- FDA placing a clinical trial on hold;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing Gimoti, or any of its components, being ordered by FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of FDA's current Good Manufacturing Practices, or other applicable requirements, or infections or cross-contaminations of a product candidate in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice and regulatory requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by FDA or the finding of regulatory violations by FDA or an institutional review board, or IRB, that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;

- third-party contractors becoming debarred or suspended or otherwise penalized by FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; or
- an IRB refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Product development costs will increase if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of or if we, FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for our product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Delays in the completion of any clinical trials and studies we may conduct for Gimoti could be harmful to our business and cause us to require additional funding.

Use of Gimoti or any future product candidates we may develop could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of the approved labeling, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

If we or others identify undesirable side effects, or other previously unknown problems, with Gimoti, a number of potentially significant negative consequences could result, including:

- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- FDA could suspend or withdraw approval of the product, or refuse to approve pending NDA supplements;
- FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Moreover, if any future product candidates we may develop are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial prospects for the product candidate, if approved. Undesirable side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in a more restrictive label than proposed, or delay or cause the denial of regulatory approvals by FDA or comparable foreign regulatory authorities. The drug-related side effects could also affect patient recruitment for our clinical trials, or the ability of enrolled patients to complete the trials, or result in potential product liability claims. We may also be required to modify our plans for future studies based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. Any of these occurrences may harm our business, financial condition and prospects significantly.

Undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of Gimoti, or our future product candidates, if approved, and could substantially increase the costs of commercializing and developing such products or product candidates.

Our business may be impacted by epidemic diseases such as the recent global outbreak of the COVID-19 coronavirus.

In March 2020, the World Health Organization declared the outbreak of COVID-19, which has spread across the United States and worldwide, to be a pandemic. A pandemic, including COVID-19 or other public health epidemics, poses the risk that we or our employees, or our third-party suppliers and manufacturers may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. To date, we have not experienced material disruptions to our financial condition or operations from COVID-19. However, there can be no assurance that we or Eversana will not be impacted in the future by the COVID-19

pandemic. The continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the raw material supply chain and the manufacture or shipment of Gimoti for commercial sale or cause us and Eversana to delay or materially modify our commercial plans, which could increase costs or decrease potential Gimoti revenues and have a material adverse effect on our business, financial condition and results of operations. For example, Eversana's commercialization efforts may be adversely affected by operational restrictions imposed on its sales force from quarantines, travel restrictions and bans and other governmental restrictions

related to COVID-19. As a result of these restrictions, their sales force may not be able to conduct in-person interactions with physicians and customers and may be restricted to conducting educational and promotional activities for Gimoti virtually, which may impact Eversana's ability to market Gimoti. In addition, the COVID-19 pandemic may disrupt the operations of our third-party suppliers and manufacturers and delay our manufacturing timelines of Gimoti, which may negatively impact our ability to successfully commercialize Gimoti and generate product sales. COVID-19 may also impact the costs and timing of our planned post-marketing commitment pharmacokinetics trial of Gimoti. Moreover, to the extent any of these risks and uncertainties adversely impact us in the ways described above or otherwise, they may also have the effect of heightening many of the other risks set forth in our 2019 annual report. The COVID-19 pandemic and mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our manufacturing capabilities and commercial plans and other results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the actions to contain its impact and treat the disease.

Disruptions at FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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
4.9 (9)	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
101.1+	3PL Agreement between the Company and Eversana Life Science Services, Inc. dated August 27, 2020
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.
- (9) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2020.

- * 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.
- † Certain portions of this exhibit have been omitted and are subject to confidential treatment.

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: November 10, 2020

By: /s/ David A. Gonyer

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

Date: November 10, 2020

By: /s/ Matthew J. D'Onofrio

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

AS CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE EVOKE PHARMA, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO EVOKE PHARMA, INC. IF PUBLICLY DISCLOSED.

This 3PL Agreement (the “**Agreement**”) is made on August 27, 2020 (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
Eversana Life Science Services, LLC, with a place of business at 190 N. Milwaukee Street, Milwaukee, WI 53202 (“**Eversana**”).

Evoke and Eversana are hereinafter referred to individually as a “**Party**” and collectively as the “**Parties**”.

BACKGROUND

Whereas, Evoke and Eversana are parties to that certain Commercial Services Agreement dated January 21, 2020 (the “**CSA**”);

Whereas, under the CSA, Eversana supervises and manages the day to day commercialization of the Product (as defined below) in the Territory under the terms and conditions set forth therein; and

Whereas, section 5.1 of the CSA expressly requires the Parties to negotiate in good faith additional terms and conditions of a sales and distribution agreement, titled the “3PL Agreement,” which shall be consistent with the general framework for sales and distribution described in the CSA.

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. RELATION TO THE COMMERCIAL SERVICES AGREEMENT

1.1. **Ancillary Agreement.** The Parties acknowledge that this Agreement is ancillary to the CSA and all terms and conditions in the CSA are incorporated herein by reference and made a part hereof. In the event of any conflict between this Agreement and the CSA with respect to any provision herein, the CSA shall control unless this Agreement expressly states that such provision in this Agreement shall supersede the CSA. All capitalized terms used but not defined herein shall have the meanings ascribed to them in the CSA.

2. DEFINITIONS

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

2.1. “**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.

- 2.2. **“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.
- 2.3. **“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.
- 2.4. **“Customers” or “Buyers”** means customers or buyers of Products that are distributed and sold by Eversana.
- 2.5. **“Diverted Product”** means: (i) expired, defective, or out of specification Product that is diverted from planned destruction; (ii) Product within Evoke’s product quality specifications that is intended for one market and sold or transferred into another market in violation of applicable laws, regulations, Evoke policies, or Evoke contracts; (iii) Product stolen from within the distribution or supply chain; (iv) Product acquired, repackaged, and sold by a third party in a standard or customary size or unit of measure that Evoke currently offers for sale in the Territory; or (v) Product sold by Evoke for use in non-domestic markets which is subsequently sold or imported for sale or use in the Territory.
- 2.6. **“FDA”** means the United States Food and Drug Administration.
- 2.7. **“Joint Management Committee”** has the meaning set forth in Section 4 of the CSA.
- 2.8. **“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.
- 2.9. **“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.
- 2.10. **“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.

- 2.11. **“Premises”** means Eversana’s corporate office and its warehouse facilities located at either; (i) 10887 Commerce Way, Unit B, Fontana, CA 92336; (ii) 4550 and 4580 Mendenhall Road, Memphis, Tennessee 38141, (iii) 5650 Challenge Drive, Memphis, TN 38118, or (iv) such other facilities as Eversana and Evoke may mutually agree.
- 2.12. **“Product”** means Gimoti™, the nasally delivered formulation of metoclopramide that is the subject of New Drug Application No. 209388.
- 2.13. **“Replacement Cost”** means Evoke’s incremental, actual manufacturing cost to replace Products lost or damaged.
- 2.14. **“Services”** means the day-to-day supervision and management by Eversana of the Commercialization of the Product in the Territory, including the Pre-Commercial Services, the Commercial Services, and the Functional Services.
- 2.15. **“Term”** shall have the meaning set forth in Section 11.
- 2.16. **“Territory”** means the United States and all of its territories and possessions.
- 2.17. **“Third Party”** means any person or entity other than Evoke, Eversana and their respective Affiliates.

3. EVERSANA 3PL OBLIGATIONS

- 3.1. **Cash Services.** Eversana shall provide order to cash services, including, at Evoke’s request, customer service, customer management, Product maintenance, pricing maintenance, order management, invoicing, reconciliation of remittance to invoice, cash application to Evoke lock box, accounts receivable and adjustments, and provide standard reporting associated therewith.
- 3.2. **Chargeback Processing.** Eversana shall provide chargeback processing services, including maintenance of hardware and software necessary to process chargebacks, maintenance of Evoke contracts (including membership eligibility, products, pricing and contract terms), processing and verification of each submitted chargeback line (including contract number, prime vendor, customer, product, contract price, sale date, Wholesale Acquisition Cost (WAC)), necessary calculations, payments due, discrepancy reporting and submission of reconciliation reports to Evoke, and provide standard reporting associated therewith.
- 3.3. **Government Reporting.** Eversana shall provide the government price reporting and other services specified in the Government Program Pricing & Rebate Administration Services section of Exhibit A attached hereto, in accordance with those agreements of Evoke with each of the Centers for Medicare & Medicaid Services (CMS), the Public Health Service (PHS), and the Department of Veterans Affairs.
- 3.4. **Logistics.** Eversana shall provide logistics services as set forth in further detail in this Agreement, including without limitation storage, warehousing, inventory management, and packing and shipping of Products to Customers.

4. EVOKE OBLIGATIONS

- 4.1 **Product Delivery.** Evoke or its designee will deliver Products to the Premises, as specified by

Eversana in Product orders pursuant to Section 5.4, during Eversana's normal business hours or at other times as agreed to by the Parties.

- 4.2. **Product Marking, Labeling and Packaging.** Evoke will mark, label, and package all Products in accordance with all Applicable Laws and include a manifest showing sizes or specific stock keeping units.
- 4.3. **Compliance.** Evoke will supply Products that comply with all Applicable Laws, consistent with Evoke's legal and regulatory compliance obligations under the CSA, including, without limitation, those with respect to the labeling, packaging, reporting of pricing under government programs of the Products.
- 4.4. **True and Correct Information.** Evoke will provide Eversana on a timely basis with true and correct information that Evoke is required to provide to Eversana under the CSA for Eversana to perform its duties hereunder, including, without limitation, copies of regulatory filings and prompt review and approval of promotional materials and sales force training materials.
- 4.5. **Delegation.** As reflected in the Delegation of Authority attached hereto as Exhibit A, Evoke has delegated to Eversana the authority to submit and, if required, to certify price reports submitted to CMS and the Department of Veterans Affairs and to satisfy any additional State reporting requirements (current and future) after Evoke has reviewed and approved the price report and authorized Eversana to submit that report.

5. SUPPLY

- 5.1. **Manufacturing.** Evoke will Manufacture or have Manufactured Product by suppliers of its choice.
- 5.2. **Exclusivity.** Eversana shall purchase from Evoke all of its requirements of the Product. Eversana shall not purchase any Product or any generic versions of the Product from any person or entity other than Evoke.
- 5.3. **Forecast.** Within sixty (60) days after the execution of this Agreement, the Joint Management Committee will meet and determine in good faith the initial launch quantities of Product to be supplied by Evoke to Eversana during the first ninety (90) days after commercial launch of the Product. Thereafter, at least sixty (60) days before the beginning of each calendar quarter, Eversana shall provide the Joint Management Committee with all information, including without limitation the four (4) week average demand for the immediately preceding ninety (90) days, necessary for the Joint Management Committee to establish the quarterly forecast for the next twelve (12) months under this Section 5.3. The most recent three (3) months of each such forecast by the Joint Management Committee shall update and replace prior forecasts as to all calendar quarters covered by such forecast. Notwithstanding the foregoing, Evoke will use commercially reasonable efforts to maintain, or require its contract manufacturer to maintain, a minimum inventory of Product sufficient to meet the most recent three (3) months of the current forecast.
- 5.4. **Orders.** On a quarterly basis, unless more frequently as deemed necessary by the Joint Management Committee, Eversana shall submit to Evoke an order for Product. Each order shall specify (i) the quantity of the Product to be shipped based on the forecast established by the Joint Management Committee under Section 5.3; (ii) a shipment date ("**Shipment Date**"), which shall be a date agreed upon by the Joint Management Committee; and (iii) a Product delivery

destination.

- 5.5. **Fulfillment of Orders.** Evoke shall use commercially reasonable efforts to accept and fill all Orders placed under this Agreement that are received by it during the Term, which specify Shipment Dates within the Term, has a Product quantity within one hundred and twenty percent (120%) of the forecasted quantity for the applicable period and which otherwise conform to the terms of this Agreement. Evoke shall acknowledge all Orders in writing within two (2) business days after receipt thereof. Evoke (itself or through its designated manufacturer or other subcontractor) shall deliver Products to the carrier by the requested Shipment Date, subject to the lead times set forth in Section 5.4.
- 5.6. **Rescheduling; Modifications.** At any time prior to the Shipment Date Eversana may request rescheduling or deferral of such order or specify a different delivery address, provided, however Evoke has reasonable discretion to grant or reject such changes, and Eversana shall reimburse Evoke for Evoke's costs and expenses for Product handling, storage and freight as a result of such change request.
- 5.7. **Shipping.** Subject to Section 5.6, Evoke (or its contract manufacturer) shall ship all Products to Eversana DAP (INCOTERM 2010) to the delivery destination specified in Eversana's order and be responsible for all handling, transportation, freight and other charges for shipments of Product to Eversana. Unless otherwise agreed by the Parties in writing, Evoke will have sole discretion to determine the time, route, and carrier of all Product shipments.
- 5.8. **Order Acceptance.** Eversana shall: (i) accept delivery of each shipment of Product ordered by Eversana; (ii) accept each shipment of Product in its entirety from the carrier as delivered; and (iii) not reject or refuse any part of any shipment of Product from the carrier.
- 5.9. **Defective Shipment.** If a shipment of Product was sent to Eversana by Evoke in error, damaged during transit, and/or short in quantity of Product, Eversana shall not revoke any acceptance of the shipment and shall notify Evoke promptly after receipt of the shipment. In the case of any concealed damage or concealed shortage in any shipment of Product, Eversana shall notify Evoke promptly upon discovery. Eversana acknowledges and agrees that the risk of loss shall pass to Eversana as set forth in section 5.10 below and risk of loss shall not pass back to Evoke because of any shipping error, damage, shortage, or for any other reason. Eversana shall provide any and all documentation requested by Evoke in connection with the matter. Eversana shall return any Product to Evoke or its designee upon request, in accordance with instructions provided by Evoke.
- 5.10. **Risk of Loss.** Eversana accepts the risk of loss of all Products at its Premises or in its possession, custody or control from the time of purchase of such Products at the Premises to the time such Product is transferred to Customers by Eversana to outbound carriers for delivery to Customers.

6. PAYMENT; TITLE

6.1 Invoicing and Payment.

- a. As set forth in the CSA, Evoke will invoice Eversana's 3PL division for Products at [***], or an otherwise agreed upon rate established by the Joint Management Committee. The invoice for all Products purchased during the first [***] after commercial launch of the Product shall be due [***] from the date of the invoice. All invoices thereafter shall be due [***] from the date of the invoice. Eversana agrees that for each sale of Products from Evoke to Eversana, Eversana will issue a resale certificate to Evoke indicating that Eversana will only resell the Products as approved by the Joint Management Committee.
- b. Eversana will invoice the Buyers and collect payment from the Buyers. Evoke shall reimburse Eversana's Commercialization Costs pursuant to Section 5.3 of the CSA.
- c. Eversana will send payment reminders to Buyers every [***] days starting on the date that is [***] days after the Buyers' receipt of the applicable invoice and will stop sending such reminders when payment for the applicable invoice is satisfied. On a monthly basis, Eversana will provide to Evoke a list of Buyers who are delinquent on payment obligations in accordance with this subsection. For clarity, if based on Manufacturer's current invoicing terms, the invoice due date is [***] days from the date of the invoice if payment is made in cash or by check and [***] days if payment is made by ACH transfer (each with a [***]% discount for payments received on or before the invoice due date).
- d. Eversana shall fill orders for a Product only with that Product and shall not substitute orders for a Product with any other pharmaceutical product or item.
- e. Eversana shall maintain a prompt delivery service to its Customers compatible with good business practice, the nature of the Product, and the requirements of Customers.
- f. Eversana will fulfill orders and ship [***] after the business day that orders are received.
- g. At the request of Evoke, Eversana will transition to non-title model services with at least [***] of notice by Evoke and commencing upon the month end following the duration of the notification. Eversana will continue to process Accounts Receivables for any Buyer that has an outstanding balance and remit payment to Evoke based on the terms outlined in this section until such time that all Accounts Receivable balances have been collected or written off. Any product currently owned by Eversana will be returned to Evoke for credit at the price of the originally purchase(s).

6.2 Title. Ownership and title to all Products at the Premises or under Eversana's custody or control shall remain with Evoke until such time the Product is sold by Eversana or its Affiliate to Customers, at which time ownership and title of the Product shall transfer to Eversana and remain with Eversana until delivery of the Product to Customers.

7. HANDLING AND STORAGE

7.1. Inventory Management. Eversana shall rotate its inventory of Product based upon the first expiry, first out (FEFO) inventory system.

*** Certain information on this page has been omitted.

- 7.2. **Product Handling.** Eversana shall maintain, handle, store, transport, deliver and/or otherwise manage and distribute Product supplied by Evoke in accordance with the handling and storage requirements applicable to each Product as contained in the package insert for the Product approved by the FDA and any other instructions provided by Evoke in writing to Eversana, and in accordance with Applicable Laws. Eversana shall not distribute or attempt to return for credit any Product that was not maintained in accordance with all applicable handling and storage requirements and specifications, this Agreement and Applicable Law, unless the Product is within the permitted excursion range.
- 7.3. **Product Modifications.** Eversana shall not alter, modify, adulterate, replace, or reproduce any Product labeling, packaging, or advertising without Evoke's prior written consent.

8. PRODUCT RETURNS AND RECALLS

- 8.1. **Policy.** Subject to Article 7 of the CSA, all Product returns and recalls shall be subject to the "Evoke Return Goods Policy" and "Evoke Recalled Goods Policy" respectively, both of which shall be approved by the Joint Management Committee at least thirty (30) days before commercial launch of the Product. Eversana shall be responsible for enforcing Customer compliance with the Evoke Return Goods Policy, carrying out all recall procedures mandated in the Evoke Recalled Goods Policy and handling the disposition of all returned and recalled Products. Unless otherwise instructed by Evoke, Eversana shall promptly destroy all returned and recalled Products in accordance with Applicable Law.
- 8.2. In the event of a conflict between this Agreement and Evoke's Return Goods Policy, this Agreement shall control.

9. COMPLIANCE MATTERS

- 9.1. **Qualifications.** Eversana shall maintain all licenses, registrations, certifications, and other qualifications required by Applicable Law for Eversana to distribute Product and otherwise perform its obligations pursuant to this Agreement (the "**Qualifications**") including, without limitation, Drug Enforcement Agency (DEA) numbers, and shall provide reasonable documentation of all such Qualifications to Evoke upon written request.
- 9.2. **Notice.** Eversana shall promptly notify Evoke of any denial, revocation or suspension of any of the Qualifications or any changes in the type or class of products which Eversana is authorized to distribute. If such denial, revocation, suspension, or change impacts Eversana's ability to perform Services under this Agreement, Evoke may, in its sole discretion, immediately upon written notice to Eversana: (i) terminate this Agreement in its entirety; or (ii) suspend the application of this Agreement with regard to any affected Product or Premises for so long as Evoke deems appropriate.
- 9.3. **Cooperation.** Eversana shall notify Evoke promptly but in no event more than [***] business days after receiving notice from any federal, state or local governmental agency of any investigation or inspection specifically concerning any Product. Eversana shall allow Evoke to assist in and/or review any response to any such notice, if Evoke so requests. Eversana shall provide Evoke with copies of any and all associated written correspondence received from such governmental

*** Certain information on this page has been omitted.

agency within [***] business days of receipt thereof. During the course of any such investigation or inspection, Eversana shall keep Evoke informed of the steps taken by Eversana to resolve any outstanding issues with any such governmental agency and the anticipated timetable of resolution of such issues as it applies to Product. Evoke acknowledges that Eversana's ability to comply with its obligations with respect to Evoke under Section 7.3 may be limited by Applicable Law.

9.4. **Status as an Authorized Distributor of Record.** Both Eversana and Evoke agree and acknowledge that (i) this Agreement and the CSA evidence the parties' "ongoing relationship" (as that term is defined by the Food and Drug Administration in 21 CFR § 203.3(u), as amended) for the distribution of Evoke's Product; and (ii) Eversana is at all times during the Term an "authorized distributor of record" (as that term is defined by the Food and Drug Administration in 21 CFR § 203.3(b), as amended) for Products. Eversana's status as an authorized distributor of record shall be reflected in Evoke's list of authorized distributors of record ("**List**") at all times during the Term. Evoke shall comply fully with 21 CFR § 203.50(d), as amended with respect to maintaining (and granting access to) the List. The parties hereto understand and agree that the Agreement may be made available to the FDA upon the FDA's request.

10. STANDARD OF CARE; LOSS LIMITATIONS

10.1

(a) Evoke shall be solely responsible for the care, custody and control of Products at all times prior to transfer of title of such Products to Eversana at the Premises. Eversana shall be solely responsible for the care, custody and control of Products at all times after such transfer of title of such Products to Eversana at the Premises.

(b) Notwithstanding anything to the contrary contained herein, in no event shall Eversana have liability (whether by indemnification or otherwise) for: (i) any loss or damage attributable to events, circumstances or conditions which shall constitute a Force Majeure; or (ii) unexplained loss, mysterious disappearance (including theft), misshipment, loss or shortage of Product disclosed upon the taking of an inventory, or other shrinkage of Product (collectively, "**shrinkage**") to the extent that such annual shrinkage does not exceed [***] of the aggregate annual number of Product units handled by Eversana.

(c) Notwithstanding anything to the contrary contained herein, Evoke's exclusive remedy for any loss or damage to Products that may arise from this Agreement or Eversana's Channel Management Services hereunder is recovery of the Replacement Cost of such Products lost or damaged.

10.3 Evoke may select all freight carriers for the transport of Products from Evoke to Eversana. If Evoke declines or fails to designate its preferred carriers, Eversana may select the carriers. In either case, even if Eversana is listed as the applicable shipper on any bill of lading or other instrument, Evoke acknowledges that: (i) Eversana is not responsible for the Products except after the time title to such Products are transferred to Eversana at the Premise; and (ii) to the extent that Product has not been purchased by Eversana, Evoke's sole recourse for freight loss, damage, injury or delay in the delivery of Products tendered by Evoke for delivery to a carrier (collectively, "**Freight Claims**") is an action by

*** Certain information on this page has been omitted.

Evoke against the applicable carrier, subject to all terms, conditions, claims procedures, and loss limitations applicable to such carrier under Applicable Laws, tariffs or agreements with such carrier. Evoke waives and releases Eversana from all Freight Claims against Eversana.

11. AUDITS

- 11.1. **Site Visit.** Evoke has conducted a virtual visit and inspection] of the Premises and observed the Eversana standard operating procedures and the standard practices and procedures employed by Eversana thereat. Evoke acknowledges that as of the Effective Date, the Premises, the Eversana standard operating procedures and such observed practices and procedures are acceptable to Evoke with respect to the performance by Eversana of its Services hereunder.
- 11.2. **Facility Audits.** Once within [***] months before commercial launch of the Product and once per year after the launch of the Product, Evoke shall have the right, to visit and physically inspect the Premises and observe Eversana's standard operating procedures and the standard practices and procedures employed by Eversana in connection with Eversana's obligations herein and under the CSA, provided, however, to the extent Evoke finds such observed practices and procedures in breach of Applicable Law or this Agreement, Eversana shall promptly take corrective action and allow Evoke to re-visit and re-inspect as soon as practicable until such breach has been cured and deemed acceptable by Evoke. Such audits shall be limited to [***] business days per occurrence and no more than eight (8) hours per day.
- 11.3. **Inventory Audits.** Notwithstanding anything to the contrary in the CSA, Evoke representatives (who may include third parties retained by Evoke to assist with the inspection) may, at Evoke's sole expense, audit the inventory of Products located at the Premises. Any third-party auditor shall execute a mutually agreeable nondisclosure agreement with Eversana. Any audit must be conducted upon reasonable prior written notice. Evoke may conduct inventory audits once per calendar quarter (or more frequently for cause). Evoke may conduct audits on practices and procedures once per calendar year (or more frequently for cause). All audits shall occur during normal business hours and shall not last more than [***] business day and shall be limited to a review of events and records occurring in since the prior audit (except where for cause). All audits shall be conducted in a manner so as to not unreasonably disrupt normal warehouse and other Eversana operations.

12. REPRESENTATIONS AND WARRANTIES

- 12.1. **Evoke's Representations and Warranties.** Evoke represents, warrants and covenants that as of the Effective Date and within the Term of this Agreement:
- a. it will comply with Applicable Law governing the purchase, handling, sale, distribution, and price reporting of Products sold by it under this Agreement;
 - b. it will own or hold (as of the commercial launch date of the Product) the duly approved New Drug Application, as defined in the Federal Food, Drug and Cosmetic Act, Title 21, United States Code, as amended, and the rules and regulations promulgated thereunder, for the Products, or is otherwise considered the "manufacturer" of the Products under the Drug Quality and Security Act;

*** Certain information on this page has been omitted.

- c. it will (as of the commercial launch date of the Product) maintain, in full force and effect, licenses, clearances, approvals, registrations, and permits required under applicable federal, state or local law for Evoke to manufacture, sell and distribute Products under this Agreement; and
- d. it has good and marketable title to the Products sold to Eversana under this Agreement, and all Products will be sold to Eversana free and clear of all liens, claims, security interests or other encumbrances.

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

- a. it will not import, sell, resell, distribute, market, or promote any Product marketed by Evoke outside the Territory;
- b. it will not export, sell, resell, distribute, market, or promote any Product to persons or entities outside of the Territory or knowingly to persons or entities inside the Territory for their export, sale, resale or distribution outside the Territory;
- c. it will not knowingly sell or distribute any Diverted Product. Should any Product that Eversana knows to be Diverted Product come into Eversana's possession, Eversana shall immediately deliver such Diverted Product to Evoke. Eversana shall promptly notify Evoke in writing upon becoming aware of any entity or person offering, selling or purchasing Diverted Product, and shall fully cooperate with any investigation of same;
- d. it will comply with all Applicable Law governing the shipping, handling, storage, and distribution of Product;
- e. it will receive, warehouse and, pursuant to Evoke's instructions, ship Products from the Premises and provide standard reporting associated therewith.
- f. it will fill orders for Product only with Product and shall not substitute any orders for Product with other items not manufactured by Evoke;
- g. it will not alter, modify, replace, or reproduce any Product labeling, packaging, or advertising without Evoke's prior written consent;
- h. it will, to the extent not prohibited by law: (i) notify Evoke promptly of any investigation or inspection of federal, state or local regulatory representatives directed to Eversana (or any of its subcontractors or affiliates) relating to or concerning the Product; (ii) allow Evoke, at Evoke's discretion, to provide comments for Eversana's consideration on any response to such governmental representatives; (iii) promptly provide to Evoke copies of any associated written correspondence received from and provided to the governmental agency to the extent permitted by law or regulation; and (iv) otherwise keep Evoke fully informed of the status and the steps taken by Eversana to resolve any outstanding issues with any such governmental agency; and
- i. it will maintain the Premises and perform the warehousing, distribution and other services specified hereunder in material compliance with (i) applicable Eversana Standard Operating Procedures and (ii) any special operating procedures specified by

Evoke, agreed to by Eversana, provided that Eversana shall not be responsible for compliance to the extent Eversana's inability to comply is directly attributable to Evoke's failure to comply with its material obligations hereunder, and further provided that in such event, Eversana has a duty to mitigate the non-compliance and immediately notify Evoke of such impossibility to comply.

13. TERM AND TERMINATION

- 13.1. **Term.** This Agreement shall take effect as of the Effective Date and shall automatically expire or terminate concurrently with the expiration or termination of CSA (the "**Term**").
- 13.2. **Termination.** This Agreement may be terminated before the termination or expiration of the CSA by mutual agreement of the Parties. Either Party may terminate this Agreement if the other Party materially breaches this Agreement, including any representation, warranty, or covenant contained herein, and such breach is not cured or cannot be cured within sixty (60) days upon receipt from the other Party of written notice specifying in detail the nature and extent of the alleged material breach.
- 13.3. **Survival.** The rights and obligations of the Parties set forth in Section 1 (Definitions), Section 9 (Compliance Matters), Section 10 (Standard or Care; Loss Limitations), and Section 13 (Term and Termination) shall survive the termination or expiration of this Agreement.

[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.

Name: David A. Gonyer

Title: Chief Executive Officer

/s/ David A. Gonyer

Eversana: Eversana Life Science Services, LLC

Name: Gregory Skalicky

Title: Chief Revenue Officer

/s/ Gregory Skalicky

EXHIBIT A
Delegation of Authority to File and Certify Price Reports

Labeler Code(s): [Insert NDC(s)]

Evoke Pharma, Inc. ("Evoke") and Eversana Life Science Services, LLC ("Eversana") are parties to the Commercial Service Agreement dated as of January 21, 2020 ("Agreement"). In accordance with the terms of the Agreement, and effective as of the date of the Agreement, Evoke hereby delegates to Eversana the authority to submit and, if required, to certify: (1) the Medicaid Average Manufacturer Price (AMP) and Best Price calculations for the legal entity and labeler code/NDCs identified above in the Drug Data Reporting for Medicaid (DDR) system maintained by the Centers for Medicare and Medicaid Services (CMS); (2) price reports submitted to the Department of Veterans Affairs; and (3) price reports needed to satisfy any additional State reporting requirements (current and future) This delegation is to be executed strictly in accordance with the following conditions:

1. On a monthly and quarterly basis, subsequent to Eversana's receipt of approved pricing data or reports for the designated period after review by an individual at Evoke authorized to approve the pricing data and reports, as listed here:

<u>Name</u>	<u>Title</u>
_____	_____
_____	_____
_____	_____

2. Only for those labeler codes/NDCs over which I have responsibility and have delegated my signature authority;
3. In the event that Eversana is not available, this delegation directly transfers to [●], subject to the above conditions as well.
4. This delegation is valid for [●] months from the date of its execution, except to the extent that the designated certifier or approver are no longer in their current positions, in which case a new delegation will be required to be executed.

If any of the above conditions are not met in any month or quarter, this delegation is ineffective absent further written direction. For example, this delegation will be ineffective in the event that approved calculations are received from an individual other than the named individuals above.

By: _____
Title: _____

(CEO, CFO or individual with equivalent authority)

Date Authorized: [●] Date Authorization Terminates: [●]

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: November 10, 2020

/s/ David A. Gonyer

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

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: November 10, 2020

/s/ Matthew J. D'Onofrio

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

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 September 30, 2020 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: November 10, 2020

/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.

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 September 30, 2020, 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: November 10, 2020

/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.

**Document and Entity
Information - shares**

**9 Months Ended
Sep. 30, 2020**

Nov. 02, 2020

Cover [Abstract]

<u>Document Type</u>	10-Q	
<u>Amendment Flag</u>	false	
<u>Document Period End Date</u>	Sep. 30, 2020	
<u>Document Fiscal Year Focus</u>	2020	
<u>Document Fiscal Period Focus</u>	Q3	
<u>Trading Symbol</u>	EVOK	
<u>Entity Registrant Name</u>	Evoke Pharma Inc	
<u>Entity Central Index Key</u>	0001403708	
<u>Entity Current Reporting Status</u>	Yes	
<u>Entity Interactive Data Current</u>	Yes	
<u>Current Fiscal Year End Date</u>	--12-31	
<u>Entity Filer Category</u>	Non-accelerated Filer	
<u>Entity Small Business</u>	true	
<u>Entity Emerging Growth Company</u>	false	
<u>Title of 12(b) Security</u>	Common Stock, par value \$0.0001 per share	
<u>Security Exchange Name</u>	NASDAQ	
<u>Entity File Number</u>	001-36075	
<u>Entity Tax Identification Number</u>	20-8447886	
<u>Entity Address, Address Line One</u>	420 Stevens Avenue	
<u>Entity Address, Address Line Two</u>	Suite 370	
<u>Entity Address, City or Town</u>	Solana Beach	
<u>Entity Address, State or Province</u>	CA	
<u>Entity Address, Postal Zip Code</u>	92075	
<u>City Area Code</u>	858	
<u>Local Phone Number</u>	345-1494	
<u>Entity Incorporation, State or Country Code</u>	DE	
<u>Entity Shell Company</u>	false	
<u>Entity Common Stock, Shares Outstanding</u>		26,390,246
<u>Document Quarterly Report</u>	true	
<u>Document Transition Report</u>	false	

Condensed Balance Sheets
(Unaudited) - USD (\$)

	Sep. 30,	Dec. 31,
	2020	2019
<u>Current Assets:</u>		
<u>Cash and cash equivalents</u>	\$ 6,280,656	\$ 5,663,833
<u>Prepaid expenses</u>	336,432	581,706
<u>Inventory</u>	86,145	
<u>Other current assets</u>	11,551	
<u>Total current assets</u>	6,714,784	6,245,539
<u>Operating lease right-of-use asset</u>	36,115	138,538
<u>Other assets</u>		11,551
<u>Total assets</u>	6,750,899	6,395,628
<u>Current Liabilities:</u>		
<u>Accounts payable and accrued expenses</u>	765,603	1,033,383
<u>Accrued compensation</u>	715,423	843,162
<u>Operating lease liability</u>	36,115	138,538
<u>Paycheck protection program loan</u>	104,168	
<u>Milestone payable</u>	5,000,000	
<u>Total current liabilities</u>	6,621,309	2,015,083
<u>Long-term Liabilities:</u>		
<u>Note payable</u>	2,000,000	
<u>Accrued interest payable</u>	53,005	
<u>Total long-term liabilities</u>	2,053,005	
<u>Total liabilities</u>	8,674,314	2,015,083
<u>Stockholders' equity:</u>		
<u>Common stock, \$0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 26,332,122 and 24,431,914 at September 30, 2020 and December 31, 2019, respectively</u>	2,633	2,443
<u>Additional paid-in capital</u>	94,691,151	90,108,492
<u>Accumulated deficit</u>	(96,617,199)	(85,730,390)
<u>Total stockholders' (deficit) equity</u>	(1,923,415)	4,380,545
<u>Total liabilities and stockholders' (deficit) equity</u>	\$ 6,750,899	\$ 6,395,628

Condensed Balance Sheets
(Parenthetical) (Unaudited) -
\$ / shares

Sep. 30, 2020 Dec. 31, 2019

Statement Of Financial Position [Abstract]

<u>Common stock, par value</u>	\$ 0.0001	\$ 0.0001
<u>Common stock, shares authorized</u>	50,000,000	50,000,000
<u>Common stock, shares issued</u>	26,332,122	24,431,914
<u>Common stock, shares outstanding</u>	26,332,122	24,431,914

Condensed Statements of Operations (Unaudited) - USD (\$)	3 Months Ended		9 Months Ended	
	Sep. 30, 2020	Sep. 30, 2019	Sep. 30, 2020	Sep. 30, 2019
<u>Operating expenses:</u>				
<u>Research and development</u>	\$ 205,032	\$ 822,444	\$ 6,450,979	\$ 2,774,924
<u>General and administrative</u>	1,874,578	814,218	4,387,284	2,955,371
<u>Total operating expenses</u>	2,079,610	1,636,662	10,838,263	5,730,295
<u>Loss from operations</u>	(2,079,610)	(1,636,662)	(10,838,263)	(5,730,295)
<u>Other income (expense):</u>				
<u>Interest income</u>	1,033	8,597	4,896	22,868
<u>Interest expense</u>	(50,528)		(53,442)	
<u>Total other income (expense)</u>	(49,495)	8,597	(48,546)	22,868
<u>Net loss</u>	\$ (2,129,105)	\$ (1,628,065)	\$ (10,886,809)	\$ (5,707,427)
<u>Net loss per share of common stock, basic and diluted</u>	\$ (0.08)	\$ (0.07)	\$ (0.43)	\$ (0.26)
<u>Weighted-average shares used to compute basic and diluted net loss per share</u>	26,146,220	24,128,060	25,191,359	21,623,648

Condensed Statements of Stockholders' (Deficit) Equity (Unaudited) - USD (\$)	Total	At The Market Offering [Member]	Common Stock [Member] At The Market Offering [Member]	Common Stock [Member] At The Market Offering [Member]	Additional Paid-In Capital [Member]	Additional Paid-In Capital [Member] At The Market Offering [Member]	Accumulated Deficit [Member]
Beginning Balance at Dec. 31, 2018	\$ 4,025,320		\$ 1,743		\$ 82,628,312		\$ (78,604,735)
Beginning Balance, Shares at Dec. 31, 2018			17,427,533				
Stock-based compensation expense	378,959				378,959		
Issuance of common stock, net	636,432		\$ 45		636,387		
Issuance of common stock, shares net			450,000				
Net loss	(1,965,266)						(1,965,266)
Ending Balance at Mar. 31, 2019	3,075,445		\$ 1,788		83,643,658		(80,570,001)
Ending Balance, Shares at Mar. 31, 2019			17,877,533				
Beginning Balance at Dec. 31, 2018	4,025,320		\$ 1,743		82,628,312		(78,604,735)
Beginning Balance, Shares at Dec. 31, 2018			17,427,533				
Net loss	(5,707,427)						
Ending Balance at Sep. 30, 2019	5,173,197		\$ 2,423		89,482,936		(84,312,162)
Ending Balance, Shares at Sep. 30, 2019			24,231,914				
Beginning Balance at Mar. 31, 2019	3,075,445		\$ 1,788		83,643,658		(80,570,001)
Beginning Balance, Shares at Mar. 31, 2019			17,877,533				
Stock-based compensation expense	344,841				344,841		
Issuance of common stock, net	5,039,956		\$ 623		5,039,333		
Issuance of common stock, shares net			6,236,423				
Net loss	(2,114,096)						(2,114,096)
Ending Balance at Jun. 30, 2019	6,346,146		\$ 2,411		89,027,832		(82,684,097)
Ending Balance, Shares at Jun. 30, 2019			24,113,956				
Stock-based compensation expense	331,303				331,303		

<u>Issuance of common stock, net</u>	123,813	\$ 12	123,801	
<u>Issuance of common stock, shares net</u>		117,958		
<u>Net loss</u>	(1,628,065)			(1,628,065)
<u>Ending Balance at Sep. 30, 2019</u>	5,173,197	\$ 2,423	89,482,936	(84,312,162)
<u>Ending Balance, Shares at Sep. 30, 2019</u>		24,231,914		
<u>Beginning Balance at Dec. 31, 2019</u>	\$ 4,380,545	\$ 2,443	90,108,492	(85,730,390)
<u>Beginning Balance, Shares at Dec. 31, 2019</u>	24,431,914	24,431,914		
<u>Stock-based compensation expense</u>	\$ 310,162		310,162	
<u>Issuance of common stock from employee stock purchase plan</u>	21,250	\$ 3	21,247	
<u>Issuance of common stock from employee stock purchase plan, shares</u>		25,000		
<u>Net loss</u>	(1,790,309)			(1,790,309)
<u>Ending Balance at Mar. 31, 2020</u>	2,921,648	\$ 2,446	90,439,901	(87,520,699)
<u>Ending Balance, Shares at Mar. 31, 2020</u>		24,456,914		
<u>Beginning Balance at Dec. 31, 2019</u>	\$ 4,380,545	\$ 2,443	90,108,492	(85,730,390)
<u>Beginning Balance, Shares at Dec. 31, 2019</u>	24,431,914	24,431,914		
<u>Issuance of common stock from warrant exercise, shares</u>	381,625			
<u>Issuance of common stock from stock option exercise, shares</u>	4,237			
<u>Net loss</u>	\$ (10,886,809)			
<u>Ending Balance at Sep. 30, 2020</u>	\$ (1,923,415)	\$ 2,633	94,691,151	(96,617,199)
<u>Ending Balance, Shares at Sep. 30, 2020</u>	26,332,122	26,332,122		
<u>Beginning Balance at Mar. 31, 2020</u>	\$ 2,921,648	\$ 2,446	90,439,901	(87,520,699)
<u>Beginning Balance, Shares at Mar. 31, 2020</u>		24,456,914		
<u>Stock-based compensation expense</u>	362,955		362,955	
<u>Issuance of common stock, net</u>	\$ 3,309,116	\$ 140	\$ 3,308,976	

<u>Issuance of common stock, shares net</u>			1,395,855	
<u>Issuance of common stock from warrant exercises</u>		\$ 15	(15)	
<u>Issuance of common stock from warrant exercise, shares</u>		158,494		
<u>Net loss</u>	(6,967,395)			(6,967,395)
<u>Ending Balance at Jun. 30, 2020</u>	(373,676)	\$ 2,601	94,111,817	(94,488,094)
<u>Ending Balance, Shares at Jun. 30, 2020</u>		26,011,263		
<u>Stock-based compensation expense</u>	478,574		478,574	
<u>Issuance of common stock from employee stock purchase plan</u>	98,165	\$ 9	98,156	
<u>Issuance of common stock from employee stock purchase plan, shares</u>		93,491		
<u>Issuance of common stock from warrant exercises</u>		\$ 22	(22)	
<u>Issuance of common stock from warrant exercise, shares</u>		223,131		
<u>Issuance of common stock from stock option exercise</u>	2,627	\$ 1	2,626	
<u>Issuance of common stock from stock option exercise, shares</u>		4,237		
<u>Net loss</u>	(2,129,105)			(2,129,105)
<u>Ending Balance at Sep. 30, 2020</u>	\$ (1,923,415)	\$ 2,633	\$ 94,691,151	\$ (96,617,199)
<u>Ending Balance, Shares at Sep. 30, 2020</u>	26,332,122	26,332,122		

**Condensed Statements of
Cash Flows (Unaudited) -
USD (\$)**

**9 Months Ended
Sep. 30, 2020 Sep. 30, 2019**

Operating activities

Net loss \$ (10,886,809) \$ (5,707,427)

Adjustments to reconcile net loss to net cash used in operating activities:

Stock-based compensation expense 1,151,691 1,055,103

Milestone expense 5,000,000

Accrued interest 53,442

Change in operating assets and liabilities:

Prepaid expenses and other assets 261,552 (345,975)

Accounts payable and other current liabilities (498,379) 383,896

Net cash used in operating activities (4,918,503) (4,614,403)

Financing activities

Proceeds from issuance of common stock, net 3,309,116 5,800,201

Proceeds from issuance of common stock from employee stock purchase plan 119,415

Proceeds from issuance of common stock from stock option exercised 2,627

Proceeds from paycheck protection program 104,168

Proceeds from Eversana line of credit 2,000,000

Net cash provided by financing activities 5,535,326 5,800,201

Net increase in cash and cash equivalents 616,823 1,185,798

Cash and cash equivalents at beginning of period 5,663,833 5,319,004

Cash and cash equivalents at end of period \$ 6,280,656 \$ 6,504,802

Organization and Basis of Presentation

9 Months Ended
Sep. 30, 2020

[Organization And Basis Of Presentation \[Abstract\]](#)

[Organization and Basis of Presentation](#)

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 and commercialization of drugs to treat gastroenterological disorders and disease.

Since its inception, the Company has devoted its efforts to developing its sole product, Gimoti™ (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. On June 19, 2020, the Company received approval from the U.S. Food and Drug Administration (“FDA”) for its 505(b)(2) New Drug Application (“NDA”) for Gimoti. The Company launched U.S. commercial sales of Gimoti in October 2020 through its commercial partner Eversana Life Science Services, LLC (“Eversana”).

The Company’s activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has launched its first commercial product, including market acceptance of the product and the potential need to obtain additional funding for 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 had approximately \$6.3 million in cash and cash equivalents at September 30, 2020, the Company anticipates that it will continue to incur losses from operations due to commercialization activities, including manufacturing commercial batches of Gimoti, and general and administrative costs to support operations. 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. 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 financial statements do not include any adjustments that may result from the outcome of this uncertainty.

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 will be sufficient to fund its operations into the second quarter of 2021, excluding any potential additional borrowings from the revolving credit facility with Eversana (the “Eversana Credit Facility”), as discussed in Note 5, and future Gimoti product revenue. This period could be shortened if there are any unanticipated increases in planned spending. Even with the remaining amount available under the Eversana Credit Facility and future Gimoti product revenue, 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 commercialization activities. 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 successfully commercialize Gimoti. Because the Company’s business is entirely dependent on the success of Gimoti, if the Company is unable to secure additional financing, successfully commercialize Gimoti or identify and execute on strategic alternatives for Gimoti or the 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.

Contract Research Organizations and Consultants

The Company relies on contract research organizations (“CROs”) and consultants to assist with ongoing regulatory discussions and submissions to FDA. If these CROs and consultants are unable to continue their support, this could adversely affect the operations of the Company.

In addition, the Company relies on third-party suppliers and manufacturer 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 commercial supply demand for Gimoti and the commercialization of Gimoti could be materially and adversely affected.

The Company also relies on Eversana for the management of the commercialization of Gimoti, distribution services and a dedicated sales team to sell Gimoti. If Eversana is unable to continue serving as a dedicated sales team or distributing Gimoti, the commercialization of Gimoti could be materially and adversely affected.

Impact of COVID-19

To date, the Company has not experienced material disruptions to its financial condition or operations from the novel coronavirus disease (“COVID-19”) pandemic. The Company has begun its commercial activities, including commercial manufacturing, and with Eversana, the commercial sales of Gimoti. However, there can be no assurance that the Company or Eversana will not be impacted by the COVID-19 pandemic. For example, Eversana’s commercialization efforts may be adversely affected by operational restrictions imposed on its sales force from quarantines, travel restrictions and bans and other governmental restrictions related to COVID-19. As a result of these restrictions, their sales force may not be able to conduct in-person interactions with physicians and customers and may be restricted to conducting educational and promotional activities for Gimoti virtually, which may impact Eversana’s ability to market Gimoti. In addition, the COVID-19 pandemic may disrupt the operations of the Company’s third-party suppliers and manufacturers and delay the Company’s manufacturing timelines of Gimoti, which may negatively impact the Company’s ability to successfully commercialize Gimoti and generate product sales. Further, the COVID-19 pandemic and mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on the Company’s business and financial condition, including impairing its ability to raise capital when needed. In April 2020, the Company applied for and was approved for a Small Business Administration (“SBA”) loan under the Paycheck Protection Program (“PPP”), established by the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act. On May 1, 2020, the Company received the loan proceeds of approximately \$104,000. Processes are being developed for companies to submit for loan forgiveness and the Company plans to submit for loan forgiveness when such processes are finalized.

Summary of Significant Accounting Policies

9 Months Ended
Sep. 30, 2020

[Accounting Policies](#)

[\[Abstract\]](#)

[Summary of Significant Accounting Policies](#)

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2019, 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, 2019, which are contained in the Company’s Annual Report on Form 10-K filed with the SEC on March 12, 2020. 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.

Inventory

Subsequent to FDA approval of Gimoti in June 2020, the Company began a manufacturing process for the production of Gimoti for sale and began capitalizing inventory. As the manufacturing process was not completed until October 2020, the inventory was classified as work-in-process at September 30, 2020. Following the completion and release of the product by the Company’s manufacturer in October 2020, inventory is being stated at the lower of cost or net realizable value and recognized on a first-in, first-out method. Prior to FDA approval, expenses associated with the manufacturing of Gimoti were recorded as research and development expense.

The Company will analyze its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments will be recognized through cost of sales in the period in which they are incurred.

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, except awards with a performance condition. Awards with performance conditions commence vesting when the satisfaction of the performance condition is probable. 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, supplemented, as necessary, 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. The Company accounts for forfeitures as the forfeitures occur.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense, costs paid to third-party contractors for product development activities and drug product materials and technology acquisition milestones. The Company has expensed costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred prior to FDA approval received June 19, 2020.

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 depended on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its pre-commercial product development, and will continue to depend on such third-party manufacturers for its commercial manufacturing. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., through its subsidiary Patheon UK Limited, for the 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. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of 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 to do so would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Warrants to purchase common stock	1,841,879	2,713,561	1,841,879	2,713,561
Common stock options	4,273,065	3,114,371	4,273,065	3,114,371
Employee stock purchase plan	4,716	7,294	4,716	7,294
Total excluded securities	<u>6,119,660</u>	<u>5,835,226</u>	<u>6,119,660</u>	<u>5,835,226</u>

**Technology Acquisition
Agreement**

**9 Months Ended
Sep. 30, 2020**

[Technology Acquisition
Agreement \[Abstract\]](#)

[Technology Acquisition
Agreement](#)

3. 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 on the one-year anniversary after the Company receives FDA approval to market Gimoti. At the time of the Gimoti NDA approval by FDA, the Company recorded the \$5 million payable owed to Mallinckrodt with a due date of June 19, 2021, along with a \$5 million research and development expense.

The remaining \$47 million in milestone payments depend on Gimoti’s commercial success. 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, subject to possible extension should any additional, later expiring, patents be granted.

4. 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 nine months ended September 30, 2019, the Company sold 6,804,381 shares of common stock at a weighted-average price per share of \$0.87 pursuant to the FBR Sales Agreement and received proceeds of approximately \$5.8 million, net of commissions and fees. During the nine months ended September 30, 2020, the Company sold 1,395,855 shares of common stock at a weighted-average price per share of \$2.42 pursuant to the FBR Sales Agreement and received proceeds of approximately \$3.3 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.

Warrant Exercises

During the nine months ended September 30, 2020, certain holders of warrants exercised their warrants to purchase 871,682 shares of the Company's common stock by a "cashless" exercise and received 381,625 shares of the Company's common stock. The warrants had exercise prices ranging from \$2.41 to \$3.12 per share. The shares were issued, and the warrants were originally sold, in reliance upon the registration exemption set forth in Section 4(a)(2) of the Securities Act of 1933.

Stock Option Exercises

During the nine months ended September 30, 2020, certain holders of stock options exercised their stock options to purchase 4,237 shares of the Company's common stock. The stock options had exercise prices of \$0.62 per share.

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.

During the nine months ended September 30, 2020, the Company granted stock options to purchase 1,172,000 shares of the Company's common stock. Of such options, 437,500 did not begin vesting until the date that FDA approved the Gimoti NDA. 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 nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,	
	2020	2019
Common Stock Options		
Risk free interest rate	0.39% - 0.96%	1.80% - 2.55%
Expected option term	5.5 - 6.0 years	4.27 - 6.0 years
Expected volatility of common stock	99.73% - 103.99%	90.34% - 112.58%
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 and nine months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Employee Stock Purchase Plan				
Risk free interest rate	0.13%	1.89%	0.13% - 1.11%	1.89% - 2.52%
Expected term	0.5 years	0.5 years	0.5 years	0.5 years
Expected volatility of common stock	111.98%	170.68%	69.72% - 111.98%	130.36% - 170.68%
Expected dividend yield	0.0%	0.0%	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 during the three and nine months ended September 30, 2020 and 2019 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 31,186	\$ 179,227	\$ 286,148	\$ 533,518
General and administrative	447,388	152,076	865,543	521,585
Total stock-based compensation expense	<u>\$ 478,574</u>	<u>\$ 331,303</u>	<u>\$ 1,151,691</u>	<u>\$ 1,055,103</u>

As of September 30, 2020, there was approximately \$2.5 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 1.13 years.

**Commercial Services and
Loan Agreements with
Eversana**

9 Months Ended

Sep. 30, 2020

**[Commercial Services And
Loan Agreements \[Abstract\]](#)**

**[Commercial Services and
Loan Agreements with
Eversana](#)**

5. Commercial Services and Loan Agreements with Eversana

On January 21, 2020, the Company entered into a commercial services agreement (the “Eversana Agreement”) with Eversana for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States. Eversana will manage the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti within the United States.

Under the terms of the Eversana Agreement, the Company maintains ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. Eversana will utilize its internal sales organization, along with other commercial functions, for market access, marketing, distribution and other related patient support services. The Company will record sales for Gimoti and retain more than 80% of net product profits once the parties’ costs are reimbursed. Eversana will receive reimbursement of its commercialization costs pursuant to an agreed upon budget and a percentage of product profits in the mid-to-high teens. Net product profits are the net sales (as defined in the Eversana Agreement) of Gimoti, less (i) reimbursed commercialization costs, (ii) manufacturing and administrative costs set at a fixed percentage of net sales, and (iii) third party royalties. During the term of the Eversana Agreement, Eversana agreed to not market, promote, or sell a competing product in the United States.

The Eversana Agreement terminates on June 19, 2025, unless terminated earlier pursuant to its terms. Upon expiration or termination of the agreement, the Company will retain all profits from product sales and assume all corresponding commercialization responsibilities. Within 30 days after each of the first three annual anniversaries of commercial launch, either party may terminate the agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the agreement: for the material breach of the other party, subject to a 60-day cure period; in the event an insolvency, petition of the other party is pending for more than 60 days; upon 30 days written notice to the other party if Gimoti is subject to a safety recall; if the other party is in breach of certain regulatory compliance representations under the agreement; if the Company discontinues the development or production of Gimoti; if the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch; or if there is a change in applicable laws that makes operation of the services as contemplated under the agreement illegal or commercially impractical. Either party may also terminate the Eversana Agreement upon a change of control of the Company’s ownership, subject, in the event that the Company initiates such termination, to a one-time payment equal to between two times and one times annualized service fees paid by the Company under the Eversana Agreement, with such amount based on which year after commercial launch the change of control occurs. Such payment amount would be reduced by the amount of previously reimbursed commercialization costs and profit split paid for the related prior twelve-month period and any revenue which occurred prior to the termination yet to be collected. In addition, Eversana may terminate the Eversana Agreement if the Company withdraws Gimoti from the market for more than 90 days.

In connection with the Eversana Agreement, the Company and Eversana also entered into the Eversana Credit Facility, pursuant to which Eversana agreed to provide a revolving Credit Facility of up to \$5 million to the Company upon FDA approval of the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility terminates on June 19, 2025, unless terminated earlier pursuant to its terms. The Eversana Credit Facility is secured by all of the Company’s personal property other than its intellectual property. Under the terms of the Eversana Credit Facility, the Company cannot grant an interest in its intellectual property to any other person. Each loan under the Eversana Credit Facility will bear interest at an annual rate

equal to 10.0%, with such interest due at the end of the loan term. In June 2020, the Company borrowed \$2 million from the Eversana Credit Facility.

The Company may prepay any amounts borrowed under the Eversana Credit Facility at any time without penalty or premium. The maturity date of all amounts, including interest, borrowed under the Eversana Credit Facility will be 90 days after the expiration or earlier termination of the Eversana Agreement. The Eversana Credit Facility also includes events of default, the occurrence and continuation of which provide Eversana with the right to exercise remedies against the Company and the collateral securing the loans under the Eversana Credit Facility, including the Company's cash. These events of default include, among other things, the Company's failure to pay any amounts due under the Eversana Credit Facility, an uncured material breach of the representations, warranties and other obligations under the Eversana Credit Facility, the occurrence of insolvency events and the occurrence of a change in control.

Summary of Significant Accounting Policies (Policies)

9 Months Ended
Sep. 30, 2020

[Accounting Policies](#)

[\[Abstract\]](#)

[Use of Estimates](#)

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.

[Inventory](#)

Inventory

Subsequent to FDA approval of Gimoti in June 2020, the Company began a manufacturing process for the production of Gimoti for sale and began capitalizing inventory. As the manufacturing process was not completed until October 2020, the inventory was classified as work-in-process at September 30, 2020. Following the completion and release of the product by the Company's manufacturer in October 2020, inventory is being stated at the lower of cost or net realizable value and recognized on a first-in, first-out method. Prior to FDA approval, expenses associated with the manufacturing of Gimoti were recorded as research and development expense.

The Company will analyze its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments will be recognized through cost of sales in the period in which they are incurred.

[Stock-Based Compensation](#)

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, except awards with a performance condition. Awards with performance conditions commence vesting when the satisfaction of the performance condition is probable. 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, supplemented, as necessary, 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. The Company accounts for forfeitures as the forfeitures occur.

[Research and Development Expenses](#)

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense, costs paid to third-party contractors for product development activities and drug product materials and technology acquisition milestones. The Company has expensed costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred prior to FDA approval received June 19, 2020.

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 depended on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its pre-commercial product development, and will continue to depend on such third-party manufacturers for its commercial manufacturing. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., through its subsidiary Patheon UK Limited, for the 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](#)

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. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of 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 to do so would be anti-dilutive:

**Summary of Significant
Accounting Policies (Tables)**

**9 Months Ended
Sep. 30, 2020**

[Accounting Policies \[Abstract\]](#)

**[Summary of Outstanding Potentially
Dilutive Securities Excluded from
Calculation of Diluted Net Loss Per
Share](#)**

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 to do so would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Warrants to purchase common stock	1,841,879	2,713,561	1,841,879	2,713,561
Common stock options	4,273,065	3,114,371	4,273,065	3,114,371
Employee stock purchase plan	4,716	7,294	4,716	7,294
Total excluded securities	<u>6,119,660</u>	<u>5,835,226</u>	<u>6,119,660</u>	<u>5,835,226</u>

**Stockholders' Equity
(Tables)**

**9 Months Ended
Sep. 30, 2020**

[Equity \[Abstract\]](#)
[Summary of Estimated Fair
Value of Stock Option Award](#)

During the nine months ended September 30, 2020, the Company granted stock options to purchase 1,172,000 shares of the Company's common stock. Of such options, 437,500 did not begin vesting until the date that FDA approved the Gimoti NDA. 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 nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,	
	2020	2019
Common Stock Options		
Risk free interest rate	0.39% - 0.96%	1.80% - 2.55%
Expected option term	5.5 - 6.0 years	4.27 - 6.0 years
Expected volatility of common stock	99.73% - 103.99%	90.34% - 112.58%
Expected dividend yield	0.0%	0.0%

[Summary of Estimated Fair
Value of Shares to be Acquired
under Employee Stock
Purchase Plan](#)

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 and nine months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Employee Stock Purchase Plan				
Risk free interest rate	0.13%	1.89%	0.13% - 1.11%	1.89% - 2.52%
Expected term	0.5 years	0.5 years	0.5 years	0.5 years
Expected volatility of common stock	111.98%	170.68%	69.72% - 111.98%	130.36% - 170.68%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

[Summary of Recognized Non-Cash Stock-Based Compensation Expense](#)

The Company recognized non-cash stock-based compensation expense to employees and directors in its research and development and its general and administrative functions during the three and nine months ended September 30, 2020 and 2019 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 31,186	\$ 179,227	\$ 286,148	\$ 533,518
General and administrative	447,388	152,076	865,543	521,585
Total stock-based compensation expense	<u>\$ 478,574</u>	<u>\$ 331,303</u>	<u>\$ 1,151,691</u>	<u>\$ 1,055,103</u>

**Organization and Basis of
Presentation - Additional
Information (Detail) - USD
(\$)**

**Organization And Basis Of Presentation [Line
Items]**

Month and year of incorporation

Cash and cash equivalents

Paycheck Protection Program [Member] |

COVID-19 [Member]

**Organization And Basis Of Presentation [Line
Items]**

Proceeds from loan

	May 01, 2020	9 Months Ended Sep. 30, 2020	Dec. 31, 2019	Sep. 30, 2019	Dec. 31, 2018
		2007-01			
		\$ 6,280,656	\$ 5,663,833	\$ 6,504,802	\$ 5,319,004

\$ 104,000

**Summary of Significant
Accounting Policies -
Summary of Outstanding
Potentially Dilutive
Securities Excluded from
Calculation of Diluted Net
Loss Per Share (Detail) -
shares**

3 Months Ended 9 Months Ended

**Sep. 30, Sep. 30, Sep. 30, Sep. 30,
2020 2019 2020 2019**

**Antidilutive Securities Excluded From Computation Of Earnings
Per Share [Line Items]**

<u>Anti-dilutive securities excluded from the calculation of diluted net loss per share</u>	6,119,660	5,835,226	6,119,660	5,835,226
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Warrants to purchase common stock [Member]

**Antidilutive Securities Excluded From Computation Of Earnings
Per Share [Line Items]**

<u>Anti-dilutive securities excluded from the calculation of diluted net loss per share</u>	1,841,879	2,713,561	1,841,879	2,713,561
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Common stock options [Member]

**Antidilutive Securities Excluded From Computation Of Earnings
Per Share [Line Items]**

<u>Anti-dilutive securities excluded from the calculation of diluted net loss per share</u>	4,273,065	3,114,371	4,273,065	3,114,371
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Employee stock purchase plan [Member]

**Antidilutive Securities Excluded From Computation Of Earnings
Per Share [Line Items]**

<u>Anti-dilutive securities excluded from the calculation of diluted net loss per share</u>	4,716	7,294	4,716	7,294
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Technology Acquisition Agreement - Additional Information (Detail)	1 Months Ended		9 Months Ended	
	May 31, 2014 USD (\$)	Jun. 30, 2017 USD (\$)	Sep. 30, 2020 USD (\$) Milestone	Jun. 30, 2016 USD (\$)
Technology Acquisition Agreement [Line Items]				
Payment expensed as in-process research and development		\$ 650,000		
Mallinckrodt Plc [Member]				
Technology Acquisition Agreement [Line Items]				
Milestone payments contingent amount			\$ 5,000,000	
Number of milestone payments Milestone			1	
Mallinckrodt Plc [Member] Gimoti [Member]				
Technology Acquisition Agreement [Line Items]				
Amount payable to Mallinckrodt				\$ 5,000,000
Borrowing due date			Jun. 19, 2021	
Research and development expense payable			\$ 5,000,000	
Mallinckrodt Plc [Member] Rights and Patents Acquired from Questcor Pharmaceuticals Inc [Member] Maximum [Member]				
Technology Acquisition Agreement [Line Items]				
Milestone payments contingent amount			\$ 52,000,000	
Development Target One [Member] Rights and Patents Acquired from Questcor Pharmaceuticals Inc [Member]				
Technology Acquisition Agreement [Line Items]				
Milestone payment	\$ 500,000			

[Development targets description](#)

Upon the initiation of the first patient dosing in the Company's Phase 3 clinical trial for Gimoti.

[Development Target Four](#)

[\[Member\] | Mallinckrodt Plc](#)

[\[Member\] | Patented](#)

[Technology \[Member\]](#)

[Technology Acquisition](#)

[Agreement \[Line Items\]](#)

[Development targets description](#)

Depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, the Company will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti.

[Milestone payments contingent amount](#)

\$ 47,000,000

[Expected expiration of patent right](#)

2032

Stockholders' Equity - Common Stock - Additional Information (Detail) - USD (\$)	9 Months Ended			
	Sep. 30, 2020	Sep. 30, 2019	Dec. 31, 2019	Nov. 30, 2017
<u>Options Granted [Line Items]</u>				
<u>Common stock, shares issued</u>	26,332,122		24,431,914	
<u>Proceeds from issuance of common stock, net</u>	\$ 3,309,116	\$ 5,800,201		
<u>Warrants converted to purchase of common stock</u>	871,682			
<u>Issuance of common stock from warrant exercise</u>	381,625			
<u>Issuance of common stock from stock option exercise, shares</u>	4,237			
<u>Exercise Price</u>	\$ 0.62			
<u>Options Granted [Member]</u>				
<u>Options Granted [Line Items]</u>				
<u>Number of stock options granted</u>	1,172,000			
<u>Options Granted [Member] Gimoti [Member]</u>				
<u>Options Granted [Line Items]</u>				
<u>Number of stock options not begin vesting</u>	437,500			
<u>Maximum [Member]</u>				
<u>Options Granted [Line Items]</u>				
<u>Weighted average exercise price of warrants</u>	\$ 3.12			
<u>Minimum [Member]</u>				
<u>Options Granted [Line Items]</u>				
<u>Weighted average exercise price of warrants</u>	\$ 2.41			
<u>FBR Sales Agreement [Member]</u>				
<u>Options Granted [Line Items]</u>				
<u>Common stock, shares issued</u>	1,395,855	6,804,381		
<u>Common stock, weighted average price per share</u>	\$ 2.42	\$ 0.87		
<u>Proceeds from issuance of common stock, net</u>	\$ 3,300,000	\$ 5,800,000		
<u>FBR Sales Agreement [Member] Maximum [Member]</u>				
<u>Options Granted [Line Items]</u>				
<u>Common stock, value of shares issuable</u>				\$ 16,000,000

**Stockholders' Equity -
Summary of Estimated Fair
Value of Stock Option
Award (Detail) - Common
stock options [Member]**

9 Months Ended

Sep. 30, 2020 Sep. 30, 2019

**Share Based Compensation Arrangement By Share Based Payment
Award [Line Items]**

<u>Expected dividend yield</u>	0.00%	0.00%
<u>Minimum [Member]</u>		

**Share Based Compensation Arrangement By Share Based Payment
Award [Line Items]**

<u>Risk free interest rate</u>	0.39%	1.80%
<u>Expected option term</u>	5 years 6 months	4 years 3 months 7 days
<u>Expected volatility of common stock</u>	99.73%	90.34%

Maximum [Member]

**Share Based Compensation Arrangement By Share Based Payment
Award [Line Items]**

<u>Risk free interest rate</u>	0.96%	2.55%
<u>Expected option term</u>	6 years	6 years
<u>Expected volatility of common stock</u>	103.99%	112.58%

**Stockholders' Equity -
Summary of Estimated Fair
Value of Shares to be
Acquired Under Employee
Stock Purchase Plan (Detail)
- Employee stock purchase
plan [Member]**

3 Months Ended 9 Months Ended

**Sep. 30, Sep. 30, Sep. 30, Sep. 30,
2020 2019 2020 2019**

**Share Based Compensation Arrangement By Share Based
Payment Award [Line Items]**

<u>Risk free interest rate</u>	0.13%	1.89%		
<u>Expected term</u>	6 months	6 months	6 months	6 months
<u>Expected volatility of common stock</u>	111.98%	170.68%		
<u>Expected dividend yield</u>	0.00%	0.00%	0.00%	0.00%
<u>Expected option term</u>	6 months	6 months	6 months	6 months
<u>Minimum [Member]</u>				

**Share Based Compensation Arrangement By Share Based
Payment Award [Line Items]**

<u>Risk free interest rate</u>			0.13%	1.89%
<u>Expected volatility of common stock</u>			69.72%	130.36%
<u>Maximum [Member]</u>				

**Share Based Compensation Arrangement By Share Based
Payment Award [Line Items]**

<u>Risk free interest rate</u>			1.11%	2.52%
<u>Expected volatility of common stock</u>			111.98%	170.68%

**Stockholders' Equity -
Summary of Recognized
Non-Cash Stock-Based
Compensation Expense
(Detail) - USD (\$)**

3 Months Ended 9 Months Ended
Sep. 30, 2020 Sep. 30, 2019 Sep. 30, 2020 Sep. 30, 2019

**Employee Service Share-based Compensation, Allocation of
Recognized Period Costs [Line Items]**

<u>Stock-based compensation expense</u>	\$	\$	\$	\$
	478,574	331,303	1,151,691	1,055,103

Research and development [Member]

**Employee Service Share-based Compensation, Allocation of
Recognized Period Costs [Line Items]**

<u>Stock-based compensation expense</u>	31,186	179,227	286,148	533,518
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General and administrative [Member]

**Employee Service Share-based Compensation, Allocation of
Recognized Period Costs [Line Items]**

<u>Stock-based compensation expense</u>	\$	\$	\$	\$
	447,388	152,076	865,543	521,585

**Stockholders' Equity -
Stock-Based Compensation -
Additional Information
(Detail)
\$ in Millions**

9 Months Ended

**Sep. 30, 2020
USD (\$)**

[Disclosure Of Compensation Related Costs Sharebased Payments \[Abstract\]](#)

[Unrecognized compensation costs](#)

\$ 2.5

[Weighted average period](#)

1 year 1 month 17 days

**Commercial Services and
Loan Agreements with
Eversana - Additional
Information (Detail) -
Eversana Agreement
[Member] - USD (\$)**

Jan. 21, 2020 Jun. 30, 2020

Commercial Services And Loan Agreements [Line Items]

Agreement termination date Jun. 19, 2025

Revolving Credit Facility [Member]

Commercial Services And Loan Agreements [Line Items]

Line of credit \$ 5,000,000

Line of credit facility, Interest rate 10.00%

Borrowings \$ 2,000,000

Gimoti [Member] | Minimum [Member]

Commercial Services And Loan Agreements [Line Items]

Percentage Of Product Profits 80.00%